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略号一覧表

略号又は略称	名称及び内容
ANA	antinuclear antibody（抗核抗体）
ASA	aminosalicylate（アミノサリチル酸）
$AUC_{0\text{-}49D}$	area under the serum concentration – time curve from time 0 to Day 490（時間から 49 日目までの血清中濃度－時間曲線下面積）
AUC_{inf}	area under the serum concentration – time curve from time 0 to the last quantifiable time（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）
AUC_{last}	area under the serum concentration – time curve from time 0 to infinity（ 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）
BMI	body mass index（体格指数）
BQL	below quantification limit（定量限界未満）
CL/F	apparent total body clearance after extravascular administration（血管外投与後のみかけの全身クリアランス）
C_{max}	maximum observed serum concentration（最高血清中濃度）
CMH	Cochran-Mantel-Haenszel
CRP	C-reactive protein（C 反応性たん白）
dsDNA	double-stranded DNA（二本鎖 DNA）
EQ	Euro QOL
FAS-DB	efficacy full analysis set for double-blind maintenance phase（二重盲検寛解維持期の有効性の主要解析対象集団）
FAS-I	efficacy full analysis set for induction phase（寛解維持期の有効性の最大解析対象集団）
FAS-OL	efficacy full analysis set for open-label maintenance phase（非盲検寛解維持期の有効性の最大解析対象集団）
GCP	Good Clinical Practice（医薬品の臨床試験の実施の基準）
IBDQ	inflammatory bowel disease questionnaire（炎症性腸疾患調査票）
MedDRA	Medical Dictionary for Regulatory Activities（ICH 国際医薬用語集）
PFS	prefilled syringe（プレフィルドシリンジ）
PGA	Physician’s Global Assessment
PK-DB	PK analysis set for double-blind maintenance phase（二重盲検寛解維持期の薬物動態の解析対象集団）
PK-I	PK analysis set for induction phase（寛解導入期の薬物動態の解析対象集団）
PK-M	PK analysis set for maintenance phase（寛解維持期の薬物動態の解析対象集団）
PK-OL	PK analysis set for open-label maintenance phase（非盲検寛解維持期の薬物動態の解析対象集団）
QOL	quality of life（生活の質）
SD	standard deviation（標準偏差）
SF-36	36-item Short-form Health Survey
SF-DB	safety analysis set for double-blind maintenance phase（二重盲検寛解維持期の安全性の解析対象集団）
SF-I	safety analysis set for induction phase（寛解導入期の安全性の解析対象集団）
SF-M	safety analysis set for maintenance phase（寛解維持期の安全性の解析対象集団）
SF-OL	safety analysis set for open-label maintenance phase（非盲検寛解維持期の安全性の解析対象集団）
$T_{1/2}$	elimination half-life（消失半減期）
TB	tuberculosis （結核）
T_{max}	time to maximum serum concentration（最高血清中濃度到達時間）
TNF	tumor necrosis factor（腫瘍壊死因子）
UC	ulcerative colitis（潰瘍性大腸炎）
VAS	Visual Analog Scale

略号又は略称	名称及び内容
Vz/F	apparent volume of distribution at the terminal phase after extravascular administration （血管外投与後の最終相におけるみかけの分布容積）

2.7.6　個々の試験のまとめ

全臨床試験一覧表

試験の種類	試験番号	試験報告書添付場所	試験の主目的	試験デザイン及び対照の種類	被験薬及び対照薬 投与方法　投与経路	被験者数	健康被験者又は患者の診断名	投与期間	試験の進行状況報告書の種類
薬物動態 免疫原性 安全性	CNTO148NAP1001	5.3.3.3.1	・日本人及び白人男性健康被験者にゴリムマブ 200 mg 又は 400 mg を単回皮下投与したときの安全性及び忍容性の評価 ・日本人及び白人男性健康被験者にゴリムマブ 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評価	単施設 ランダム化 二重盲検 プラセボ対照	ゴリムマブ 200, 400 mg 又はプラセボを単回皮下投与	49 例	健康被験者	単回投与	完了 完全な報告書
有効性 安全性 薬物動態 薬力学 免疫原性	C0524T16	5.3.5.1.1	・中等症から重症の活動期潰瘍性大腸炎（UC）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 clinical response を指標とした有効性の評価 ・中等症から重症の活動期 UC 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の評価	多施設共同 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	291 例	中等症から重症の活動期 UC 患者	単回投与	中止 完全な報告書
有効性 安全性 薬物動態 薬力学 免疫原性	C0524T17	5.3.5.1.2 5.3.5.1.4	・中等症から重症の活動期 UC 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 clinical response を指標とした有効性の評価 ・中等症から重症の活動期 UC 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の評価	多施設共同 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 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 xxx→yyy mg：0 週の投与量→2 週の投与量	1065 例	中等症から重症の活動期 UC 患者	2 週	完了 完全な報告書

(1)

試験の種類	試験番号	試験報告書添付場所	試験の主目的	試験デザイン及び対照の種類	被験薬及び対照薬 投与方法　投与経路	被験者数	健康被験者又は患者の診断名	投与期間	試験の進行状況報告書の種類
有効性 安全性 薬物動態 免疫原性	C0524T18	5.3.5.1.3-1 5.3.5.1.3-2 5.3.5.1.4	・寛解導入試験である C0524T16 試験又は C0524T17 試験でゴリムマブにより clinical response が認められた中等症から重症の活動期 UC 患者を対象とした，54 週までの clinical response 維持を指標とする 2 用量のゴリムマブを皮下投与したときの有効性の評価 ・中等症から重症の活動期 UC 患者を対象とした，2 用量のゴリムマブを皮下投与したときの寛解維持療法での安全性の評価 継続投与試験 ・54 週間の寛解維持試験を完了し継続投与試験に組み入れられた中等症から重症の活動期 UC 患者を対象に，更に 3 年間ゴリムマブを投与したときの有効性，薬物動態及び安全性を評価すること	多施設共同 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 週以降の継続投与試験： 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	1228 例	中等症から重症の活動期 UC 患者	52 週 継続投与期 最長 212 週	完了 完全な報告書
有効性 安全性 薬物動態 免疫原性	CNTO148UCO3001	5.3.5.1.5-1 5.3.5.1.5-2	・寛解導入期でゴリムマブにより clinical response が認められた中等症から重症の活動期日本人 UC 患者を対象に，寛解維持期 54 週までの clinical response 維持を指標として，4 週ごとにゴリムマブ 100 mg を皮下投与したときの有効性を評価すること ・中等症から重症の活動期日本人 UC 患者を対象に，ゴリムマブの安全性を評価すること ・本試験及び C0524T18 試験の有効性及び安全性の類似性を確認すること	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） xxx→yyy mg：0 週の投与量→2 週の投与量	寛解導入期 144 例 寛解維持期 123 例	中等症から重症の活動期 UC 患者	寛解導入期 2 週 寛解維持期 52 週	完了 完全な報告書

2.7.6.1　臨床第 I 相試験（CNTO148NAP1001，評価資料：5.3.3.3.1）

標題：

日本人及び白人健康被験者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薬物動態及び安全性を評価する第 I 相試験

実施期間：2010 年 11 月 ■ 日～2011 年 4 月 ■ 日

開発の相：第 I 相

試験の目的（主目的）：

- 日本人及び白人男性健康被験者にゴリムマブ 200 mg 又は 400 mg を単回皮下投与したときの安全性及び忍容性の評価
- 日本人及び白人男性健康被験者にゴリムマブ 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評価

試験方法：

本試験は，日本人及び白人健康被験者を対象にゴリムマブを単回皮下投与したときの薬物動態，免疫原性及び安全性を評価する，ランダム化，交互並行，プラセボ対照，二重盲検試験であった。約 48 例を 2 群に登録する計画であった（A 群：日本人 24 例，B 群：白人 24 例）。

各群（日本人又は白人）ともに，被験者は 2 つの用量コホート（ゴリムマブ 200 mg 又は 400 mg）に順次登録された。各用量コホートに登録後，被験者はゴリムマブ又はプラセボに 10:2 の比でランダムに割り付けられた。200 mg コホートの少なくとも 2 週までの予備的な安全性及び忍容性データより，おおむね安全で忍容性が認められた場合，400 mg を投与することとした。最終観察は投与 77 日後（Day 78）に計画されていた。

被験者数（計画時及び解析時）：

計画時　計 48 例：日本人 24 例，白人 24 例

解析時　計 49 例：日本人 25 例（ゴリムマブ；21 例，プラセボ；4 例）及び白人 24 例（ゴリムマブ；20 例，プラセボ；4 例）の安全性が評価された。ゴリムマブが投与された全 41 例で薬物動態が評価された。

診断及び主な組入れ基準：

BMI（body mass index）19 kg/m^2 以上 29 kg/m^2 以下かつ体重 50 kg 以上 80 kg 以下，年齢 18 歳以上 45 歳以下の健康な日本人及び白人男性。

被験薬，用量及び投与方法：

ヒト型抗 TNFα モノクローナル抗体であるゴリムマブは，単回使用プレフィルドシリンジ（以下 PFS）に充填した皮下注射用滅菌液として供給された。PFS にはゴリムマブ 100 mg（液剤

1 mL）のほか，ヒスチジン，ソルビトール及びポリソルベート 80 が含まれ，pH は 5.5 であった。保存剤は含まなかった。

対照薬，用量及び投与方法：

プラセボは，単回使用 PFS に充填した皮下注射用滅菌液として供給された。PFS にはヒスチジン，ソルビトール及びポリソルベート 80 が含まれ，pH は 5.5 であった。

投与期間：単回投与

評価基準：

薬物動態

血清中ゴリムマブ濃度－時間推移から，ノンコンパートメントモデル解析法により血清中ゴリムマブの薬物動態パラメータを算出した。薬物動態パラメータとして，C_{max}，T_{max}，AUC_{inf}，AUC_{last}，$T_{1/2}$，CL/F 及び V_z/F 等を評価した。

免疫原性

抗ゴリムマブ抗体の発現状況は，ゴリムマブが投与され，抗体測定用の血清サンプルが得られたすべての被験者について検討し，本試験で陽性を示した被験者の割合を示した。

安全性

ゴリムマブの安全性及び忍容性は，身体所見，注射部位反応，心電図，臨床検査，バイタルサイン，結核評価及び有害事象により評価した。安全性は，治験薬投与後，Day 78（12 週）まで観察した。治験終了時に臨床的に顕著な異常が続いていた場合は，回復するまで又は臨床的に安定するまで治験担当医師により調査された。なお，有害事象名は MedDRA ver.13.1 を用いてコーディングした。また，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」又は不明の有害事象を治験薬の使用と関連性のある有害事象とした。

統計手法：

仮説検定は計画しなかった。記述統計を使用してデータを要約した。連続変数は適宜，観察数，平均値，標準偏差（以下 SD），最小値，中央値及び最大値を算出した。カテゴリカル変数は適宜，観察数及び百分率を要約した。本試験は正式な中間解析は計画しなかった。

試験結果：

対象集団

本試験は単一施設で実施し，計 49 例がランダムに割り付けられ治験薬の投与を受けた（日本人：25 例，白人：24 例）。治験中止例は 5 例であった（日本人：3 例，白人：2 例）。白人被験者 1 例が Day 36 にアンフェタミン陽性であり，Day 43 に治験担当医師の判断で治験中止となった。3 例（日本人：2 例，白人：1 例）が同意撤回し，1 例（日本人）が追跡不能であった。

日本人の年齢（中央値）は 28 歳，体重（中央値）は 65.30 kg であった。白人の年齢（中央値）は 30 歳，体重（中央値）は 75.85 kg であった。

治験薬投与 6 日後以降追跡不能となった 1 例を除き，すべてのゴリムマブ投与例（治験中止例 4 例を含む）から，計画された薬物動態パラメータを算出するための十分な薬物濃度データが得られた。追跡不能となった 1 例からは，C_{max} 及び T_{max} のデータのみ算出した。

薬物動態

ゴリムマブ 200 mg 又は 400 mg の単回皮下投与後，ゴリムマブは全身循環に緩やかに移行し，T_{max}（中央値）は日本人及び白人ともに 3.5～5.0 日であった。C_{max}（平均値 ± SD）は，日本人及び白人ともに用量に比例して増加した（200 mg 及び 400 mg でそれぞれ，日本人：15.85 ± 2.98 及び 31.32 ± 8.01 μg/mL，白人：13.20 ± 5.42 及び 25.90 ± 5.87 μg/mL）。同様に，AUC_{inf}（平均値 ± SD）も，日本人及び白人ともに用量にほぼ比例して増加した（日本人：268.87 ± 51.79 及び 597.15 ± 175.58 μg·day/mL，白人：246.11 ± 86.16 及び 535.54 ± 146.79 μg·day/mL）。

日本人での C_{max} 及び AUC_{inf} の平均値は白人と比較して若干高かったものの，分布範囲はおおむね白人の分布範囲と重なっていた。また，体重あたりのみかけのクリアランス（CL/F，平均値 ± SD）は日本人及び白人ともに，用量によらず一定であり，日本人と白人はおおむね一致していた（日本人：11.47 ± 1.66 及び 11.11 ± 3.16 mL/day/kg，白人：12.46 ± 4.29 及び 10.55 ± 2.09 mL/day/kg）。体重あたりのみかけの分布容積（V_z/F，平均値 ± SD）についても，いずれの用量でも日本人と白人でおおむね一致していた（日本人：202.87 ± 38.26 及び 191.62 ± 50.07 mL/kg，白人：234.19 ± 98.17 及び 204.55 ± 37.11 mL/kg）。$T_{1/2}$（平均値 ± SD）も日本人と白人でほぼ同様であった（日本人：12.27 ± 1.48 及び 12.10 ± 1.26 日，白人：13.15 ± 3.18 及び 13.65 ± 1.96 日）。

表 2.7.6.1-1 ゴリムマブの薬物動態パラメータ（平均値 ± SD）

	Golimumab			
	200 mg		400 mg	
	Caucasian	Japanese	Caucasian	Japanese
Subjects evaluable for PK	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
AUC_{last} (μg·day/mL)	238.64 ± 81.87	262.27 ± 51.42	519.94 ± 142.39	588.17 ± 171.54
AUC_{inf} (μg·day/mL)	246.11 ± 86.16	268.87 ± 51.79	535.54 ± 146.79	597.15 ± 175.58
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
CL/F (mL/day)	910.53 ± 324.18	768.09 ± 140.56	789.46 ± 179.73	718.51 ± 192.63
CL/F (mL/day/kg)[b]	12.46 ± 4.29	11.47 ± 1.66	10.55 ± 2.09	11.11 ± 3.16
V_z/F (mL)	17256.65 ± 7522.98	13529.89 ± 2796.50	15309.61 ± 3321.93	12454.98 ± 3342.77
V_z/F (mL/kg)[b]	234.19 ± 98.17	202.87 ± 38.26	204.55 ± 37.11	191.62 ± 50.07
[a] T_{max} reported as median (minimum, maximum) [b] Body weight-adjusted value.				
Adapted from RE441:[K_PK_40_A], 03AUG2011 10:45				

参照元：CNTO148NAP1001 Clinical Study Report p.9

免疫原性

血清サンプルが得られた 36 例（日本人 18 例，白人 18 例）に，Day 78（12 週）まで抗ゴリムマブ抗体陽性の被験者は認められなかった。

安全性

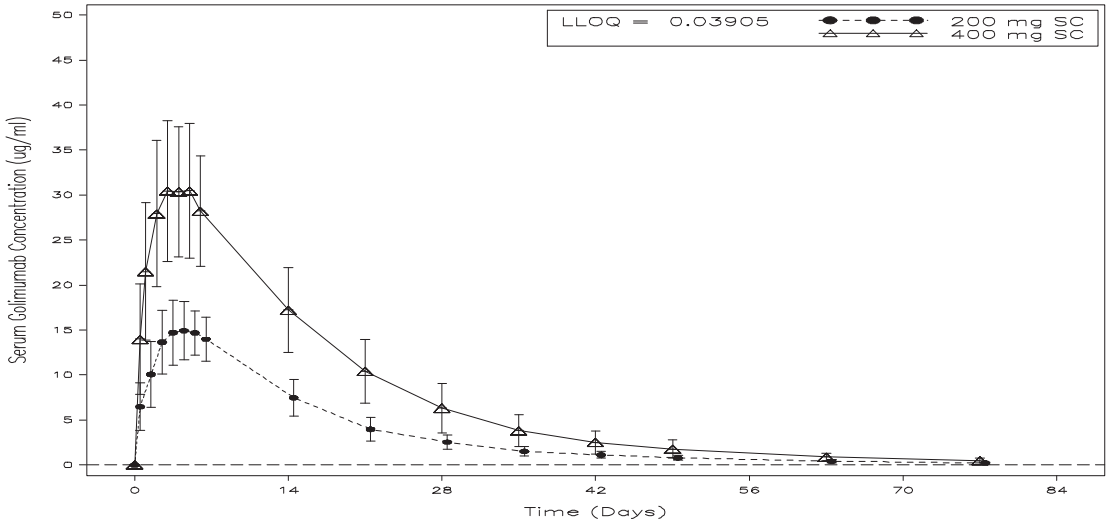
死亡及び重篤な有害事象の発現はなかった。ゴリムマブ 200 mg 又は 400 mg 若しくはプラセボを日本人及び白人男性健康被験者へ単回皮下投与した結果，おおむね安全で忍容性は良好であり，安全性の結果は日本人と白人でほぼ同様であった。

試験の欠点（Study limitations）

特筆すべきものは認められなかった。

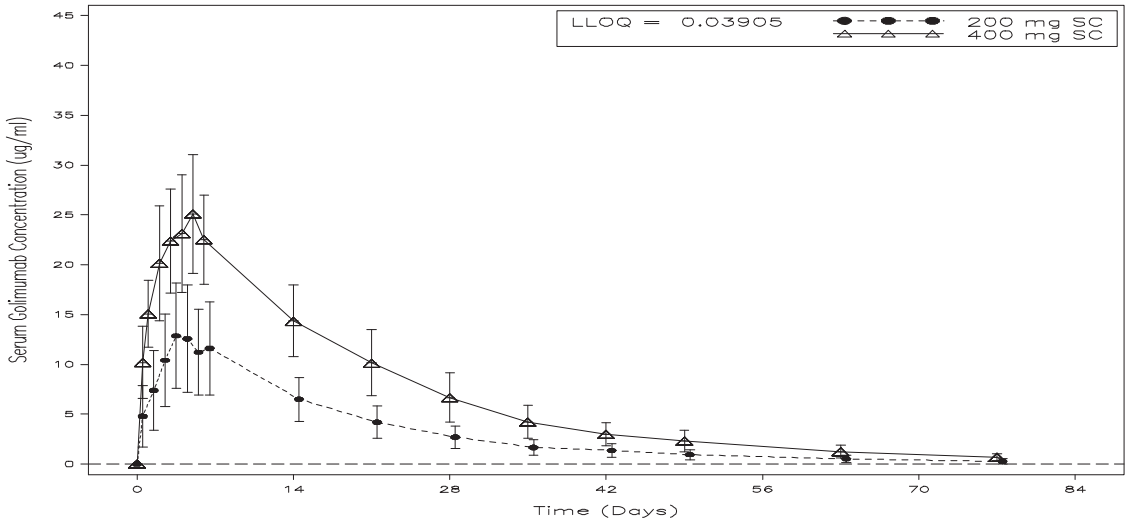
結論

- 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は日本人及び白人ともに線形性を示した。
- 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は，体重を考慮すると，日本人と白人で同様であった。
- ゴリムマブ 200 mg 又は 400 mg を単回皮下投与したときの抗ゴリムマブ抗体陽性の被験者の割合は 0%（0/36）であった。
- 日本人及び白人男性健康被験者へのゴリムマブ 200 mg 又は 400 mg 若しくはプラセボの単回皮下投与は，おおむね安全で忍容性は良好であり，安全性の結果は日本人と白人でほぼ同様であった。



参照元：CNTO148NAP1001 Clinical Study Report Figure 3

図 2.7.6.1-1 日本人健康被験者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）



参照元：CNTO148NAP1001 Clinical Study Report Figure 4

図 2.7.6.1-2 白人健康被験者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）

表 2.7.6.1-2 すべての有害事象（日本人）

		Golimumab		
	Placebo	200 mg	400 mg	Combined
Treated subjects in Japanese group	4	11	10	21
Avg duration of follow-up (days)	78.0	71.4	73.0	72.1
Subjects with 1 or more adverse events	1 (25.0%)	9 (81.8%)	5 (50.0%)	14 (66.7%)
System-organ class/preferred term				
一般・全身障害および投与部位の状態	1 (25.0%)	7 (63.6%)	1 (10.0%)	8 (38.1%)
注射部位疼痛	1 (25.0%)	7 (63.6%)	1 (10.0%)	8 (38.1%)
注射部位紅斑	0 (0.0%)	1 (9.1%)	1 (10.0%)	2 (9.5%)
注射部位そう痒感	0 (0.0%)	1 (9.1%)	0 (0.0%)	1 (4.8%)
感染症および寄生虫症	1 (25.0%)	2 (18.2%)	5 (50.0%)	7 (33.3%)
上気道感染	0 (0.0%)	1 (9.1%)	3 (30.0%)	4 (19.0%)
ウイルス性上気道感染	0 (0.0%)	1 (9.1%)	2 (20.0%)	3 (14.3%)
ウイルス感染	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (4.8%)
ウイルス性咽頭炎	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
神経系障害	1 (25.0%)	2 (18.2%)	0 (0.0%)	2 (9.5%)
頭痛	1 (25.0%)	2 (18.2%)	0 (0.0%)	2 (9.5%)
呼吸器、胸郭および縦隔障害	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (4.8%)
咳嗽	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (4.8%)
胃腸障害	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
消化不良	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

RE441:[S_AE_40_2_A], 28JUN2011 14:39

参照元：CNTO148NAP1001 Clinical Study Report Attachment 3.1

表 2.7.6.1-3 すべての有害事象（白人）

	Placebo	Golimumab 200 mg	Golimumab 400 mg	Golimumab Combined
Treated subjects in Caucasian group	4	10	10	20
Avg duration of follow-up (days)	78.0	74.4	74.9	74.7
Subjects with 1 or more adverse events	3 (75.0%)	9 (90.0%)	8 (80.0%)	17 (85.0%)
System-organ class/preferred term				
一般・全身障害および投与部位の状態	2 (50.0%)	9 (90.0%)	3 (30.0%)	12 (60.0%)
注射部位疼痛	2 (50.0%)	9 (90.0%)	2 (20.0%)	11 (55.0%)
疲労	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (5.0%)
注射部位そう痒感	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (5.0%)
注射部位紅斑	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
感染症および寄生虫症	2 (50.0%)	3 (30.0%)	2 (20.0%)	5 (25.0%)
ウイルス性上気道感染	1 (25.0%)	1 (10.0%)	1 (10.0%)	2 (10.0%)
咽頭炎	0 (0.0%)	1 (10.0%)	0 (0.0%)	1 (5.0%)
上気道感染	1 (25.0%)	1 (10.0%)	0 (0.0%)	1 (5.0%)
ウイルス感染	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (5.0%)
神経系障害	0 (0.0%)	2 (20.0%)	2 (20.0%)	4 (20.0%)
頭痛	0 (0.0%)	2 (20.0%)	1 (10.0%)	3 (15.0%)
痙攣	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (5.0%)
浮動性めまい	0 (0.0%)	1 (10.0%)	0 (0.0%)	1 (5.0%)
呼吸器、胸郭および縦隔障害	0 (0.0%)	1 (10.0%)	2 (20.0%)	3 (15.0%)
咳嗽	0 (0.0%)	1 (10.0%)	1 (10.0%)	2 (10.0%)
咽喉乾燥	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (5.0%)
傷害、中毒および処置合併症	0 (0.0%)	0 (0.0%)	2 (20.0%)	2 (10.0%)
関節捻挫	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (5.0%)
肉離れ	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (5.0%)
胃腸障害	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (5.0%)
上腹部痛	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (5.0%)
皮膚および皮下組織障害	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (5.0%)
ざ瘡様皮膚炎	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (5.0%)
筋骨格系および結合組織障害	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
筋肉痛	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

RE441:[S AE 40 2 B], 28JUN2011 14:39

参照元：CNTO148NAP1001 Clinical Study Report Attachment 3.2

表 2.7.6.1-4 治験薬の使用と関連性のある有害事象（日本人）

		Golimumab		
	Placebo	200 mg	400 mg	Combined
Treated subjects in Japanese group	4	11	10	21
Avg duration of follow-up (days)	78.0	71.4	73.0	72.1
Subjects with 1 or more reasonably related adverse events	1 (25.0%)	6 (54.5%)	2 (20.0%)	8 (38.1%)
System-organ class/preferred term				
一般・全身障害および投与部位の状態	1 (25.0%)	6 (54.5%)	1 (10.0%)	7 (33.3%)
注射部位疼痛	1 (25.0%)	6 (54.5%)	1 (10.0%)	7 (33.3%)
注射部位紅斑	0 (0.0%)	1 (9.1%)	1 (10.0%)	2 (9.5%)
注射部位そう痒感	0 (0.0%)	1 (9.1%)	0 (0.0%)	1 (4.8%)
呼吸器、胸郭および縦隔障害	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (4.8%)
咳嗽	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (4.8%)

RE441:[S AE 42 2 A], 28JUN2011 14:40

参照元：CNTO148NAP1001 Clinical Study Report Attachment 3.4

表 2.7.6.1-5 治験薬の使用と関連性のある有害事象（白人）

		Golimumab		
	Placebo	200 mg	400 mg	Combined
Treated subjects in Caucasian group	4	10	10	20
Avg duration of follow-up (days)	78.0	74.4	74.9	74.7
Subjects with 1 or more reasonably related adverse events	1 (25.0%)	4 (40.0%)	3 (30.0%)	7 (35.0%)
System-organ class/preferred term				
一般・全身障害および投与部位の状態	1 (25.0%)	4 (40.0%)	1 (10.0%)	5 (25.0%)
注射部位疼痛	0 (0.0%)	4 (40.0%)	1 (10.0%)	5 (25.0%)
注射部位そう痒感	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (5.0%)
注射部位紅斑	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
感染症および寄生虫症	0 (0.0%)	1 (10.0%)	1 (10.0%)	2 (10.0%)
咽頭炎	0 (0.0%)	1 (10.0%)	0 (0.0%)	1 (5.0%)
ウイルス性上気道感染	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (5.0%)
胃腸障害	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (5.0%)
上腹部痛	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (5.0%)
神経系障害	0 (0.0%)	1 (10.0%)	0 (0.0%)	1 (5.0%)
浮動性めまい	0 (0.0%)	1 (10.0%)	0 (0.0%)	1 (5.0%)
頭痛	0 (0.0%)	1 (10.0%)	0 (0.0%)	1 (5.0%)

RE441:[S AE 42 2 B], 28JUN2011 14:40

参照元：CNTO148NAP1001 Clinical Study Report Attachment 3.5

2.7.6.2　臨床第 II/III 相試験（C0524T16，参考資料：5.3.5.1.1）

標題：

中等症から重症の活動期潰瘍性大腸炎（以下 UC）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を評価する第 II/III 相，多施設共同，ランダム化，プラセボ対照，二重盲検試験

実施期間：2007 年 8 月 ■ 日～2009 年 5 月 ■ 日

開発の相：第 II/III 相

試験の目的：

主目的

1. 中等症から重症の活動期 UC 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 clinical response を指標とした有効性の評価
2. 中等症から重症の活動期 UC 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の評価

副次目的

1. ゴリムマブ静脈内投与による寛解導入療法の clinical remission を指標とした有効性の評価
2. ゴリムマブ静脈内投与による寛解導入療法の mucosal healing を指標とした有効性の評価
3. ゴリムマブ静脈内投与による寛解導入療法の疾患特異的健康関連 QOL 指標を指標とした有効性の評価
4. ゴリムマブの寛解維持療法試験（C0524T18 試験，以下 T18 試験）で評価する対象集団の設定

その他（中間解析）

1. 中等症から重症の活動期 UC 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用量反応性の評価
2. 安全性及び有効性の結果に基づく静脈内投与量の選択
3. ゴリムマブの寛解維持療法試験（T18 試験）で評価する対象集団の設定

試験方法：

本試験は第 II/III 相多施設共同試験で，2 つのパートに分かれている。Part 1 は第 II 相，投与量探索パート，Part 2 は第 III 相，検証パートであった。両パートとも，ランダム化，プラセボ対照，二重盲検，並行群間比較により実施した。Part 1 では 176 例が 0 週に 1:1:1:1 でゴリムマブ 1 mg/kg，2 mg/kg，4 mg/kg 又はプラセボにランダムに割り付けられ，単回静脈内投与を受けた。

Part 2 は，177 例目の被験者がランダム化された時点に開始し，約 500 例がランダムに割り付けられる計画であった。Part 1 のデータの中間解析評価の間に Part 2 に登録された被験者は，Part 1 と同用量のゴリムマブ又はプラセボに均等に割り付けられた。中間解析後，ゴリムマブ 2 mg/kg 及び 4 mg/kg が Part 2 の用量として選択され，新たに Part 2 に登録された被験者はゴリムマブ 2 mg/kg，4 mg/kg 又はプラセボに均等に割り付けられた。

本試験への登録は，反復皮下投与による寛解導入試験（C0524T17 試験）の用量反応性の解析結果及び 2 つの寛解導入試験（C0524T16 試験及び C0524T17 試験）結果の総合的な評価から，2009 年 1 月 ■日に中止された。既に登録されていた被験者は，治験実施計画書に従って試験を継続し，ゴリムマブの寛解維持療法試験（T18 試験）への参加が可能であった。

被験者数（計画時及び解析時）：

Part 1 では 176 例がランダムに割り付けられた。Part 2 は，177 例目の被験者がランダム割付けされた時点から開始し，約 500 例がランダムに割り付けられる計画であった。本試験への登録は 2009 年 1 月 ■日に中止された。本試験には計 291 例がランダムに割り付けられ，内訳はゴリムマブ 214 例（1 mg/kg，2 mg/kg，4 mg/kg それぞれ 62 例，75 例，77 例）及びプラセボ 77 例であった。

診断及び主な組入れ基準：

ベースライン（0 週）の Mayo スコアが 6 以上 12 以下かつ，内視鏡検査サブスコアが 2 以上という定義により中等症から重症の活動期 UC と診断された 18 歳以上の男性又は女性患者。被験者は，生検により UC の診断が確定された，外来患者であること（すなわち，切迫した結腸切除のリスクがないこと）。被験者は，以下に挙げる既存治療のうち 1 つ以上に対して効果不十分であったか，または忍容性が得られなかった患者であること：経口 5-アミノサリチル酸，経口コルチコステロイド，又は免疫調節薬であるアザチオプリン若しくは 6-メルカプトプリン。コルチコステロイド依存（すなわち，コルチコステロイドを漸減すると UC 症状が再発する）の患者も本試験へ参加可能とした。

直腸のみ又は結腸の 20 cm 未満に限局した UC であり，人工肛門，瘻孔，腸閉塞又は切除されていない腺腫様結腸ポリープのある患者は除外した。潜在性又は活動性の肉芽腫性感染症（結核を含む）の既往，感染症の素因，悪性腫瘍の既往又は潜在的可能性の高い患者は除外した。うっ血性心不全，リンパ増殖性疾患，全身性エリテマトーデス又は脱髄疾患の既往又は合併のある患者は除外した。また，抗 TNF 薬の投与歴のある患者は除外した。

被験薬，用量及び投与方法：

ゴリムマブは 2 mL の単回使用ガラスバイアルに充填された 1 mL の静脈内輸注用滅菌液（ゴリムマブ 100 mg/mL）として供給された。輸注用の薬液は被験者の体重及び割付け群に応じて治験実施医療機関の非盲検下の職員により調整された。被験薬は，100 mL の 0.9%塩化ナトリウム溶液に希釈し，30 分以上かけて投与された。

対照薬，用量及び投与方法：

プラセボは 2 mL の単回使用ガラスバイアルに充填された 1 mL の静脈内輸注用滅菌液として治験依頼者より供給された。バイアルには 1 mL のプラセボが充填された。輸注用の薬液は被験者の割付け群に応じて治験実施医療機関の盲検下の職員により調整された。対照薬は，100 mL の 0.9%塩化ナトリウム溶液に希釈し，30 分以上かけて投与された。

投与期間：

0 週にゴリムマブ（1 mg/kg，2 mg/kg，4 mg/kg）又はプラセボをランダムに割り付けられた被験者へ単回静脈内投与した。

評価：

薬物動態等　血清中ゴリムマブ濃度，抗ゴリムマブ抗体

有効性

評価項目：Mayo スコア，内視鏡検査，C-反応性たん白（以下 CRP），糞便中ラクトフェリン及びカルプロテクチン

評価基準：6 週の clinical response（Mayo スコアがベースラインから 30%以上かつ 3 点以上減少するとともに，rectal bleeding サブスコアが 1 点以上減少するか，rectal bleeding サブスコアが 0 又は 1 になった場合），clinical remission（Mayo スコアが 2 点以下であり，1 を超えるサブスコアがない状態）及び mucosal healing（Mayo スコアの内視鏡検査サブスコアが 0 又は 1 の場合）

患者報告アウトカム：Inflammatory Bowel Disease Questionnaire（以下 IBDQ），SF-36 及び Euro QOL-5D（以下 EQ-5D）

安全性　有害事象及び臨床検査［血液学的検査，血液生化学検査，抗核抗体（ANA）及び抗 dsDNA 抗体］。なお，有害事象名は MedDRA ver.12.0 を用いてコーディングした。また，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」又は不明の有害事象を治験薬の使用と関連性のある有害事象とした。

統計手法：

人口統計学的特性及びベースラインの疾患特性を要約した。カイ二乗検定又は Cochran-Mantel-Haenszel カイ二乗検定を適宜用いて，基準（6 週の clinical response 及び clinical remission 等）を達成した被験者の割合を比較した。連続量の有効性パラメータは分散分析を用いて比較した。すべての統計的検定は，特に規定しない限り，有意水準 0.05（両側）で行った。

解析対象集団：

解析対象集団にはランダム割付けされたすべての被験者（Part 1 及び Part 2 併合）を含めた。有効性の解析はランダム割付けされたすべての被験者を対象として行った。安全性及び薬物動態は実際に治験薬の投与を受けた被験者を対象とし，投与群ごとに評価した（4 mg/kg 群に割付け

られ有害事象により 0.4 mg/kg の投与となった 1 例は 1 mg/kg 群に含めた）。治験担当医師により不適切な行為があった治験実施医療機関（施設番号：6706）の被験者のデータは，有効性の解析からは除外したが，薬物動態及び安全性の解析には含めた。

試験結果：

被験者及び投与状況

ゴリムマブ 214 例（1 mg/kg，2 mg/kg，4 mg/kg それぞれ 62 例，75 例，77 例）及びプラセボ 77 例，計 291 例がランダムに割り付けられた。291 例中 290 例がゴリムマブ又はプラセボの単回静脈内投与を受けた。人口統計学的特性，ベースラインの疾患特性及び UC に対する他の治療（コルチコステロイド，免疫調節薬及びアミノサリチル酸）を併用していた被験者の割合は，いずれの群でもおおむね同様であった。291 例中 270 例（92.8%）が試験を完了［259 例（89.0%）が 6 週評価終了後に寛解維持試験である T18 試験に移行，11 例（3.8%）が 16 週の評価を完了］し，21 例（7.2%）が治験を中止した。治験を中止した 21 例のうち，13 例（4.5%，ランダム割付けされたが治験薬を投与されなかった 1 例を含む）は 6 週よりも前に，8 例（2.7%）は 6 週から 16 週の間に治験を中止した。ゴリムマブ群（3.7%）に比べプラセボ群（6.5%）の方が 6 週よりも前に治験を中止した被験者の割合が高かった。

薬物動態及び免疫原性

血清中ゴリムマブ濃度は，ゴリムマブの単回静脈内投与量（1 mg/kg，2 mg/kg，4 mg/kg）にほぼ比例して増加した。ゴリムマブの用量の増加に伴い，6 週の血清中ゴリムマブが定量下限未満の被験者の割合は減少した。血清サンプルが得られた被験者において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。

有効性

6 週の clinical response には，いずれのゴリムマブ群もプラセボ群と比較して統計学的に有意な差は認められなかったが，2 mg/kg 群及び 4 mg/kg 群ではプラセボ群に比べ高い傾向がみられた（プラセボ群，2 mg/kg 群，4 mg/kg 群の順にそれぞれ 30.1%，44.0%，41.6%）。6 週の clinical remission 及び mucosal healing には，いずれのゴリムマブ群もプラセボ群と比較して統計学的に有意な差は認められなかった。Mayo スコアのベースラインからの変化量（中央値）には，いずれのゴリムマブ群もプラセボ群と比較して統計学的に有意な差は認められなかったが，2 mg/kg 群及び 4 mg/kg 群で 6 週にプラセボ群に比べ改善傾向がみられた（プラセボ群，2 mg/kg 群，4 mg/kg 群の順にそれぞれ−1.0，−2.0，−2.0）。CRP 値（中央値）は 2 週までに全投与群で減少し，各ゴリムマブ群ではプラセボ群に比べ大きく減少した（プラセボ群，1 mg/kg 群，2 mg/kg 群，4 mg/kg 群の順にそれぞれ−0.37，−2.12，−1.42，−1.02）。4 mg/kg 群の糞便中ラクトフェリン濃度（中央値；対数変換値）は，いずれの時点でもプラセボ群に比較して統計学的に有意な減少が認められた［2 週：プラセボ群 0.00，4 mg/kg 群−0.50（以下同順，p = 0.009），4 週：−0.09，−0.42（p = 0.046）］。4 mg/kg 群の糞便中カルプロテクチン濃度のベースラインからの変化量（中央値；対数変換値）は，いずれの時点でもプラセボ群に比較して統計学的に有意な減少が認められた［2 週：プラセボ群 0.01，4 mg/kg 群−0.45（p = 0.003），4 週：−0.14，−0.32（p = 0.008），6 週：−0.18，−0.24（p = 0.046）］。2 mg/kg 群でも，2 週にプラセボ群に比較して統計学的に有意な減少が認められた［プラセボ群 0.01，2 mg/kg 群−0.17（p = 0.009）］。6 週の IBDQ のベースラ

インからの変化量（中央値）は 2 mg/kg 群及び 4 mg/kg 群でプラセボ群に比べ統計学的に有意な改善が認められた［プラセボ群 9.5，2 mg/kg 群 21.0（p = 0.031），4 mg/kg 群 18.5（p = 0.016）］。6 週の SF-36 及び EQ-5D では臨床的に意義のある改善は認められなかった。血清中のゴリムマブの曝露と clinical response との関連性は低かった。

安全性

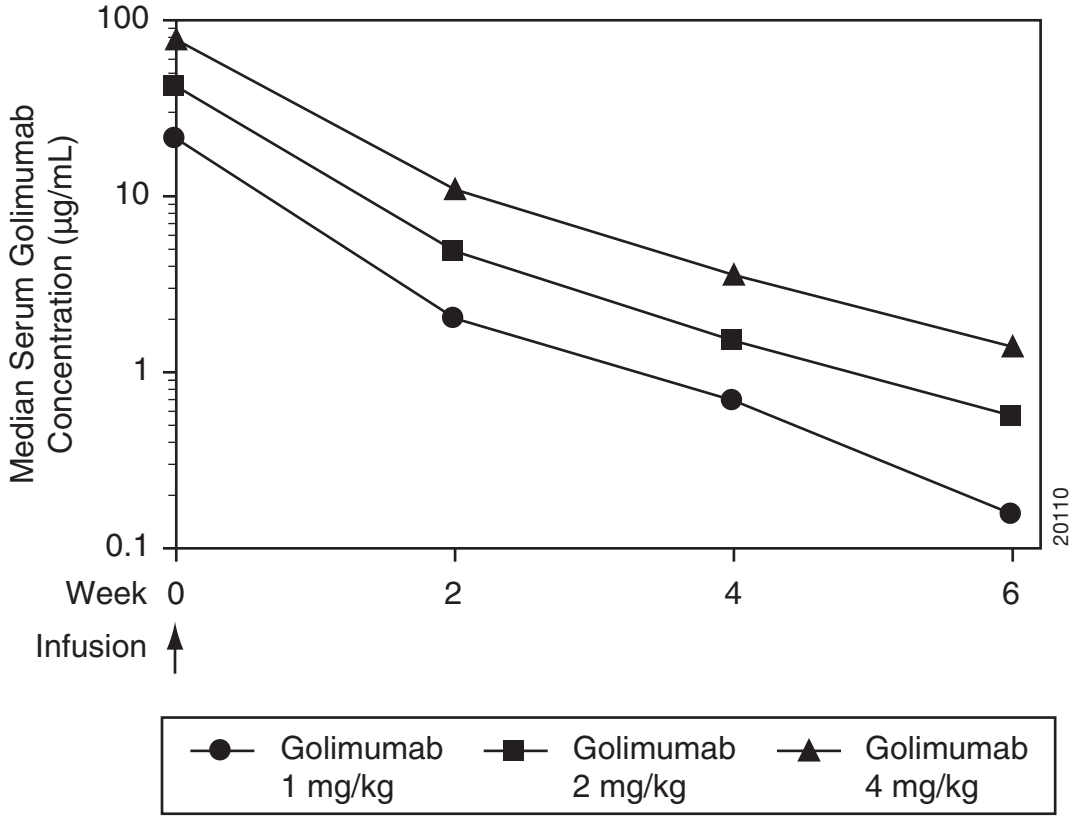
6 週までで有害事象が認められた被験者の割合は，プラセボ群に比較してゴリムマブ群でわずかに高かった（プラセボ群 31.2%，ゴリムマブ群 36.6%）。最も発現割合が高かった SOC は，ゴリムマブ群では「胃腸障害」，プラセボ群では「全身障害および投与局所様態」であった。ゴリムマブ群で 6 週までに発現割合が高かった有害事象（2%以上）は，潰瘍性大腸炎（3.8%），咳嗽（2.8%）及び頭痛（2.8%）であった。プラセボ群で 6 週までに発現割合が高かった有害事象（2%以上）は，そう痒症（3.9%），潰瘍性大腸炎（2.6%），貧血（2.6%），悪心（2.6%），疲労（2.6%），ヘマトクリット減少（2.6%）及びヘモグロビン減少（2.6%）であった。本試験の全期間で死亡例はなかった。重篤な有害事象を発現した被験者の割合は全般的に低く，ゴリムマブ群及びプラセボ群で同程度であった（それぞれ 3.8%及び 2.6%）。感染症を発現した被験者の割合は，プラセボ群に比較しゴリムマブ群で高かった（プラセボ群 6.5%，ゴリムマブ群 10.8%）。抗菌薬による治療が必要であった感染症を発現した被験者の割合もプラセボ群に比較しゴリムマブ群で高かった（プラセボ群 1.3%，ゴリムマブ群 6.1%）。治験担当医師により感染症と判断された重篤な有害事象がゴリムマブを投与した 4 例に発現したが，いずれも治療により回復した。プラセボ群では感染症と判断された重篤な有害事象は認められなかった。結核及び日和見感染は本試験の全期間で認められなかった。注入反応を認めた被験者の割合は低かった（プラセボ群 0.0%，ゴリムマブ群 2.3%）。いずれの注入反応も軽度又は中等度であり，重篤な事象は認められなかった。アナフィラキシーや遅発性過敏症が疑われた症例はなかった。皮膚の扁平上皮癌が 4 mg/kg 群の 1 例に認められた。血液学的検査及び血液生化学検査で特に目立った傾向はなかった。少数の被験者で顕著な臨床検査値異常が認められたが，多くは一過性のものであった。

試験の欠点（Study limitations）

本試験は 291 例目のランダム割付け後に登録を中止したため，Part 2 でランダム割付けされた 115 例では，主要評価項目の解析で十分な検出力は得られなかった。そのため，有効性の結果は探索的であると考えられる。

結論

中等症から重症の活動期 UC 患者を対象としたゴリムマブ単回静脈内投与は，clinical response，clinical remission 及び mucosal healing を指標とした疾患活動性の有意な改善にはつながらなかった。薬物動態及び全体的なゴリムマブの有効性から，UC 患者において十分な効果が得られる適切な曝露量を維持するためには，単回投与量の増量，あるいは 2 週又は 4 週での 2 回目の静脈内導入用量の追加投与が必要であると考えられる。UC 患者でのゴリムマブの忍容性はおおむね良好であり，安全性プロファイルは，本剤の他の適応症及び他の抗 TNF 薬と同様であった。有効性は想定していたよりも低かったことを考慮し，本試験への登録は中止された。また，静脈内投与による寛解導入療法の更なる開発は今後行わない予定である。



参照元：C0524T16 Clinical Study Report Figure 4

図 2.7.6.2-1 ゴリムマブを単回静脈内投与したときの 6 週までの
血清中ゴリムマブ濃度-時間濃度推移（中央値）：全投与被験者

表 2.7.6.2-1 ゴリムマブを単回静脈内投与したときの 6 週までの血清中ゴリムマブ濃度が定量下限未満だった被験者の人数

	Golimumab		
	1 mg/kg	2 mg/kg	4 mg/kg
Subjects treated	63	74	76
Baseline, preadministration			
n	60	72	75
Subjects without detectable concentration	59 (98.3%)	69 (95.8%)	75 (100.0%)
Week 2			
n	56	71	71
Subjects without detectable concentration	0 (0.0%)	0 (0.0%)	0 (0.0%)
Week 4			
n	54	68	76
Subjects without detectable concentration	3 (5.6%)	0 (0.0%)	0 (0.0%)
Week 6			
n	48	64	68
Subjects without detectable concentration	13 (27.1%)	7 (10.9%)	0 (0.0%)

RE310:[K CONC 90 B], 29OCT2009 17:35

参照元：C0524T16 Clinical Study Report Table 5

表 2.7.6.2-2 6 週の clinical response（医療機関 6706 を除く）

	Placebo	Golimumab			
		1 mg/kg	2 mg/kg	4 mg/kg	Combined
Randomized subjects (excluding site 6706)	73	61	75	77	213
Week 6					
n	73	61	75	77	213
Subjects in clinical response[a,b]	22 (30.1%)	22 (36.1%)	33 (44.0%)	32 (41.6%)	87 (40.8%)
p-value		0.467	0.081	0.145	0.104

[a] Subjects who had a prohibited change in medication or had an ostomy or colectomy prior to Week 6 are considered not to be in clinical response.
[b] Subjects who had insufficient data at Week 6 are considered not to be in clinical response.

RE310:[E CRES 93 B], 14DEC2009 16:30

参照元：C0524T16 Clinical Study Report Table 6

表 2.7.6.2-3 すべての有害事象（6 週まで）

	Placebo	Golimumab			
		1 mg/kg	2 mg/kg	4 mg/kg	Combined
Subjects treated	77	63	74	76	213
Avg duration of follow-up (weeks)	5.94	6.13	6.06	6.10	6.09
Subjects with 1 or more adverse events	24 (31.2%)	26 (41.3%)	22 (29.7%)	30 (39.5%)	78 (36.6%)
System-organ class/preferred term					
胃腸障害	5 (6.5%)	6 (9.5%)	10 (13.5%)	8 (10.5%)	24 (11.3%)
潰瘍性大腸炎	2 (2.6%)	3 (4.8%)	5 (6.8%)	0 (0.0%)	8 (3.8%)
悪心	2 (2.6%)	0 (0.0%)	1 (1.4%)	2 (2.6%)	3 (1.4%)
腹痛	0 (0.0%)	1 (1.6%)	1 (1.4%)	0 (0.0%)	2 (0.9%)
下腹部痛	1 (1.3%)	1 (1.6%)	0 (0.0%)	1 (1.3%)	2 (0.9%)
上腹部痛	0 (0.0%)	0 (0.0%)	1 (1.4%)	1 (1.3%)	2 (0.9%)
消化不良	0 (0.0%)	0 (0.0%)	1 (1.4%)	1 (1.3%)	2 (0.9%)
痔核	1 (1.3%)	1 (1.6%)	0 (0.0%)	1 (1.3%)	2 (0.9%)
嘔吐	0 (0.0%)	1 (1.6%)	1 (1.4%)	0 (0.0%)	2 (0.9%)
腹部膨満	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
肛門直腸不快感	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
口唇炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
結腸ポリープ	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
下痢	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
胃腸出血	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
胃腸音異常	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
口唇腫脹	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
感染症および寄生虫症	6 (7.8%)	8 (12.7%)	5 (6.8%)	8 (10.5%)	21 (9.9%)
咽頭炎	0 (0.0%)	1 (1.6%)	3 (4.1%)	0 (0.0%)	4 (1.9%)
鼻咽頭炎	1 (1.3%)	1 (1.6%)	0 (0.0%)	2 (2.6%)	3 (1.4%)

表 2.7.6.2-3 すべての有害事象（6 週まで）（続き）

		Golimumab			
	Placebo	1 mg/kg	2 mg/kg	4 mg/kg	Combined
上気道感染	1 (1.3%)	2 (3.2%)	0 (0.0%)	1 (1.3%)	3 (1.4%)
蜂巣炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
クロストリジウム感染	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
エンテロウイルス感染	1 (1.3%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
毛包炎	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
ウイルス性胃腸炎	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
下気道感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
マラリア	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
口腔ヘルペス	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
膿疱性皮疹	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
敗血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
ウイルス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
気管支炎	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
中耳炎	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ウイルス性気道感染	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
皮膚および皮下組織障害	6 (7.8%)	6 (9.5%)	3 (4.1%)	8 (10.5%)	17 (8.0%)
湿疹	0 (0.0%)	2 (3.2%)	0 (0.0%)	0 (0.0%)	2 (0.9%)
多汗症	0 (0.0%)	1 (1.6%)	0 (0.0%)	1 (1.3%)	2 (0.9%)
そう痒症	3 (3.9%)	1 (1.6%)	0 (0.0%)	1 (1.3%)	2 (0.9%)
水疱	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
ざ瘡様皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
アレルギー性皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
皮膚乾燥	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
紅斑	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
苔癬様角化症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
乾癬	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
発疹	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)

表 2.7.6.2-3 すべての有害事象（6 週まで）（続き）

		Golimumab			
	Placebo	1 mg/kg	2 mg/kg	4 mg/kg	Combined
丘疹	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
そう痒性皮疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
瘢痕痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
皮膚亀裂	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
蕁麻疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
脱毛症	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
寝汗	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
顔面腫脹	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
呼吸器、胸郭および縦隔障害	1 (1.3%)	3 (4.8%)	4 (5.4%)	4 (5.3%)	11 (5.2%)
咳嗽	0 (0.0%)	2 (3.2%)	3 (4.1%)	1 (1.3%)	6 (2.8%)
口腔咽頭痛	0 (0.0%)	0 (0.0%)	2 (2.7%)	1 (1.3%)	3 (1.4%)
湿性咳嗽	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
鼻漏	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
喘鳴	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
喘息	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
全身障害および投与局所様態	7 (9.1%)	3 (4.8%)	3 (4.1%)	3 (3.9%)	9 (4.2%)
発熱	0 (0.0%)	1 (1.6%)	2 (2.7%)	0 (0.0%)	3 (1.4%)
悪寒	1 (1.3%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
疲労	2 (2.6%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
酩酊感	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
インフルエンザ様疾患	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
注入部位疼痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
末梢性浮腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
疼痛	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
無力症	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
胸部不快感	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
びくびく感	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

表 2.7.6.2-3 すべての有害事象（6 週まで）（続き）

		Golimumab			
	Placebo	1 mg/kg	2 mg/kg	4 mg/kg	Combined
浮腫	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血液およびリンパ系障害	3 (3.9%)	4 (6.3%)	2 (2.7%)	2 (2.6%)	8 (3.8%)
貧血	2 (2.6%)	1 (1.6%)	2 (2.7%)	0 (0.0%)	3 (1.4%)
白血球減少症	0 (0.0%)	2 (3.2%)	0 (0.0%)	1 (1.3%)	3 (1.4%)
白血球増加症	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
好中球減少症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
特発性血小板減少性紫斑病	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
神経系障害	1 (1.3%)	1 (1.6%)	3 (4.1%)	2 (2.6%)	6 (2.8%)
頭痛	1 (1.3%)	1 (1.6%)	3 (4.1%)	2 (2.6%)	6 (2.8%)
錯感覚	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
臨床検査	3 (3.9%)	3 (4.8%)	1 (1.4%)	1 (1.3%)	5 (2.3%)
アラニン・アミノトランスフェラーゼ増加	1 (1.3%)	1 (1.6%)	1 (1.4%)	1 (1.3%)	3 (1.4%)
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 (1.6%)	1 (1.4%)	0 (0.0%)	2 (0.9%)
血圧上昇	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
血小板数増加	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
ヘマトクリット減少	2 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ヘモグロビン減少	2 (2.6%)	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	2 (2.6%)	1 (1.6%)	2 (2.7%)	0 (0.0%)	3 (1.4%)
関節痛	1 (1.3%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
筋痙縮	1 (1.3%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
筋骨格痛	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
精神障害	1 (1.3%)	2 (3.2%)	0 (0.0%)	1 (1.3%)	3 (1.4%)
異常な夢	1 (1.3%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
激越	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
不眠症	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
腎および尿路障害	1 (1.3%)	1 (1.6%)	0 (0.0%)	1 (1.3%)	2 (0.9%)
腎結石症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)

表 2.7.6.2-3 すべての有害事象（6 週まで）（続き）

	Placebo	Golimumab 1 mg/kg	Golimumab 2 mg/kg	Golimumab 4 mg/kg	Golimumab Combined
腎仙痛	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
着色尿	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
排尿困難	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血管障害	1 (1.3%)	0 (0.0%)	1 (1.4%)	1 (1.3%)	2 (0.9%)
潮紅	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
高血圧	1 (1.3%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
眼障害	1 (1.3%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
視力障害	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
眼球乾燥	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
免疫系障害	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
季節性アレルギー	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
傷害、中毒および処置合併症	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
擦過傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
多発性外傷	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
代謝および栄養障害	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
低カリウム血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
食欲不振	1 (1.3%)	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%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
扁平上皮癌	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)

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参照元：C0524T16 Clinical Study Report Attachment 4.1

表 2.7.6.2-4 治験薬の使用と関連性のある有害事象（6 週まで）

		Golimumab			
	Placebo	1 mg/kg	2 mg/kg	4 mg/kg	Combined
Subjects treated	77	63	74	76	213
Avg duration of follow-up (weeks)	5.94	6.13	6.06	6.10	6.09
Subjects with 1 or more reasonably related adverse events	9 (11.7%)	12 (19.0%)	7 (9.5%)	9 (11.8%)	28 (13.1%)
System-organ class/preferred term					
皮膚および皮下組織障害	3 (3.9%)	4 (6.3%)	1 (1.4%)	4 (5.3%)	9 (4.2%)
そう痒症	2 (2.6%)	1 (1.6%)	0 (0.0%)	1 (1.3%)	2 (0.9%)
水疱	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
ざ瘡様皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
湿疹	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
多汗症	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
乾癬	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
丘疹	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
そう痒性皮疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
蕁麻疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
寝汗	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
感染症および寄生虫症	2 (2.6%)	2 (3.2%)	2 (2.7%)	1 (1.3%)	5 (2.3%)
咽頭炎	0 (0.0%)	1 (1.6%)	2 (2.7%)	0 (0.0%)	3 (1.4%)
蜂巣炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
上気道感染	1 (1.3%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
ウイルス性気道感染	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
胃腸障害	3 (3.9%)	0 (0.0%)	2 (2.7%)	2 (2.6%)	4 (1.9%)
口唇炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
潰瘍性大腸炎	1 (1.3%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)

表 2.7.6.2-4 治験薬の使用と関連性のある有害事象（6 週まで）（続き）

		Golimumab			
	Placebo	1 mg/kg	2 mg/kg	4 mg/kg	Combined
胃腸出血	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
口唇腫脹	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
悪心	2 (2.6%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
下腹部痛	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
全身障害および投与局所様態	2 (2.6%)	2 (3.2%)	2 (2.7%)	0 (0.0%)	4 (1.9%)
発熱	0 (0.0%)	1 (1.6%)	1 (1.4%)	0 (0.0%)	2 (0.9%)
悪寒	1 (1.3%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
酩酊感	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
びくびく感	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
臨床検査	1 (1.3%)	2 (3.2%)	1 (1.4%)	0 (0.0%)	3 (1.4%)
アラニン・アミノトランスフェラーゼ増加	1 (1.3%)	1 (1.6%)	1 (1.4%)	0 (0.0%)	2 (0.9%)
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 (1.6%)	1 (1.4%)	0 (0.0%)	2 (0.9%)
血圧上昇	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
神経系障害	0 (0.0%)	1 (1.6%)	0 (0.0%)	2 (2.6%)	3 (1.4%)
頭痛	0 (0.0%)	1 (1.6%)	0 (0.0%)	2 (2.6%)	3 (1.4%)
精神障害	1 (1.3%)	2 (3.2%)	0 (0.0%)	1 (1.3%)	3 (1.4%)
異常な夢	1 (1.3%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
激越	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
不眠症	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
呼吸器、胸郭および縦隔障害	0 (0.0%)	2 (3.2%)	1 (1.4%)	0 (0.0%)	3 (1.4%)
咳嗽	0 (0.0%)	1 (1.6%)	1 (1.4%)	0 (0.0%)	2 (0.9%)
喘鳴	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
血液およびリンパ系障害	1 (1.3%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
白血球減少症	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
特発性血小板減少性紫斑病	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
眼障害	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)
視力障害	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.5%)

表 2.7.6.2-4 治験薬の使用と関連性のある有害事象（6 週まで）（続き）

		Golimumab			
	Placebo	1 mg/kg	2 mg/kg	4 mg/kg	Combined
血管障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
潮紅	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.5%)
代謝および栄養障害	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
食欲不振	1 (1.3%)	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 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
関節痛	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

RE310:[S AE 42 2 B], 29OCT2009 17:30

参照元：C0524T16 Clinical Study Report Attachment 4.7

2.7.6.3　臨床第 II/III 相試験（C0524T17，評価資料：5.3.5.1.2, 5.3.5.1.4）

標題：

中等症から重症の活動期潰瘍性大腸炎（以下 UC）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を評価する第 II/III 相，多施設共同，ランダム化，プラセボ対照，二重盲検試験

実施期間：2007 年 7 月 ■日～2010 年 11 月 ■日

地域：　5 地域　アジア，オセアニア，北米，ヨーロッパ，アフリカ

参加国：　25 ヵ国　日本，インド，オーストラリア，ニュージーランド，米国，カナダ，ブルガリア，ハンガリー，ポーランド，ルーマニア，セルビア，スロバキア，ウクライナ，リトアニア，ロシア，チェコ共和国，オーストリア，ベルギー，フランス，オランダ，デンマーク，スウェーデン，ドイツ，イスラエル，南アフリカ

実施施設：　217 施設（日本 21 施設）

開発の相：第 II/III 相

試験の目的：

Part 1

1. 中等症から重症の活動期 UC 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用量反応の評価
2. 安全性及び有効性に基づき，継続して実施される Part 2 のゴリムマブ皮下投与による寛解導入療法の用量選択

Part 2

主目的

1. 中等症から重症の活動期 UC 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 clinical response を指標とした有効性の評価
2. 中等症から重症の活動期 UC 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の評価

副次目的

1. ゴリムマブ皮下投与による寛解導入療法の clinical remission を指標とした有効性の評価
2. ゴリムマブ皮下投与による寛解導入療法の mucosal healing を指標とした有効性の評価
3. ゴリムマブ皮下投与による寛解導入療法の疾患特異的健康関連 QOL 指標を用いた有効性の評価

4. ゴリムマブの寛解維持療法試験（C0524T18 試験，以下 T18 試験）で評価する対象集団の設定

試験方法：

本試験は第 II/III 相多施設共同試験で，2 つのパートに分かれている。Part 1 は第 II 相，投与量探索パート，Part 2 は第 III 相，検証パートであった。両パートとも，ランダム化，プラセボ対照，二重盲検，並行群間比較により実施した。Part 1 では 169 例が 0 週に 1:1:1:1 で下記の用法・用量にランダムに割り付けられた。

- 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→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→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→200 mg 群）

Part 2 は，170 例目の被験者がランダム化された時点に開始し，約 875 例が Part 2 の 0 週にランダムに割り付けられる計画であった。Part 1 のデータの評価の間に Part 2 に登録された被験者は，Part 1 と同用量のゴリムマブ又はプラセボに均等に割り付けられた。中間解析後，ゴリムマブ 200→100 mg 及び 400→200 mg が Part 2 の用量として選択され，新たに Part 2 に登録された被験者はゴリムマブ 200→100 mg，400→200 mg 又はプラセボに均等に割り付けられた。6 週の clinical response を評価した。登録されたパートにかかわらず，6 週評価を受けたすべての被験者は，寛解維持療法試験（T18 試験）への参加が可能であった。T18 試験に登録されない被験者に対し，治験薬最終投与後 16 週まで安全性の追跡調査をした。

被験者数：

各パートにランダムに割り付けられた被験者は，以下のとおりである。

- Part 1：169 例
- Part 2：896 例
  - 用量選択前：122 例
  - 用量選択後：774 例

診断及び主な組入れ基準：

ベースライン（0 週）の Mayo スコアが 6 以上 12 以下かつ，内視鏡検査サブスコアが 2 以上という定義により中等症から重症の活動期 UC と診断された 18 歳以上の男性又は女性患者。被験者は，生検により UC の診断が確定された，外来患者であること（すなわち，切迫した結腸切除のリスクがないこと）。被験者は，以下に挙げる既存治療のうち 1 つ以上に対して効果不十分であったか，または忍容性が得られなかった患者であること：経口 5-アミノサリチル酸，経口コルチコステロイド，又は免疫調節薬であるアザチオプリン若しくは 6-メルカプトプリン。コルチコ

ステロイド依存（すなわち，コルチコステロイドを漸減すると UC 症状が再燃する）の患者も本試験へ参加可能とした。

切迫した結腸切除のリスクがある患者は登録されなかった。直腸のみ又は結腸の 20 cm 未満に限局した UC であり，人工肛門，瘻孔，腸閉塞又は切除されていない腺腫様結腸ポリープのある患者は除外した。潜在性又は活動性の肉芽腫性感染症（結核を含む）の既往，感染症の素因，悪性腫瘍の既往又は潜在的可能性の高い患者は除外した。うっ血性心不全，リンパ増殖性疾患，全身性エリテマトーデス又は脱髄疾患の既往又は合併のある患者は除外した。また，抗 TNF 薬の投与歴のある患者は除外した。

被験薬：

ゴリムマブは単回使用プレフィルドシリンジ（以下 PFS）の皮下注射用滅菌液として供給された。各 PFS には，ヒスチジン，ソルビトール及びポリソルベート 80 が含まれた pH 5.5 の水溶性媒体に，ゴリムマブ 50 mg（0.5 mL）又は 100 mg（1 mL）のいずれかが充填された。防腐剤は添加されていなかった。単回使用 PFS の液体被験薬はすぐに使用できる状態で供給された。治験実施医療機関では，被験薬が充填された PFS を 2℃から 8℃で保管した。

対照薬：

プラセボは被験薬と同じ単回使用 PFS に 0.5 mL 又は 1.0 mL の皮下注射用滅菌液として治験依頼者より供給された。各 PFS にはヒスチジン，ソルビトール及びポリソルベート 80 が pH 5.5 で充填された。防腐剤は添加されていなかった。単回使用 PFS の液体対照薬はすぐに使用できる状態で供給された。治験実施医療機関では，対照薬が充填された PFS を 2℃から 8℃で保管した。

用量，投与方法及び投与期間：

0 週及び 2 週に，ゴリムマブ又はプラセボをランダムに割り付けられた被験者へ皮下投与した。投与量は以下のとおり。

- 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→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→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→200 mg 群）

評価：

薬物動態等　血清中ゴリムマブ濃度，抗ゴリムマブ抗体，副次評価のための生検に同意した被験者の組織学的スコア，血清バイオマーカー，生検に基づく RNA 及び全血の RNA

有効性

評価項目：Mayo スコア，内視鏡検査，C-反応性たん白（以下 CRP），糞便中ラクトフェリン及びカルプロテクチン

評価基準：6 週の clinical response（Mayo スコアがベースラインから 30%以上かつ 3 点以上減少するとともに，rectal bleeding サブスコアが 1 点以上減少するか，rectal

bleeding サブスコアが 0 又は 1 になった場合），clinical remission（Mayo スコアが 2 点以下であり，1 を超えるサブスコアがない状態）及び mucosal healing（Mayo スコアの内視鏡検査サブスコアが 0 又は 1 の場合）

患者報告アウトカム：Inflammatory Bowel Disease Questionnaire（以下 IBDQ），SF-36 及び Euro QOL（以下 EQ）-5D

安全性　有害事象及び臨床検査［血液学的検査，血液生化学検査，抗核抗体（ANA）及び抗 dsDNA 抗体］。なお，有害事象名は MedDRA ver.13.0 を用いてコーディングした。また，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」又は不明の有害事象を治験薬の使用と関連性のある有害事象とした。

症例数設計の根拠：

本試験開始時には潰瘍性大腸炎患者を対象としたゴリムマブのデータは得られていなかったため，中等症から重症の活動期の潰瘍性大腸炎患者を対象としたインフリキシマブの臨床試験（Active Ulcerative Colitis Trials：ACT 1 及び ACT 2 試験）の結果から，本試験で clinical response を示す被験者の割合を推定した。Part 2 で 6 週に clinical response が認められる被験者の割合を，2 種類の投与量のゴリムマブ群でそれぞれ 65%及び 55%，プラセボ群で 45%と仮定した場合，各群 150 例（合計 450 例）の被験者がいれば，有意水準 0.05（両側）で 90%の検出力が得られると考えられ，C0524T18 試験で十分な検出力を確保するために，Part 2 の目標被験者数を 500 例と設定した。しかし，C0524T16 試験の中止により，C0524T18 試験の検出力を確保するために，Part 2 の目標被験者数を 875 例に増加することとした。投与量選択前の Part 2 に 122 例が登録されたため，主要解析対象集団の目標被験者数（投与量選択後の Part 2 の目標被験者数）を 753 例とした。被験者数を 753 例とした場合，有意水準 0.05 及び 0.01（両側）で，それぞれ 99%及び 96%の検出力が得られる。

統計手法：

ランダム化されたすべての被験者について人口統計学的特性及びベースラインの疾患特性を要約した。カイ二乗検定又は Cochran-Mantel-Haenszel カイ二乗検定を適宜用いて，基準（6 週の clinical response 及び clinical remission 等）を達成した被験者の割合を比較した。連続量の有効性パラメータは分散分析又は van der Waerden 正規スコアに基づく分散分析を適宜用いて比較した。すべての統計的検定は，特に規定しない限り，有意水準 0.05（両側）で行った。

主要解析対象集団は用量選択後の Part 2 にランダム割付けされたすべての被験者とした。有意水準 0.05（両側）のカイ二乗検定により 6 週の clinical response を達成した被験者の割合について，投与群間を比較した。第 I 種の過誤率を 0.05 のレベルにコントロールするため，固定順序による逐次的な検定手順を使用した。この検定手順では，最初に 400→200 mg 群とプラセボ群の比較を両側有意水準 0.05 で実施し，この検定の結果が有意な場合のみ 200→100 mg 群を両側有意水準 0.05 でプラセボ群と比較することとした。200→100 mg 群の検定結果に関係なく，400→200 mg 群の検定結果が有意な場合に，本治験の結果を有意とみなすこととした。

解析対象集団：

主要解析対象集団は用量選択後の Part 2 にランダム割付けされたすべての被験者とした。海外規制当局の要求に基づき，主要解析対象集団に加えて以下に示す事前に規定した解析対象集団についても有効性を評価した。

- Part 1 でランダム化された被験者
- Part 2 でランダム化された被験者
- Part 2 で用量選択前にランダム化された被験者
- Part 2 で用量選択後にランダム化された最初の 450 例の被験者
- ランダム化されたすべての被験者（Part 1 及び 2 の併合）

有効性の解析対象集団に合わせて，人口統計学的特性及びベースラインの疾患特性についても，主要解析対象集団に加えランダム化されたすべての被験者を中心に上記の事前に規定した解析対象集団で評価した。

安全性及び薬物動態は，治験薬の投与を受けたすべての被験者（すなわち Part 1 及び 2 の併合）及び用量選択後に Part 2 で治験薬の投与を受けた被験者を対象として評価した。安全性及び薬物動態は Part 1 でランダム化された被験者でもそれぞれ評価した。

GCP 不遵守があった治験実施医療機関（施設番号：7257 及び 7407）の被験者のデータは，有効性の解析対象からは除外したが，薬物動態及び安全性の解析には含めた。

試験結果：

被験者及び投与状況

ゴリムマブ 734 例（100→50 mg，200→100 mg，400→200 mg それぞれ 72 例，331 例，331 例）及びプラセボ 331 例，計 1065 例がランダムに割り付けられた。4 例（未投与の 1 例，0 週及び 2 週に誤った用量の投与を受けた 3 例）を除くすべてのランダム化された被験者は割り付けられた用量の投与を受けた。1065 例中 1015 例（95.3%）が試験を完了［969/1065 例（91.0%）が 6 週評価終了後に寛解維持療法試験である T18 試験に移行，46/1065 例（4.3%）が 16 週の評価を完了］した。50/1065 例（4.7%）が治験を中止した。50 例のうち 35/1065 例（3.3%）が 6 週よりも前に，15/1065 例（1.4%）が 6 週から 16 週の間に中止した。

人口統計学的特性，ベースラインの疾患特性及び UC に対する他の治療（コルチコステロイド，免疫調節薬及びアミノサリチル酸）を併用していた被験者の割合は，いずれの投与群でもおおむね同様であった。これらの結果は事前に規定した解析対象集団（上記「解析対象集団」参照）で評価し，ランダム化されたすべての被験者の結果と一貫していた。

用量選択後の Part 2 の被験者の内訳を表 2.7.6.3-1 に，人口統計学的特性を表 2.7.6.3-2 に示す。

表 2.7.6.3-1 被験者の内訳（Part 2 用量選択後）

	Placebo	Golimumab 200 mg → 100 mg	Golimumab 400 mg → 200 mg	Golimumab Combined	Total
Randomized subjects in Part 2 after the dose selection	258	258	258	516	774
Subjects who terminated study participation	6 (2.3%)	6 (2.3%)	6 (2.3%)	12 (2.3%)	18 (2.3%)
Reason for termination					
Withdrawal of consent	2 (0.8%)	1 (0.4%)	2 (0.8%)	3 (0.6%)	5 (0.6%)
Lost to follow-up	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)	1 (0.1%)
Death	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other	4 (1.6%)	5 (1.9%)	3 (1.2%)	8 (1.6%)	12 (1.6%)

RE311:[P_DC_22_3_B_BB], 08DEC2010 16:08

参照元：C0524T17 Clinical Study Report Attachment 1.10

表 2.7.6.3-2 人口統計学的特性（Part 2 投与量選択後）

	Placebo	Golimumab 200 mg → 100 mg	Golimumab 400 mg → 200 mg	Golimumab Combined	Total
Randomized subjects in Part 2 after the dose selection	258	258	258	516	774
Sex					
n	258	258	258	516	774
Male	130 (50.4%)	140 (54.3%)	154 (59.7%)	294 (57.0%)	424 (54.8%)
Female	128 (49.6%)	118 (45.7%)	104 (40.3%)	222 (43.0%)	350 (45.2%)
Race					
n	258	258	258	516	774
Caucasian	199 (77.1%)	212 (82.2%)	211 (81.8%)	423 (82.0%)	622 (80.4%)
Black	7 (2.7%)	4 (1.6%)	7 (2.7%)	11 (2.1%)	18 (2.3%)
Asian	44 (17.1%)	28 (10.9%)	29 (11.2%)	57 (11.0%)	101 (13.0%)
Other	8 (3.1%)	14 (5.4%)	11 (4.3%)	25 (4.8%)	33 (4.3%)
Age (yrs)					
n	258	258	258	516	774
Mean ± SD	39.7 ± 13.35	39.7 ± 13.79	40.9 ± 13.95	40.3 ± 13.87	40.1 ± 13.70
Median	38.0	38.0	39.0	38.0	38.0
IQ range	(28.0, 50.0)	(28.0, 50.0)	(29.0, 52.0)	(28.0, 51.0)	(28.0, 51.0)
Range	(18, 72)	(18, 78)	(18, 77)	(18, 78)	(18, 78)
Weight (kg)					
n	257	258	258	516	773
Mean ± SD	71.32 ± 16.944	73.49 ± 17.759	74.47 ± 18.784	73.98 ± 18.267	73.09 ± 17.871
Median	69.00	72.05	72.25	72.10	71.00
IQ range	(58.00, 80.50)	(60.00, 83.50)	(61.00, 86.40)	(60.65, 84.10)	(60.00, 84.00)
Range	(37.9, 125.0)	(33.0, 137.8)	(37.4, 149.7)	(33.0, 149.7)	(33.0, 149.7)
Height (cm)					
n	258	258	258	516	774
Mean ± SD	169.7 ± 10.06	171.1 ± 9.74	171.0 ± 9.12	171.1 ± 9.43	170.6 ± 9.66
Median	169.0	172.0	171.0	171.0	170.0
IQ range	(163.0, 176.0)	(164.0, 178.0)	(164.0, 178.0)	(164.0, 178.0)	(164.0, 178.0)
Range	(143, 196)	(147, 205)	(148, 196)	(147, 205)	(143, 205)

RE311:[P_DEM_1_B_BB], 08DEC2010 16:12

参照元：C0524T17 Clinical Study Report Attachment 1.14

薬物動態及び免疫原性

血清中ゴリムマブ濃度は，ゴリムマブの 0 週及び 2 週の皮下投与量（100→50 mg，200→100 mg，400→200 mg）にほぼ比例して増加した。6 週の血清中ゴリムマブ濃度は大多数の被験者で定量限界（0.03905 μg/mL）を上回っていた。用量選択後の Part 2 の被験者の結果でも，治験薬の投与を受けたすべての被験者の結果とおおむね同様であった。最終安全性評価時点までに，血清サンプルが得られた 721 例中 3 例（0.4%）で抗ゴリムマブ抗体陽性が認められた。

有効性

主要評価項目は 6 週の clinical response とした。主要解析対象集団の 6 週の clinical response は，プラセボ群［30.3%（76/251 例）］と比較して 200→100 mg 群［51.0%（129/253 例）］及び 400→200 mg 群［54.9%（141/257 例）］で統計学的に有意な差が認められた（それぞれ p<0.0001）。主な副次評価項目は 6 週での clinical remission，mucosal healing 及び IBDQ のベースラインからの変化量とした。主要解析対象集団では，プラセボ群と比較して 200→100 mg 群及び 400→200 mg 群で以下のとおり統計学的に有意な差が認められた。

- Clinical remission：プラセボ群 6.4%（16/251 例），200→100 mg 群 17.8%（45/253 例）（p<0.0001）及び 400→200 mg 群 17.9%（46/257 例）（p<0.0001）
- Mucosal healing：プラセボ群 28.7%（72/251 例），200→100 mg 群 42.3%（107/253 例）（p=0.0014）及び 400→200 mg 群 45.1%（116/257 例）（p=0.0001）

IBDQ スコアの平均変化量（標準偏差）もプラセボ群［14.8（31.25）］と比較して 200→100 mg 群［27.0（33.72）］及び 400→200 mg 群［26.9（34.28）］で統計学的に有意な差が認められた（それぞれ p<0.0001）。

主要解析対象集団での 6 週のその他の臨床評価及びバイオマーカーの結果は以下のとおりであった。

- Mayo スコアの平均値の減少（標準偏差）は，プラセボ群［−1.6（2.53）］と比較して 200→100 mg 群［−3.1（2.90）］及び 400→200 mg 群［−3.1（2.95）］で統計学的に有意な差が認められた（それぞれ p<0.0001）。
- Partial Mayo スコアの平均値の減少は，プラセボ群と比較して 200→100 mg 群及び 400→200 mg 群の方が大きかった。
- Mayo サブスコアの各項目では，プラセボ群と比較して 200→100 mg 群及び 400→200 mg 群の方が改善を示した。Mayo サブスコアが正常又は軽度の被験者の割合は増加し，Mayo サブスコアが中等度又は重度の被験者の割合は減少した。
- 粘膜の状態が正常又は非活動性（すなわち内視鏡検査でスコアが 0）の被験者の割合は，プラセボ群［4.0%（10/251 例）］と比較して 200→100 mg 群［8.3%（21/253 例），p=0.0437］及び 400→200 mg 群［12.1%（31/257 例），p=0.0008］で統計学的に有意に高かった。

- CRP 濃度のベースラインからの平均変化量（標準偏差）は，プラセボ群［1.59（20.497）］と比較して 200→100 mg 群［−3.35（20.032），p<0.0001］及び 400→200 mg 群［−2.78（22.558），p=0.0003］で統計学的に有意な減少が認められた。
- 糞便中ラクトフェリン濃度のベースラインからの平均変化量（対数変換値）（標準偏差）は，2 週でプラセボ群［−0.16（0.728）］と比較して 200→100 mg 群［−0.28（0.861），p=0.0952］及び 400→200 mg 群［−0.49（0.933），p=0.0003］で統計学的に有意な減少が認められ，400→200 mg 群では 6 週までその効果が持続した。
- 糞便中カルプロテクチン濃度のベースラインからの平均変化量（対数変換値）（標準偏差）は，2 週でプラセボ群［−0.14（0.639）］と比較して 200→100 mg 群［−0.30（0.644），p=0.0034］及び 400→200 mg 群［−0.34（0.654），p=0.0015］で統計学的に有意な減少が認められ，400→200 mg 群では 6 週までその効果が持続した。
- 組織学的スコアの評価のために生検することに同意した被験者で，グレード 5 の炎症が認められた被験者の割合は，ベースラインに比べ 6 週の方がプラセボ群及びゴリムマブ併合群ともに低く，400→200 mg 群が最も低かった。

主要解析対象集団で 6 週の患者報告アウトカムの結果は，以下のとおりである。

- SF-36 の身体的側面の QOL サマリースコアの平均増加量（標準偏差）は，プラセボ群［2.51（7.200）］に比べ 200→100 mg 群［4.51（7.132），p=0.0009］及び 400→200 mg 群［3.78（7.643），p=0.0591］，精神的側面の QOL サマリースコアは，プラセボ群［1.60（8.618）］に比べ 200→100 mg 群［4.57（10.736），p=0.0017］及び 400→200 mg 群［5.12（10.328），p<0.0001）］であり，統計学的に有意な差が認められた。
- EQ VAS スコアの平均改善量（標準偏差）は，プラセボ群［5.1（18.73）］に比べ 200→100 mg 群［11.5（22.22），p=0.0005］及び 400→200 mg 群［10.8（21.00），p=0.0012］で統計学的に有意な改善が認められた。

事前に規定した他の解析対象集団で評価した主要評価項目，副次評価項目，臨床評価項目，バイオマーカーの評価項目及び患者報告アウトカムの結果は，主要解析対象集団とおおむね同様の結果であった。

ゴリムマブを投与したすべての被験者の 6 週で，Mayo スコアのベースラインからの変化量（中央値）と血清中ゴリムマブ濃度に明らかな関連性が認められた。血清中ゴリムマブ濃度の四分位層が高い集団ほど Mayo スコアのベースラインからの変化量（中央値）の改善が大きかった（血清中ゴリムマブ濃度の第 1 四分位点未満，第 1 四分位点以上中央値未満，中央値以上第 3 四分位点未満，第 3 四分位点以上の順に，−1.0，−3.0，−3.0，−4.0）。血清中ゴリムマブ濃度が高い四分位層の集団の方が，clinical response 及び clinical remission が認められた被験者の割合は高かった。

安全性

安全性の解析は治験薬を投与されたすべての被験者で行った（すなわち Part 1 及び Part 2 の併合）。6 週までで有害事象が認められた被験者の割合は，ゴリムマブ群［39.1%（287/734 例）］とプラセボ群［38.2%（126/330 例）］でおおむね同様であった。ゴリムマブ群及びプラセボ群そ

れぞれで最も発現割合が高かった器官別大分類（SOC）は，「感染症および寄生虫症」［ゴリムマブ群 12.0%（88/734 例），プラセボ群 10.9%（36/330 例）］及び「胃腸障害」［ゴリムマブ群 10.5%（77/734 例），プラセボ群 12.4%（41/330 例）］であった。6 週までにプラセボ群で発現割合が高かった有害事象（3%以上）は，頭痛［5.2%（17/330 例）］，潰瘍性大腸炎［3.9%（13/330 例）］及び鼻咽頭炎［3.3%（11/330 例）］であった。200→100 mg 群及び 400→200 mg 群で発現割合が高かった有害事象（いずれかの群で 3%以上）は，頭痛［200→100 mg 群，400→200 mg 群，以下同順：3.0%（10/331 例），4.5%（15/332 例）］，悪心［0.9%（3/331 例），3.6%（12/332 例）］，発熱［1.8%（6/331 例），3.0%（10/332 例）］，鼻咽頭炎［3.3%（11/331 例），2.4%（8/332 例）］であった。安全性の最終評価までに 1 例が死亡した。当該被験者は 400→200 mg 群であり，重篤な坐骨直腸膿瘍により死亡した。

6 週までに重篤な有害事象を発現した被験者の割合は全般的に低く［プラセボ群 6.1%（20/330 例），ゴリムマブ群 3.0%（22/734 例）］，200→100 mg 群及び 400→200 mg 群では同程度であった［それぞれ 2.7%（9/331 例）及び 3.3%（11/332 例）］。最も発現割合が高かった重篤な有害事象は，プラセボ群，200→100 mg 群及び 400→200 mg 群のいずれの群でも潰瘍性大腸炎であった［それぞれ 2.4%（8/330 例），0.9%（3/331 例）及び 1.2%（4/332 例）］。有害事象により治験薬の投与を中止した被験者はほとんどいなかった。6 週までに治験担当医師により感染症と判断された有害事象が認められた被験者の割合は，プラセボ群［12.1%（40/330 例）とゴリムマブ群［12.0%（88/734 例）］で同程度で，200→100 mg 群及び 400→200 mg 群もほぼ同様であった［それぞれ 11.8%（39/331 例）及び 12.3%（41/332 例）］。抗菌薬による治療が必要であった感染症を発現した被験者の割合は，全般的に低く，プラセボ群とゴリムマブ群でおおむね同様であった［それぞれ 7.0%（23/330 例），5.4%（40/734 例）］。

治験担当医師に感染症と判断された重篤な有害事象の発現割合は，プラセボ群［1.8%（6/330 例）］とゴリムマブ群［0.5%（4/734 例）］ともに低く，200→100 mg 群及び 400→200 mg 群はほぼ同様であった［それぞれ 0.3%（1/331 例）及び 0.9%（3/332 例）］。治験期間中に活動性結核は認められなかった。安全性の最終評価までに 4 例の日和見感染が認められた。1 例は食道カンジダ症（400→200 mg 群），2 例はサイトメガロウイルス感染（プラセボ群 1 例，200→100 mg 群 1 例），1 例は重篤なサイトメガロウイルス感染（100→50 mg 群）であった。6 週までに注射部位反応が認められた被験者の割合は，全般的に低く［プラセボ群 1.5%（5/330 例），ゴリムマブ群 3.4%（25/734 例）］，200→100 mg 群及び 400→200 mg 群は同様であった［それぞれ 3.3%（11/331 例）及び 3.0%（10/332 例）］。重篤な注射部位反応は認められなかった。遅発性過敏症又はアナフィラキシー反応が疑われる有害事象は認められなかった。2 例の悪性腫瘍が報告された。400→200 mg 群の 1 例は上皮内癌及び結腸癌，プラセボ群の 1 例は甲状腺癌であった。いずれの悪性腫瘍も本試験でのゴリムマブ投与によるものではなかった。

血液学的検査及び血液生化学検査で特に目立った傾向はなかった。

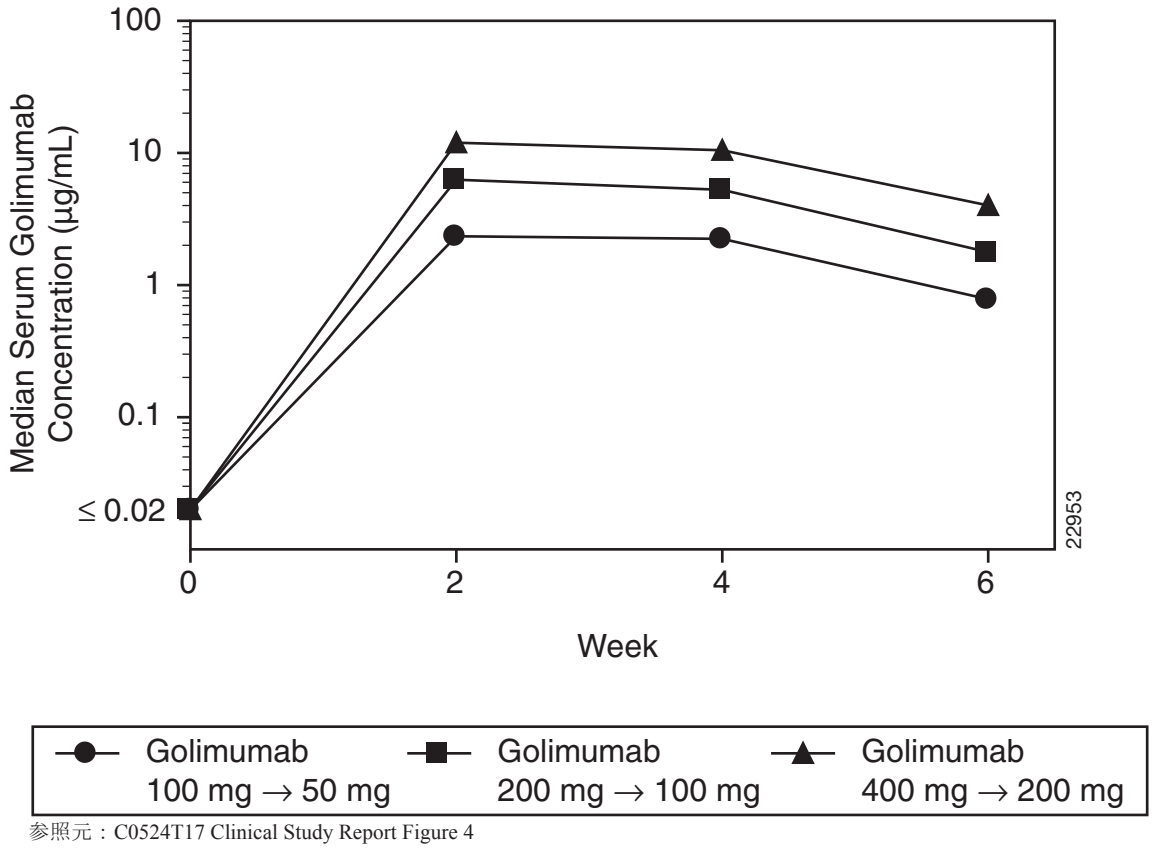
用量選択後の Part 2 の結果は，治験薬の投与を受けたすべての被験者の結果とおおむね同様であった。Part 1 及び Part 2 併合のすべての有害事象を表 2.7.6.3-5 に，用量選択後の Part 2 のすべての有害事象を表 2.7.6.3-6 に示す。

試験の欠点（Study limitations）

特筆すべきものは認められなかった。

結論

中等症から重症の活動期 UC 患者を対象としたゴリムマブ 200→100 mg 及び 400→200 mg の皮下投与は，6 週での clinical response，clinical remission，mucosal healing 及び患者報告アウトカムを指標に評価したところ，プラセボに比較していずれのゴリムマブ群も同様に有意な改善を示した。高用量の血清ゴリムマブ曝露は，Mayo スコア及び clinical response と clinical remission を指標とした UC の活動性をより大きく改善すると考えられた。ゴリムマブの忍容性はおおむね良好であり，安全性プロファイルは，本剤の他の適応症及び他の抗 TNF 薬と同様であった。全体として，本試験の結果は，中等症から重症の活動期 UC 成人患者に対するゴリムマブ皮下投与寛解導入療法の良好なベネフィット・リスクプロファイルを支持するものであった。



参照元：C0524T17 Clinical Study Report Figure 4
被験者 7078-00001 の 4 週及び 6 週のデータを除く

図 2.7.6.3-1 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-時間濃度推移（中央値）：全投与被験者

表 2.7.6.3-3 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が定量下限未満だった被験者の人数

	Golimumab		
	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg
Subjects treated	71	331	332
Baseline, preadministration			
n	67	323	327
Subjects without detectable concentration	66 (98.5%)	321 (99.4%)	323 (98.8%)
Week 2, preadministration			
n	65	322	321
Subjects without detectable concentration	2 (3.1%)	0 (0.0%)	1 (0.3%)
Week 4			
n[a]	64	308	311
Subjects without detectable concentration	0 (0.0%)	1 (0.3%)	0 (0.0%)
Week 6			
n[a]	59	292	285
Subjects without detectable concentration	2 (3.4%)	1 (0.3%)	1 (0.4%)

[a] One sample collected for subject 7078-00001 was excluded.

RE311:[K CONC 90 F DD], 07APR2011 11:05

参照元：C0524T17 Clinical Study Report Attachment 2.3

表 2.7.6.3-4 6 週の clinical response（用量選択後 Part 2，医療機関 7257 及び 7407 を除く）

		Golimumab		
	Placebo	200 mg → 100 mg	400 mg → 200 mg	Combined
Randomized subjects in part 2 of C0524T17 after the dose selection (excluding sites 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.

[E CRES 93 B BB T17.rtf] [CNTO148\C0524T17\DBR WEEK6\RE EXCLUDE7407\e-cres-93-b-bb-t17.sas] 20JUN2013, 10:35

参照元：Correction Report for C0524T17 Clinical Study Report Attachment 3.1

表 2.7.6.3-5 すべての有害事象（6 週まで）

		Golimumab				
	Placebo	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg	Combined	All Golimumab
Subjects treated	330	71	331	332	663	734
Avg duration of follow-up (weeks)	6.05	5.95	6.08	6.09	6.09	6.07
Avg exposure (number of administrations)	1.98	1.97	1.99	1.99	1.99	1.99
Subjects with 1 or more adverse events	126 (38.2%)	34 (47.9%)	124 (37.5%)	129 (38.9%)	253 (38.2%)	287 (39.1%)
System-organ class/preferred term						
感染症および寄生虫症	36 (10.9%)	7 (9.9%)	40 (12.1%)	41 (12.3%)	81 (12.2%)	88 (12.0%)
鼻咽頭炎	11 (3.3%)	2 (2.8%)	11 (3.3%)	8 (2.4%)	19 (2.9%)	21 (2.9%)
上気道感染	5 (1.5%)	0 (0.0%)	5 (1.5%)	4 (1.2%)	9 (1.4%)	9 (1.2%)
胃腸炎	1 (0.3%)	0 (0.0%)	3 (0.9%)	2 (0.6%)	5 (0.8%)	5 (0.7%)
副鼻腔炎	2 (0.6%)	0 (0.0%)	1 (0.3%)	4 (1.2%)	5 (0.8%)	5 (0.7%)
気管支炎	2 (0.6%)	0 (0.0%)	3 (0.9%)	1 (0.3%)	4 (0.6%)	4 (0.5%)
口腔ヘルペス	1 (0.3%)	2 (2.8%)	2 (0.6%)	0 (0.0%)	2 (0.3%)	4 (0.5%)
咽頭炎	0 (0.0%)	0 (0.0%)	2 (0.6%)	2 (0.6%)	4 (0.6%)	4 (0.5%)
クロストリジウム感染	0 (0.0%)	0 (0.0%)	2 (0.6%)	1 (0.3%)	3 (0.5%)	3 (0.4%)
毛包炎	1 (0.3%)	0 (0.0%)	3 (0.9%)	0 (0.0%)	3 (0.5%)	3 (0.4%)
ウイルス性胃腸炎	1 (0.3%)	1 (1.4%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	3 (0.4%)
尿路感染	0 (0.0%)	0 (0.0%)	2 (0.6%)	1 (0.3%)	3 (0.5%)	3 (0.4%)
真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.6%)	2 (0.3%)	2 (0.3%)
インフルエンザ	1 (0.3%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
歯膿瘍	1 (0.3%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
ダニ皮膚炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
エロモナス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
アメーバ症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
肛門性器疣贅	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
ブラストシスティス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
膀胱炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
耳感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
丹毒	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
外耳蜂巣炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)

表 2.7.6.3-5 すべての有害事象（6 週まで）（続き）

		Golimumab				
	Placebo	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg	Combined	All Golimumab
皮膚真菌感染	0 (0.0%)	1 (1.4%)	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%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
潜伏結核	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
限局性感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
食道カンジダ症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
爪真菌症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
口腔カンジダ症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
爪囲炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
百日咳	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
肺炎	1 (0.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
直腸膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
気道感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
鼻炎	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
腟感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
ウイルス性上気道感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
外陰腟真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
急性扁桃炎	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
肛門膿瘍	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
細菌感染	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
カンジダ症	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
サイトメガロウイルス感染	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
感染性小腸結腸炎	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血腫感染	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
単純ヘルペス	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ブドウ球菌感染	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ウイルス感染	3 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
胃腸障害	41 (12.4%)	7 (9.9%)	26 (7.9%)	44 (13.3%)	70 (10.6%)	77 (10.5%)
悪心	7 (2.1%)	1 (1.4%)	3 (0.9%)	12 (3.6%)	15 (2.3%)	16 (2.2%)

表 2.7.6.3-5 すべての有害事象（6 週まで）（続き）

		Golimumab				
	Placebo	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg	Combined	All Golimumab
潰瘍性大腸炎	13 (3.9%)	2 (2.8%)	7 (2.1%)	6 (1.8%)	13 (2.0%)	15 (2.0%)
腹痛	5 (1.5%)	1 (1.4%)	2 (0.6%)	8 (2.4%)	10 (1.5%)	11 (1.5%)
嘔吐	4 (1.2%)	1 (1.4%)	1 (0.3%)	5 (1.5%)	6 (0.9%)	7 (1.0%)
消化不良	1 (0.3%)	0 (0.0%)	3 (0.9%)	2 (0.6%)	5 (0.8%)	5 (0.7%)
下腹部痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (1.2%)	4 (0.6%)	4 (0.5%)
上腹部痛	1 (0.3%)	0 (0.0%)	2 (0.6%)	2 (0.6%)	4 (0.6%)	4 (0.5%)
便秘	4 (1.2%)	1 (1.4%)	1 (0.3%)	2 (0.6%)	3 (0.5%)	4 (0.5%)
裂肛	0 (0.0%)	1 (1.4%)	0 (0.0%)	2 (0.6%)	2 (0.3%)	3 (0.4%)
アフタ性口内炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.6%)	3 (0.5%)	3 (0.4%)
下痢	4 (1.2%)	1 (1.4%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	3 (0.4%)
痔核	1 (0.3%)	0 (0.0%)	1 (0.3%)	2 (0.6%)	3 (0.5%)	3 (0.4%)
肛門周囲痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
腹部膨満	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
肛門直腸不快感	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
結腸ポリープ	1 (0.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
齲歯	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
十二指腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
便失禁	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
食中毒	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
肛門肥大乳頭	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
口の錯感覚	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
直腸攣縮	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
口内炎	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
歯痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
腹部不快感	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
腸炎	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
鼓腸	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
排便回数増加	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
胃食道逆流性疾患	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

表 2.7.6.3-5 すべての有害事象（6 週まで）（続き）

		Golimumab				
	Placebo	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg	Combined	All Golimumab
血便排泄	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
過敏性腸症候群	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
直腸出血	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
直腸ポリープ	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
舌水疱形成	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
全身障害および投与局所様態	20 (6.1%)	10 (14.1%)	23 (6.9%)	28 (8.4%)	51 (7.7%)	61 (8.3%)
発熱	7 (2.1%)	2 (2.8%)	6 (1.8%)	10 (3.0%)	16 (2.4%)	18 (2.5%)
注射部位紅斑	0 (0.0%)	3 (4.2%)	5 (1.5%)	4 (1.2%)	9 (1.4%)	12 (1.6%)
疲労	1 (0.3%)	1 (1.4%)	4 (1.2%)	4 (1.2%)	8 (1.2%)	9 (1.2%)
インフルエンザ様疾患	1 (0.3%)	0 (0.0%)	1 (0.3%)	3 (0.9%)	4 (0.6%)	4 (0.5%)
無力症	1 (0.3%)	0 (0.0%)	0 (0.0%)	3 (0.9%)	3 (0.5%)	3 (0.4%)
高熱	0 (0.0%)	0 (0.0%)	2 (0.6%)	1 (0.3%)	3 (0.5%)	3 (0.4%)
注射部位そう痒感	0 (0.0%)	1 (1.4%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	3 (0.4%)
末梢性浮腫	1 (0.3%)	0 (0.0%)	2 (0.6%)	1 (0.3%)	3 (0.5%)	3 (0.4%)
注射部位血腫	1 (0.3%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
注射部位炎症	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
注射部位疼痛	1 (0.3%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
注射部位反応	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.6%)	2 (0.3%)	2 (0.3%)
注射部位腫脹	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	2 (0.3%)
注射部位蕁麻疹	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	2 (0.3%)
医薬品副作用	2 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
胸痛	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
悪寒	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
冷感	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
注射部位出血	1 (0.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
疼痛	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
熱感	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
治癒不良	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
圧迫感	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

表 2.7.6.3-5 すべての有害事象（6 週まで）（続き）

		Golimumab				
	Placebo	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg	Combined	All Golimumab
乾燥症	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
神経系障害	26 (7.9%)	6 (8.5%)	19 (5.7%)	17 (5.1%)	36 (5.4%)	42 (5.7%)
頭痛	17 (5.2%)	5 (7.0%)	10 (3.0%)	15 (4.5%)	25 (3.8%)	30 (4.1%)
浮動性めまい	1 (0.3%)	0 (0.0%)	3 (0.9%)	3 (0.9%)	6 (0.9%)	6 (0.8%)
感覚鈍麻	0 (0.0%)	1 (1.4%)	2 (0.6%)	0 (0.0%)	2 (0.3%)	3 (0.4%)
錯感覚	1 (0.3%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	2 (0.3%)	2 (0.3%)
肘部管症候群	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
異常感覚	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
虚血性脳卒中	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
意識消失	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
感覚障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
味覚異常	3 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
知覚過敏	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
筋緊張低下	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
片頭痛	3 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
振戦	1 (0.3%)	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	21 (6.4%)	4 (5.6%)	16 (4.8%)	12 (3.6%)	28 (4.2%)	32 (4.4%)
発疹	5 (1.5%)	2 (2.8%)	2 (0.6%)	3 (0.9%)	5 (0.8%)	7 (1.0%)
そう痒症	1 (0.3%)	0 (0.0%)	2 (0.6%)	2 (0.6%)	4 (0.6%)	4 (0.5%)
脱毛症	0 (0.0%)	0 (0.0%)	2 (0.6%)	1 (0.3%)	3 (0.5%)	3 (0.4%)
皮膚乾燥	1 (0.3%)	0 (0.0%)	1 (0.3%)	2 (0.6%)	3 (0.5%)	3 (0.4%)
紅斑	1 (0.3%)	1 (1.4%)	2 (0.6%)	0 (0.0%)	2 (0.3%)	3 (0.4%)
多汗症	0 (0.0%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	2 (0.3%)	2 (0.3%)
ざ瘡	3 (0.9%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
水疱	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
皮膚炎	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
アレルギー性皮膚炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
アトピー性皮膚炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
湿疹	2 (0.6%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)

表 2.7.6.3-5 すべての有害事象（6 週まで）（続き）

		Golimumab				
	Placebo	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg	Combined	All Golimumab
嵌入爪	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
爪の障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
寝汗	1 (0.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
そう痒性皮疹	1 (0.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
脂漏性皮膚炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
皮膚線条	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
蕁麻疹	1 (0.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
結節性紅斑	4 (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
爪破損	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
全身性そう痒症	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
乾癬	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
毛孔性皮疹	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
斑状皮疹	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
皮膚剥脱	1 (0.3%)	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	13 (3.9%)	3 (4.2%)	13 (3.9%)	11 (3.3%)	24 (3.6%)	27 (3.7%)
貧血	7 (2.1%)	1 (1.4%)	9 (2.7%)	5 (1.5%)	14 (2.1%)	15 (2.0%)
好中球減少症	1 (0.3%)	1 (1.4%)	1 (0.3%)	3 (0.9%)	4 (0.6%)	5 (0.7%)
好酸球増加症	1 (0.3%)	0 (0.0%)	1 (0.3%)	2 (0.6%)	3 (0.5%)	3 (0.4%)
白血球減少症	1 (0.3%)	1 (1.4%)	2 (0.6%)	0 (0.0%)	2 (0.3%)	3 (0.4%)
鉄欠乏性貧血	1 (0.3%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
白血球増加症	1 (0.3%)	0 (0.0%)	0 (0.0%)	2 (0.6%)	2 (0.3%)	2 (0.3%)
リンパ球増加症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.6%)	2 (0.3%)	2 (0.3%)
単球減少症	2 (0.6%)	0 (0.0%)	0 (0.0%)	2 (0.6%)	2 (0.3%)	2 (0.3%)
リンパ球減少症	2 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
血小板減少症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
単球増加症	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血小板増加症	1 (0.3%)	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	16 (4.8%)	2 (2.8%)	8 (2.4%)	15 (4.5%)	23 (3.5%)	25 (3.4%)
関節痛	7 (2.1%)	0 (0.0%)	3 (0.9%)	6 (1.8%)	9 (1.4%)	9 (1.2%)

表 2.7.6.3-5 すべての有害事象（6 週まで）（続き）

		Golimumab				
	Placebo	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg	Combined	All Golimumab
筋痙縮	1 (0.3%)	0 (0.0%)	2 (0.6%)	3 (0.9%)	5 (0.8%)	5 (0.7%)
背部痛	2 (0.6%)	2 (2.8%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	3 (0.4%)
四肢痛	1 (0.3%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	2 (0.3%)	2 (0.3%)
骨痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
軟骨疾患	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
関節ロック	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
筋攣縮	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
筋骨格痛	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
筋肉痛	2 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
頚部痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
骨減少症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
骨粗鬆症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
骨粗鬆症性骨折	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
骨硬化症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
関節障害	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
関節硬直	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
関節腫脹	3 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
顎痛	1 (0.3%)	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	15 (4.5%)	2 (2.8%)	9 (2.7%)	10 (3.0%)	19 (2.9%)	21 (2.9%)
咳嗽	9 (2.7%)	0 (0.0%)	3 (0.9%)	3 (0.9%)	6 (0.9%)	6 (0.8%)
口腔咽頭痛	3 (0.9%)	1 (1.4%)	1 (0.3%)	2 (0.6%)	3 (0.5%)	4 (0.5%)
喘息	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
慢性閉塞性肺疾患	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.6%)	2 (0.3%)	2 (0.3%)
呼吸困難	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
鼻出血	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
湿性咳嗽	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
呼吸障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
アレルギー性鼻炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
鼻漏	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)

表 2.7.6.3-5 すべての有害事象（6 週まで）（続き）

		Golimumab				
	Placebo	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg	Combined	All Golimumab
咽喉刺激感	1 (0.3%)	1 (1.4%)	0 (0.0%)	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%)	1 (0.2%)	1 (0.1%)
咽喉乾燥	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
鼻部不快感	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
口腔咽頭水疱形成	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
臨床検査	14 (4.2%)	2 (2.8%)	5 (1.5%)	13 (3.9%)	18 (2.7%)	20 (2.7%)
アラニン・アミノトランスフェラーゼ増加	5 (1.5%)	0 (0.0%)	1 (0.3%)	2 (0.6%)	3 (0.5%)	3 (0.4%)
ヘモグロビン減少	1 (0.3%)	1 (1.4%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	3 (0.4%)
血中アルブミン減少	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	2 (0.3%)
ヘマトクリット減少	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	2 (0.3%)
トランスアミナーゼ上昇	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.6%)	2 (0.3%)	2 (0.3%)
体重増加	1 (0.3%)	1 (1.4%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	2 (0.3%)
白血球数減少	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
アスパラギン酸アミノトランスフェラーゼ増加	4 (1.2%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
血中アルカリホスファターゼ増加	2 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
血中カルシウム減少	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
血中カルシウム増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
血中カリウム減少	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
血中尿素増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
リンパ球数減少	1 (0.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
リンパ球数増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
骨髄球数増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
好中球数減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
好中球数増加	1 (0.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
腎機能検査異常	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
循環血液量低下	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
体重減少	2 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
白血球数増加	1 (0.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
α１フェトプロテイン増加	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

表 2.7.6.3-5 すべての有害事象（6 週まで）（続き）

		Golimumab				
	Placebo	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg	Combined	All Golimumab
杆状核好中球数増加	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
肝酵素上昇	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
肝機能検査異常	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
リンパ球数異常	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
巨核球	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
単球数異常	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
骨髄球存在	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血小板数増加	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
バーセル陽性	1 (0.3%)	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	5 (1.5%)	2 (2.8%)	7 (2.1%)	3 (0.9%)	10 (1.5%)	12 (1.6%)
挫傷	3 (0.9%)	1 (1.4%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	3 (0.4%)
熱傷	0 (0.0%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	2 (0.3%)	2 (0.3%)
動物咬傷	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
足関節部骨折	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
転倒	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
関節捻挫	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
靭帯断裂	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
四肢損傷	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
処置後合併症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
処置による疼痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
筋挫傷	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
皮膚裂傷	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
眼障害	4 (1.2%)	0 (0.0%)	4 (1.2%)	3 (0.9%)	7 (1.1%)	7 (1.0%)
結膜炎	0 (0.0%)	0 (0.0%)	2 (0.6%)	1 (0.3%)	3 (0.5%)	3 (0.4%)
白内障	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
上強膜炎	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
緑内障	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
視力障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
眼瞼痙攣	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

表 2.7.6.3-5 すべての有害事象（6 週まで）（続き）

		Golimumab				
	Placebo	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg	Combined	All Golimumab
霰粒腫	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
眼充血	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
腎および尿路障害	2 (0.6%)	1 (1.4%)	1 (0.3%)	5 (1.5%)	6 (0.9%)	7 (1.0%)
排尿困難	1 (0.3%)	0 (0.0%)	0 (0.0%)	2 (0.6%)	2 (0.3%)	2 (0.3%)
頻尿	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
血尿	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
腎嚢胞	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
腎臓痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
腎仙痛	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
精神障害	6 (1.8%)	3 (4.2%)	1 (0.3%)	2 (0.6%)	3 (0.5%)	6 (0.8%)
不眠症	3 (0.9%)	2 (2.8%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	4 (0.5%)
不安	1 (0.3%)	1 (1.4%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	2 (0.3%)
うつ病	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
リビドー減退	1 (0.3%)	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	3 (0.9%)	1 (1.4%)	1 (0.3%)	3 (0.9%)	4 (0.6%)	5 (0.7%)
無月経	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
乳房痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
月経困難症	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
精巣上体炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
頻発月経	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
陰部そう痒症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
良性前立腺肥大症	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
前立腺炎	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
外陰腟灼熱感	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血管障害	5 (1.5%)	0 (0.0%)	1 (0.3%)	4 (1.2%)	5 (0.8%)	5 (0.7%)
高血圧	2 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.6%)	3 (0.5%)	3 (0.4%)
潮紅	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
ほてり	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
深部静脈血栓症	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

表 2.7.6.3-5 すべての有害事象（6 週まで）（続き）

		Golimumab				
	Placebo	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg	Combined	All Golimumab
静脈炎	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
代謝および栄養障害	10 (3.0%)	0 (0.0%)	0 (0.0%)	4 (1.2%)	4 (0.6%)	4 (0.5%)
食欲減退	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
脱水	2 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
糖尿病	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
高カルシウム血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
低アルブミン血症	2 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
高リン酸塩血症	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
低カリウム血症	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
低蛋白血症	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ラクトース不耐性	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
栄養障害	3 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ビタミン D 欠乏	1 (0.3%)	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）	1 (0.3%)	0 (0.0%)	0 (0.0%)	3 (0.9%)	3 (0.5%)	3 (0.4%)
上皮内癌	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
結腸癌	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
胃腸管腺腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
子宮平滑筋腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
甲状腺癌	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
心臓障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
心血管障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
動悸	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
耳および迷路障害	3 (0.9%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
耳の障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
回転性めまい	1 (0.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
耳不快感	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
耳痛	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
免疫系障害	1 (0.3%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)

表 2.7.6.3-5 すべての有害事象（6 週まで）（続き）

		Golimumab				
	Placebo	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg	Combined	All Golimumab
季節性アレルギー	1 (0.3%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
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%)	1 (0.2%)	1 (0.1%)
ジルベール症候群	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
肝胆道系障害	1 (0.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
肝炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
肝嚢胞	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
社会環境	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
パートナーの妊娠	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
外科および内科処置	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
副鼻腔手術	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
内分泌障害	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
クッシング様	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

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参照元：C0524T17 Clinical Study Report Attachment 4.1

表 2.7.6.3-6 すべての有害事象（Part 2 用量選択後，6 週まで）

	Placebo	Golimumab		
		200 mg → 100 mg	400 mg → 200 mg	Combined
Treated subjects in Part 2 after the dose selection	257	259	258	517
Avg duration of follow-up (weeks)	6.08	6.09	6.08	6.08
Avg exposure (number of administrations)	1.98	1.99	1.99	1.99
Subjects with 1 or more adverse events	98 (38.1%)	93 (35.9%)	94 (36.4%)	187 (36.2%)
System-organ class/preferred term				
感染症および寄生虫症	30 (11.7%)	31 (12.0%)	31 (12.0%)	62 (12.0%)
鼻咽頭炎	10 (3.9%)	8 (3.1%)	6 (2.3%)	14 (2.7%)
上気道感染	3 (1.2%)	4 (1.5%)	3 (1.2%)	7 (1.4%)
咽頭炎	0 (0.0%)	2 (0.8%)	2 (0.8%)	4 (0.8%)
副鼻腔炎	1 (0.4%)	1 (0.4%)	3 (1.2%)	4 (0.8%)
尿路感染	0 (0.0%)	2 (0.8%)	1 (0.4%)	3 (0.6%)
気管支炎	1 (0.4%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
クロストリジウム感染	0 (0.0%)	2 (0.8%)	0 (0.0%)	2 (0.4%)
毛包炎	1 (0.4%)	2 (0.8%)	0 (0.0%)	2 (0.4%)
真菌感染	0 (0.0%)	0 (0.0%)	2 (0.8%)	2 (0.4%)
ウイルス性胃腸炎	1 (0.4%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
インフルエンザ	1 (0.4%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
口腔ヘルペス	0 (0.0%)	2 (0.8%)	0 (0.0%)	2 (0.4%)
歯膿瘍	0 (0.0%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
ダニ皮膚炎	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
エロモナス感染	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
肛門性器疣贅	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
ブラストシスティス感染	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
膀胱炎	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
外耳蜂巣炎	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
胃腸炎	1 (0.4%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
帯状疱疹	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
感染	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
潜伏結核	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
限局性感染	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
食道カンジダ症	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
爪真菌症	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
口腔カンジダ症	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
爪囲炎	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
百日咳	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
肺炎	1 (0.4%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
直腸膿瘍	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
気道感染	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
腟感染	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
外陰腟真菌感染	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
急性扁桃炎	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

表 2.7.6.3-6 すべての有害事象（Part 2 用量選択後，6 週まで）（続き）

	Placebo	Golimumab		
		200 mg → 100 mg	400 mg → 200 mg	Combined
肛門膿瘍	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
細菌感染	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
カンジダ症	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
サイトメガロウイルス感染	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
感染性小腸結腸炎	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血腫感染	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
単純ヘルペス	2 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ブドウ球菌感染	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ウイルス感染	2 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
胃腸障害	31 (12.1%)	18 (6.9%)	31 (12.0%)	49 (9.5%)
潰瘍性大腸炎	10 (3.9%)	7 (2.7%)	5 (1.9%)	12 (2.3%)
悪心	7 (2.7%)	3 (1.2%)	6 (2.3%)	9 (1.7%)
腹痛	2 (0.8%)	1 (0.4%)	5 (1.9%)	6 (1.2%)
嘔吐	4 (1.6%)	1 (0.4%)	5 (1.9%)	6 (1.2%)
下腹部痛	0 (0.0%)	0 (0.0%)	3 (1.2%)	3 (0.6%)
アフタ性口内炎	0 (0.0%)	1 (0.4%)	2 (0.8%)	3 (0.6%)
上腹部痛	0 (0.0%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
裂肛	0 (0.0%)	0 (0.0%)	2 (0.8%)	2 (0.4%)
便秘	3 (1.2%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
消化不良	1 (0.4%)	2 (0.8%)	0 (0.0%)	2 (0.4%)
痔核	0 (0.0%)	0 (0.0%)	2 (0.8%)	2 (0.4%)
肛門周囲痛	0 (0.0%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
腹部膨満	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
肛門直腸不快感	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
十二指腸炎	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
便失禁	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
食中毒	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
口の錯感覚	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
口内炎	1 (0.4%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
腹部不快感	2 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
下痢	2 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
腸炎	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
鼓腸	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
排便回数増加	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
胃食道逆流性疾患	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血便排泄	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
過敏性腸症候群	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
直腸出血	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
直腸ポリープ	2 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
全身障害および投与局所様態	18 (7.0%)	16 (6.2%)	16 (6.2%)	32 (6.2%)
発熱	7 (2.7%)	4 (1.5%)	7 (2.7%)	11 (2.1%)
疲労	1 (0.4%)	3 (1.2%)	2 (0.8%)	5 (1.0%)
注射部位紅斑	0 (0.0%)	3 (1.2%)	1 (0.4%)	4 (0.8%)
高熱	0 (0.0%)	2 (0.8%)	1 (0.4%)	3 (0.6%)

表 2.7.6.3-6 すべての有害事象（Part 2 用量選択後，6 週まで）（続き）

	Placebo	Golimumab		
		200 mg → 100 mg	400 mg → 200 mg	Combined
末梢性浮腫	1 (0.4%)	2 (0.8%)	1 (0.4%)	3 (0.6%)
注射部位疼痛	1 (0.4%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
注射部位反応	0 (0.0%)	0 (0.0%)	2 (0.8%)	2 (0.4%)
無力症	1 (0.4%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
悪寒	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
インフルエンザ様疾患	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
注射部位血腫	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
注射部位出血	1 (0.4%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
注射部位炎症	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
注射部位そう痒感	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
注射部位蕁麻疹	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
医薬品副作用	2 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
熱感	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
治癒不良	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
圧迫感	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
乾燥症	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
神経系障害	20 (7.8%)	16 (6.2%)	11 (4.3%)	27 (5.2%)
頭痛	14 (5.4%)	8 (3.1%)	9 (3.5%)	17 (3.3%)
浮動性めまい	1 (0.4%)	2 (0.8%)	3 (1.2%)	5 (1.0%)
感覚鈍麻	0 (0.0%)	2 (0.8%)	0 (0.0%)	2 (0.4%)
錯感覚	1 (0.4%)	2 (0.8%)	0 (0.0%)	2 (0.4%)
肘部管症候群	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
異常感覚	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
虚血性脳卒中	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
感覚障害	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
味覚異常	2 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
筋緊張低下	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
片頭痛	3 (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
皮膚および皮下組織障害	17 (6.6%)	14 (5.4%)	8 (3.1%)	22 (4.3%)
脱毛症	0 (0.0%)	2 (0.8%)	1 (0.4%)	3 (0.6%)
そう痒症	0 (0.0%)	1 (0.4%)	2 (0.8%)	3 (0.6%)
発疹	4 (1.6%)	2 (0.8%)	1 (0.4%)	3 (0.6%)
皮膚乾燥	1 (0.4%)	0 (0.0%)	2 (0.8%)	2 (0.4%)
紅斑	1 (0.4%)	2 (0.8%)	0 (0.0%)	2 (0.4%)
多汗症	0 (0.0%)	2 (0.8%)	0 (0.0%)	2 (0.4%)
ざ瘡	3 (1.2%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
アレルギー性皮膚炎	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
アトピー性皮膚炎	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
嵌入爪	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
爪の障害	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
寝汗	1 (0.4%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
そう痒性皮疹	1 (0.4%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
脂漏性皮膚炎	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
蕁麻疹	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)

表 2.7.6.3-6 すべての有害事象（Part 2 用量選択後，6 週まで）（続き）

	Placebo	Golimumab		
		200 mg → 100 mg	400 mg → 200 mg	Combined
皮膚炎	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
湿疹	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
結節性紅斑	4 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
全身性そう痒症	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
乾癬	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
毛孔性皮疹	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
斑状皮疹	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
皮膚剥脱	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血液およびリンパ系障害	10 (3.9%)	11 (4.2%)	8 (3.1%)	19 (3.7%)
貧血	6 (2.3%)	7 (2.7%)	3 (1.2%)	10 (1.9%)
好酸球増加症	0 (0.0%)	1 (0.4%)	2 (0.8%)	3 (0.6%)
好中球減少症	0 (0.0%)	1 (0.4%)	2 (0.8%)	3 (0.6%)
鉄欠乏性貧血	1 (0.4%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
白血球増加症	1 (0.4%)	0 (0.0%)	2 (0.8%)	2 (0.4%)
白血球減少症	1 (0.4%)	2 (0.8%)	0 (0.0%)	2 (0.4%)
リンパ球増加症	0 (0.0%)	0 (0.0%)	2 (0.8%)	2 (0.4%)
単球減少症	2 (0.8%)	0 (0.0%)	2 (0.8%)	2 (0.4%)
血小板減少症	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
リンパ球減少症	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
単球増加症	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血小板増加症	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
筋骨格系および結合組織障害	10 (3.9%)	7 (2.7%)	9 (3.5%)	16 (3.1%)
関節痛	6 (2.3%)	2 (0.8%)	3 (1.2%)	5 (1.0%)
筋痙縮	1 (0.4%)	2 (0.8%)	3 (1.2%)	5 (1.0%)
四肢痛	0 (0.0%)	2 (0.8%)	0 (0.0%)	2 (0.4%)
背部痛	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
骨痛	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
軟骨疾患	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
関節ロック	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
筋攣縮	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
頚部痛	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
骨減少症	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
関節障害	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
関節硬直	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
関節腫脹	2 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
筋骨格痛	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
筋肉痛	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
呼吸器、胸郭および縦隔障害	13 (5.1%)	6 (2.3%)	9 (3.5%)	15 (2.9%)
咳嗽	9 (3.5%)	2 (0.8%)	3 (1.2%)	5 (1.0%)
喘息	0 (0.0%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
慢性閉塞性肺疾患	0 (0.0%)	0 (0.0%)	2 (0.8%)	2 (0.4%)
口腔咽頭痛	2 (0.8%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
呼吸困難	1 (0.4%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
呼吸障害	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)

表 2.7.6.3-6 すべての有害事象（Part 2 用量選択後，6 週まで）（続き）

	Placebo	Golimumab		
		200 mg → 100 mg	400 mg → 200 mg	Combined
アレルギー性鼻炎	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
鼻漏	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
上気道うっ血	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
咽喉乾燥	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
鼻部不快感	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
咽喉刺激感	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
臨床検査	11 (4.3%)	5 (1.9%)	8 (3.1%)	13 (2.5%)
アラニン・アミノトランスフェラーゼ増加	3 (1.2%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
白血球数減少	0 (0.0%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
アスパラギン酸アミノトランスフェラーゼ増加	3 (1.2%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
血中アルカリホスファターゼ増加	1 (0.4%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
血中尿素増加	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
ヘモグロビン減少	1 (0.4%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
リンパ球数減少	1 (0.4%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
リンパ球数増加	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
骨髄球数増加	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
好中球数減少	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
好中球数増加	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
腎機能検査異常	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
トランスアミナーゼ上昇	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
循環血液量低下	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
白血球数増加	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
杆状核好中球数増加	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血中カルシウム減少	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
肝酵素上昇	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
肝機能検査異常	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
巨核球	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
骨髄球存在	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血小板数増加	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
バーセル陽性	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
体重減少	2 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
体重増加	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
傷害、中毒および処置合併症	4 (1.6%)	3 (1.2%)	3 (1.2%)	6 (1.2%)
挫傷	3 (1.2%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
熱傷	0 (0.0%)	2 (0.8%)	0 (0.0%)	2 (0.4%)
靭帯断裂	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
処置による疼痛	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
皮膚裂傷	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
眼障害	4 (1.6%)	2 (0.8%)	3 (1.2%)	5 (1.0%)
結膜炎	0 (0.0%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
白内障	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
上強膜炎	1 (0.4%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
緑内障	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)

表 2.7.6.3-6 すべての有害事象（Part 2 用量選択後，6 週まで）（続き）

	Placebo	Golimumab		
		200 mg → 100 mg	400 mg → 200 mg	Combined
眼瞼痙攣	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
霰粒腫	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
眼充血	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
腎および尿路障害	2 (0.8%)	1 (0.4%)	4 (1.6%)	5 (1.0%)
排尿困難	1 (0.4%)	0 (0.0%)	2 (0.8%)	2 (0.4%)
血尿	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
頻尿	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
腎臓痛	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
腎仙痛	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血管障害	3 (1.2%)	1 (0.4%)	3 (1.2%)	4 (0.8%)
高血圧	1 (0.4%)	1 (0.4%)	2 (0.8%)	3 (0.6%)
ほてり	1 (0.4%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
静脈炎	1 (0.4%)	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）	1 (0.4%)	0 (0.0%)	3 (1.2%)	3 (0.6%)
上皮内癌	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
結腸癌	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
胃腸管腺腫	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
子宮平滑筋腫	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
甲状腺癌	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
精神障害	3 (1.2%)	1 (0.4%)	2 (0.8%)	3 (0.6%)
不眠症	1 (0.4%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
不安	1 (0.4%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
うつ病	1 (0.4%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
心臓障害	0 (0.0%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
心血管障害	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
動悸	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
耳および迷路障害	2 (0.8%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
耳の障害	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
回転性めまい	1 (0.4%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
耳痛	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
免疫系障害	0 (0.0%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
季節性アレルギー	0 (0.0%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
代謝および栄養障害	8 (3.1%)	0 (0.0%)	2 (0.8%)	2 (0.4%)
高カルシウム血症	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
低アルブミン血症	2 (0.8%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
脱水	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
高リン酸塩血症	2 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
低カリウム血症	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
低蛋白血症	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ラクトース不耐性	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
栄養障害	2 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ビタミンD欠乏	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

表 2.7.6.3-6 すべての有害事象（Part 2 用量選択後，6 週まで）（続き）

		Golimumab		
	Placebo	200 mg → 100 mg	400 mg → 200 mg	Combined
生殖系および乳房障害	1 (0.4%)	1 (0.4%)	1 (0.4%)	2 (0.4%)
乳房痛	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
頻発月経	0 (0.0%)	0 (0.0%)	1 (0.4%)	1 (0.2%)
陰部そう痒症	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
外陰腟灼熱感	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
先天性、家族性および遺伝性障害	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
ジルベール症候群	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
肝胆道系障害	1 (0.4%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
肝炎	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (0.2%)
肝嚢胞	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
内分泌障害	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
クッシング様	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
外科および内科処置	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
副鼻腔手術	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

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参照元：C0524T17 Clinical Study Report Attachment 4.4

表 2.7.6.3-7 治験薬の使用と関連性のある有害事象（6 週まで）

		Golimumab				
	Placebo	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg	Combined	All Golimumab
Subjects treated	330	71	331	332	663	734
Avg duration of follow-up (weeks)	6.05	5.95	6.08	6.09	6.09	6.07
Avg exposure (number of administrations)	1.98	1.97	1.99	1.99	1.99	1.99
Subjects with 1 or more reasonably related adverse events	51 (15.5%)	11 (15.5%)	54 (16.3%)	58 (17.5%)	112 (16.9%)	123 (16.8%)
System-organ class/preferred term						
全身障害および投与局所様態	11 (3.3%)	8 (11.3%)	14 (4.2%)	18 (5.4%)	32 (4.8%)	40 (5.4%)
注射部位紅斑	0 (0.0%)	3 (4.2%)	5 (1.5%)	4 (1.2%)	9 (1.4%)	12 (1.6%)
発熱	4 (1.2%)	1 (1.4%)	2 (0.6%)	4 (1.2%)	6 (0.9%)	7 (1.0%)
疲労	1 (0.3%)	1 (1.4%)	2 (0.6%)	2 (0.6%)	4 (0.6%)	5 (0.7%)
インフルエンザ様疾患	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.9%)	3 (0.5%)	3 (0.4%)
注射部位そう痒感	0 (0.0%)	1 (1.4%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	3 (0.4%)
高熱	0 (0.0%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	2 (0.3%)	2 (0.3%)
注射部位炎症	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
注射部位疼痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
注射部位反応	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.6%)	2 (0.3%)	2 (0.3%)
注射部位腫脹	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	2 (0.3%)
注射部位蕁麻疹	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	2 (0.3%)
無力症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
冷感	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
注射部位血腫	1 (0.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
末梢性浮腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
疼痛	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
医薬品副作用	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
熱感	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
治癒不良	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
注射部位出血	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
圧迫感	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

表 2.7.6.3-7 治験薬の使用と関連性のある有害事象（6 週まで）（続き）

		Golimumab				
	Placebo	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg	Combined	All Golimumab
感染症および寄生虫症	15 (4.5%)	2 (2.8%)	19 (5.7%)	15 (4.5%)	34 (5.1%)	36 (4.9%)
鼻咽頭炎	6 (1.8%)	0 (0.0%)	6 (1.8%)	1 (0.3%)	7 (1.1%)	7 (1.0%)
咽頭炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.6%)	3 (0.5%)	3 (0.4%)
副鼻腔炎	1 (0.3%)	0 (0.0%)	1 (0.3%)	2 (0.6%)	3 (0.5%)	3 (0.4%)
気管支炎	1 (0.3%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
毛包炎	1 (0.3%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	2 (0.3%)	2 (0.3%)
口腔ヘルペス	1 (0.3%)	1 (1.4%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	2 (0.3%)
クロストリジウム感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
膀胱炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
皮膚真菌感染	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
ウイルス性胃腸炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
帯状疱疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
限局性感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
食道カンジダ症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
爪真菌症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
口腔カンジダ症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
爪囲炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
百日咳	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
肺炎	1 (0.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
気道感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
歯膿瘍	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
上気道感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
尿路感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
腟感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
外陰腟真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
急性扁桃炎	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
肛門膿瘍	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

表 2.7.6.3-7 治験薬の使用と関連性のある有害事象（6 週まで）（続き）

		Golimumab				
	Placebo	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg	Combined	All Golimumab
カンジダ症	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
サイトメガロウイルス感染	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
単純ヘルペス	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ブドウ球菌感染	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ウイルス感染	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
胃腸障害	9 (2.7%)	2 (2.8%)	4 (1.2%)	12 (3.6%)	16 (2.4%)	18 (2.5%)
悪心	2 (0.6%)	0 (0.0%)	0 (0.0%)	6 (1.8%)	6 (0.9%)	6 (0.8%)
腹痛	1 (0.3%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
アフタ性口内炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
便秘	1 (0.3%)	0 (0.0%)	0 (0.0%)	2 (0.6%)	2 (0.3%)	2 (0.3%)
下腹部痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
潰瘍性大腸炎	1 (0.3%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
下痢	1 (0.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
消化不良	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
口内炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
嘔吐	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
腹部不快感	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
腸炎	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
鼓腸	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
胃食道逆流性疾患	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血便排泄	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
直腸ポリープ	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
舌水疱形成	1 (0.3%)	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	14 (4.2%)	2 (2.8%)	9 (2.7%)	4 (1.2%)	13 (2.0%)	15 (2.0%)
紅斑	1 (0.3%)	1 (1.4%)	2 (0.6%)	0 (0.0%)	2 (0.3%)	3 (0.4%)
そう痒症	1 (0.3%)	0 (0.0%)	1 (0.3%)	2 (0.6%)	3 (0.5%)	3 (0.4%)
発疹	3 (0.9%)	1 (1.4%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	3 (0.4%)
皮膚乾燥	1 (0.3%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
多汗症	0 (0.0%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	2 (0.3%)	2 (0.3%)

表 2.7.6.3-7 治験薬の使用と関連性のある有害事象（6 週まで）（続き）

		Golimumab				
	Placebo	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg	Combined	All Golimumab
脱毛症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
アレルギー性皮膚炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
爪の障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
そう痒性皮疹	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
ざ瘡	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
湿疹	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
結節性紅斑	3 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
寝汗	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
爪破損	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
全身性そう痒症	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
毛孔性皮疹	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
斑状皮疹	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
神経系障害	14 (4.2%)	1 (1.4%)	4 (1.2%)	7 (2.1%)	11 (1.7%)	12 (1.6%)
頭痛	7 (2.1%)	1 (1.4%)	1 (0.3%)	6 (1.8%)	7 (1.1%)	8 (1.1%)
浮動性めまい	1 (0.3%)	0 (0.0%)	1 (0.3%)	2 (0.6%)	3 (0.5%)	3 (0.4%)
異常感覚	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
感覚鈍麻	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
錯感覚	1 (0.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
味覚異常	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
知覚過敏	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
筋緊張低下	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
片頭痛	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
振戦	1 (0.3%)	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 (1.5%)	0 (0.0%)	3 (0.9%)	8 (2.4%)	11 (1.7%)	11 (1.5%)
関節痛	2 (0.6%)	0 (0.0%)	1 (0.3%)	5 (1.5%)	6 (0.9%)	6 (0.8%)
筋痙縮	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.6%)	3 (0.5%)	3 (0.4%)
頚部痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
四肢痛	1 (0.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
背部痛	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

表 2.7.6.3-7 治験薬の使用と関連性のある有害事象（6 週まで）（続き）

		Golimumab				
	Placebo	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg	Combined	All Golimumab
関節腫脹	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
筋肉痛	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
臨床検査	6 (1.8%)	0 (0.0%)	3 (0.9%)	7 (2.1%)	10 (1.5%)	10 (1.4%)
アラニン・アミノトランスフェラーゼ増加	2 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
トランスアミナーゼ上昇	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.6%)	2 (0.3%)	2 (0.3%)
アスパラギン酸アミノトランスフェラーゼ増加	2 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
ヘモグロビン減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
リンパ球数減少	1 (0.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
好中球数減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
好中球数増加	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
体重減少	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
体重増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
白血球数減少	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
α１フェトプロテイン増加	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血中アルカリホスファターゼ増加	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
肝機能検査異常	1 (0.3%)	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	7 (2.1%)	0 (0.0%)	3 (0.9%)	4 (1.2%)	7 (1.1%)	7 (1.0%)
咳嗽	5 (1.5%)	0 (0.0%)	2 (0.6%)	2 (0.6%)	4 (0.6%)	4 (0.5%)
口腔咽頭痛	1 (0.3%)	0 (0.0%)	0 (0.0%)	2 (0.6%)	2 (0.3%)	2 (0.3%)
喘息	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
咽喉乾燥	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
口腔咽頭水疱形成	1 (0.3%)	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	2 (0.6%)	0 (0.0%)	2 (0.6%)	3 (0.9%)	5 (0.8%)	5 (0.7%)
白血球減少症	0 (0.0%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	2 (0.3%)	2 (0.3%)
好中球減少症	1 (0.3%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
貧血	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
鉄欠乏性貧血	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
リンパ球減少症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
血小板減少症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)

表 2.7.6.3-7 治験薬の使用と関連性のある有害事象（6 週まで）（続き）

		Golimumab				
	Placebo	100 mg → 50 mg	200 mg → 100 mg	400 mg → 200 mg	Combined	All Golimumab
眼障害	1 (0.3%)	0 (0.0%)	2 (0.6%)	1 (0.3%)	3 (0.5%)	3 (0.4%)
結膜炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.3%)	2 (0.3%)	2 (0.3%)
視力障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
眼充血	1 (0.3%)	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	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.6%)	3 (0.5%)	3 (0.4%)
精巣上体炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
頻発月経	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
陰部そう痒症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
傷害、中毒および処置合併症	2 (0.6%)	1 (1.4%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	2 (0.3%)
挫傷	2 (0.6%)	1 (1.4%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	2 (0.3%)
耳および迷路障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
回転性めまい	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	1 (0.1%)
代謝および栄養障害	2 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
食欲減退	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
糖尿病	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
脱水	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
栄養障害	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
外科および内科処置	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
副鼻腔手術	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
血管障害	2 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
ほてり	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)	1 (0.1%)
深部静脈血栓症	1 (0.3%)	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）	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
甲状腺癌	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
精神障害	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
不眠症	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
リビドー減退	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

RE311:[S AE 42 5 G DD], 13DEC2010 16:21

参照元：C0524T17 Clinical Study Report Attachment 4.8

表 2.7.6.3-8 重篤な有害事象を発現した症例の一覧

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/ Injection-site Reaction[c,d]
Placebo	Part 1	7003-00003	3[redacted]/F	AUSTRALIA/Caucasian	0 mg	11	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	32	32	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
					0 mg	11	脱水	DEHYDRATION	32	11	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
		7727-00003	2[redacted]/M	UNITED STATES/Caucasian	0 mg	15	貧血	ANEMIA	29	4	Resolved	No	Severe	Possible	None/not applicable	No /No
					0 mg	15	肛門直腸不快感	PERIANAL IRRITATION	25		Ongoing	No	Mild	Unlikely	None/not applicable	No /No
					0 mg	15	潰瘍性大腸炎	WORSENING ULCERATIVE COLITIS	25	7	Resolved	No	Severe	Possible	None/not applicable	No /No
					0 mg	15	潰瘍性大腸炎	WORSENING ULCERATIVE COLITIS	31	2	Resolved	Yes	Severe	Possible	None/not applicable	No /No
					0 mg	15	下痢	WORSENING DIARRHEA	21		Ongoing	No	Mild	Probable	None/not applicable	No /No
					0 mg	15	血便排泄	INCREASED BLOOD IN STOOL	21		Ongoing	No	Mild	Probable	None/not applicable	No /No
					0 mg	15	関節腫脹	BILATERAL ANKLE SWELLING	29		Ongoing	No	Mild	Unlikely	None/not applicable	No /No
					0 mg	15	栄養障害	MALNUTRITION	29		Ongoing	No	Severe	Possible	None/not applicable	No /No
					0 mg	15	筋挫傷	PULLED GROIN MUSCLE	18	9	Resolved	No	Mild	Not related	None/not applicable	No /No
		7756-00006	6[redacted]/F	UNITED STATES/Caucasian	0 mg	15	アラニン・アミノトランスフェラーゼ増加	ELEVATED ALT	30		Ongoing	No	Mild	Unlikely	None/not applicable	No /No
					0 mg	15	深部静脈血栓症	DEEP VENOUS THROMBOSIS	36		Ongoing	No	Moderate	Possible	None/not applicable	No /No

表 2.7.6.3-8 重篤な有害事象を発現した症例の一覧 （続き）

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/ Injection-site Reaction[c,d]
					0 mg	15	深部静脈血栓症	DEEP VENOUS THROMBOSIS OF LEFT LOWER EXTREMITY	35	2	Resolved	Yes	Severe	Possible	None/not applicable	No /No
					0 mg	15	リンパ球数異常	ABNORMAL LYMPHOCYTES	30		Ongoing	No	Mild	Unlikely	None/not applicable	No /No
					0 mg	15	単球数異常	ABNORMAL MONOCYTES	30		Ongoing	No	Mild	Unlikely	None/not applicable	No /No
					0 mg	15	好中球数増加	ELEVATED NEUTROPHILS	16		Ongoing	No	Mild	Unlikely	None/not applicable	No /No
					0 mg	15	好中球数増加	ELEVATED NEUTROPHILS/ ABS	16		Ongoing	No	Mild	Unlikely	None/not applicable	No /No
					0 mg	15	血小板数増加	ELEVATED PLATELET COUNT	16		Ongoing	No	Mild	Unlikely	None/not applicable	No /No
					0 mg	15	白血球数増加	ELEVATED WBC	16		Ongoing	No	Mild	Unlikely	None/not applicable	No /No
	Part 2b	6179-00007	4[redacted]/F	FRANCE/Caucasian	0 mg	1	関節腫脹	SWELLEN LEFT KNEE	5	71	Resolved	No	Moderate	Possible	None/not applicable	No /No
					0 mg	15	結節性紅斑	ERYTHEMA NODOSUM	29	5	Resolved	No	Moderate	Possible	None/not applicable	No /No
					0 mg	15	結節性紅斑	ERYTHEMA NOSODUM	33	43	Resolved	Yes	Moderate	Possible	None/not applicable	No /No
		6233-00005	4[redacted]/F	HUNGARY/ Caucasian	0 mg	1	貧血	ANAEMIA	11	27	Resolved	No	Severe	Not related	None/not applicable	No /No
					0 mg	1	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	11	27	Resolved	Yes	Severe	Not related	None/not applicable	No /No
					0 mg	1	低アルブミン血症	HYPOALBUMINAEMIA	2	55	Resolved	No	Moderate	Not related	None/not applicable	No /No
					0 mg	1	低カリウム血症	HYPOKALAEMIA	11	10	Resolved	No	Moderate	Not related	None/not applicable	No /No

表 2.7.6.3-8 重篤な有害事象を発現した症例の一覧 （続き）

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/ Injection-site Reaction[c,d]
					0 mg	14	肝嚢胞	CYSTA HEPATIS	15		Ongoing	No	Mild	Not related	None/not applicable	No /No
		7003-00012	3[redacted]/F	AUSTRALIA/Caucasian	0 mg	19	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	23	12	Resolved	Yes	Severe	Not related	None/not applicable	No /No
					0 mg	19	サイトメガロウイルス感染	CMV INFECTION - CYTOMEGALOVIRUS	34		Ongoing	No	Mild	Possible	None/not applicable	Yes/No
					0 mg	19	肝機能検査異常	ELEVATED LFT'S	25		Ongoing	No	Moderate	Possible	None/not applicable	No /No
		7008-00021	3[redacted]/M	AUSTRALIA/Caucasian	0 mg	13	関節障害	ARTHROPATHY	44	4	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
					0 mg	13	潰瘍性大腸炎	WORSENING ULCERATIVE COLITIS	18	25	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
					0 mg	13	血腫感染	INFECTED HAEMATOMA	36	12	Resolved	Yes	Moderate	Not related	None/not applicable	Yes/No
					0 mg	13	栄養障害	MALNUTRITION	33	10	Resolved	No	Moderate	Not related	None/not applicable	No /No
		7026-00015	3[redacted]/F	AUSTRIA/Caucasian	0 mg	1	腹痛	ABDOMINAL CRAMPS	8	35	Resolved	No	Severe	Unlikely	None/not applicable	No /No
					0 mg	15	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	17	26	Resolved	Yes	Severe	Not related	None/not applicable	No /No
					0 mg	15	結節性紅斑	ERYTHEMA NODOSUM	17	26	Resolved	Yes	Severe	Not related	None/not applicable	No /No
					0 mg	15	副鼻腔炎	SINUSITIS MAXILLARIS	16	8	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
		7026-00017	6[redacted]/F	AUSTRIA/Caucasian	0 mg	1	うつ病	DEPRESSION	3	39	Resolved	No	Mild	Unlikely	None/not applicable	No /No

表 2.7.6.3-8 重篤な有害事象を発現した症例の一覧 （続き）

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/ Injection-site Reaction[c,d]
					0 mg	15	医薬品副作用	ELEVATED LIVER ENZYMES DUE TO ISONIAZID THERAPY	43	39	Resolved	Yes	Severe	Possible	None/not applicable	No /No
		7080-00008	6[redacted]/M	BULGARIA/ Caucasian	0 mg	15	咳嗽	COUGH	20	10	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
					0 mg	15	筋緊張低下	HYPOTONIA	20	2	Resolved	No	Severe	Possible	None/not applicable	No /No
					0 mg	15	悪心	NAUSEA	18	4	Resolved	No	Mild	Not related	None/not applicable	Yes/No
					0 mg	15	肺炎	PNEUMONIA	20	11	Resolved	Yes	Severe	Possible	None/not applicable	Yes/No
					0 mg	15	発熱	HIGH TEMPERATURE	18	5	Resolved	No	Severe	Possible	None/not applicable	Yes/No
					0 mg	15	嘔吐	VOMITING	18	3	Resolved	No	Mild	Not related	None/not applicable	Yes/No
		7204-00008	3[redacted]/M	GERMANY/ Caucasian	0 mg	1	貧血	ANAEMIA	27	71	Resolved	No	Mild	Not related	None/not applicable	No /No
					0 mg	1	鼻咽頭炎	COMMON COLD	21	7	Resolved	No	Mild	Possible	None/not applicable	Yes/No
					0 mg	1	ウイルス感染	VIRAL INFECTION	4	14	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	Yes/No
		7226-00012	2[redacted]/F	HUNGARY/ Caucasian	0 mg	15	貧血	ANAEMIA	17	10	Resolved	Yes	Severe	Not related	None/not applicable	No /No
					0 mg	15	細菌感染	GRAM NEG. NOT IDENTIFIED BACTERIA	20	7	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
					0 mg	15	発熱	FEVER	19	1	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
		7235-00001	3[redacted]/F	HUNGARY/ Caucasian	0 mg	15	貧血	ANAEMIA	30	4	Resolved	Yes	Moderate	Not related	None/not applicable	No /No

表 2.7.6.3-8 重篤な有害事象を発現した症例の一覧 （続き）

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/ Injection-site Reaction[c,d]
					0 mg	15	関節痛	PAIN OF THE LEFT ANKLE	37	28	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
					0 mg	15	上強膜炎	EPISCLERITIS	18	5	Resolved	No	Mild	Unlikely	None/not applicable	No /No
					0 mg	15	筋肉痛	PAIN OF THE LEG-MUSCLES	21	11	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
		7278-00006	4[redacted]/F	ISRAEL/Caucasian	0 mg	1	結節性紅斑	ERYTHEMA NODESUM	2	118	Resolved	No	Moderate	Probable	Permanent discontinuation of study agent	No /No
					0 mg	1	結節性紅斑	ERYTHEMA NODESUM	9	111	Resolved	Yes	Moderate	Probable	Permanent discontinuation of study agent	No /No
					0 mg	1	末梢性浮腫	BILATERAL PEDAL ADEMA	107		Ongoing	No	Moderate	Not related	None/not applicable	No /No
					0 mg	1	発熱	FEVER	3	7	Resolved	No	Mild	Probable	None/not applicable	No /No
					0 mg	1	斑状皮疹	MACULAR SKIN ERUPTION	9	14	Resolved	Yes	Moderate	Probable	Permanent discontinuation of study agent	No /No
		7734-00012	6[redacted]/F	UNITED STATES/Caucasian	0 mg	1	血小板数増加	INCREASED PLATELETS	12		Ongoing	No	Moderate	Not related	None/not applicable	No /No
					0 mg	12	赤血球大小不同症	ANISOCYTOSIS	64	42	Resolved	No	Moderate	Not related	None/not applicable	No /No
					0 mg	12	杆状核好中球数増加	INCREASED BANDS	30	35	Resolved	No	Mild	Not related	None/not applicable	No /No
					0 mg	12	カンジダ症	THRUSH	40	4	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
					0 mg	12	脱水	DEHYDRATION	40	9	Resolved	Yes	Severe	Possible	None/not applicable	No /No
					0 mg	12	潮紅	FLUSHING	117	7	Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.3-8 重篤な有害事象を発現した症例の一覧 （続き）

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/ Injection-site Reaction[c,d]
					0 mg	12	単純ヘルペス	HERPES SIMPLEX I REACTIVATION	41	18	Resolved	Yes	Severe	Possible	None/not applicable	Yes/No
					0 mg	12	栄養障害	MALNUTRITION	40	25	Resolved	Yes	Moderate	Possible	None/not applicable	No /No
					0 mg	12	巨核球	LARGE PLATELETS	30	12	Resolved	No	Mild	Not related	None/not applicable	No /No
					0 mg	12	骨髄球存在	PRESENCE OF METAMYELOCYTES	30	53	Resolved	No	Moderate	Not related	None/not applicable	No /No
					0 mg	12	骨髄球存在	PRESENCE OF MYELOCYTES	30	76	Resolved	No	Moderate	Not related	None/not applicable	No /No
					0 mg	12	悪心	NAUSEA	40	12	Resolved	Yes	Severe	Definite	None/not applicable	No /No
					0 mg	12	多染性	POLYCHROMASIA	64	42	Resolved	No	Moderate	Not related	None/not applicable	No /No
					0 mg	12	バーセル陽性	BURR CELLS	30	12	Resolved	No	Mild	Not related	None/not applicable	No /No
					0 mg	12	体重減少	WEIGHT LOSS	26	99	Resolved	No	Moderate	Not related	None/not applicable	No /No
		7753-00001	4[redacted]/F	UNITED STATES/Black	0 mg	1	潰瘍性大腸炎	ULCERATIVE COLITIS FLARE	3	6	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
					0 mg	1	高血圧	HYPERTENSION	3	125	Resolved	No	Mild	Not related	None/not applicable	No /No
					0 mg	1	悪心	NAUSEA	3	7	Resolved	No	Moderate	Not related	None/not applicable	No /No
					0 mg	1	ビタミンD欠乏	VITAMIN D. DEFICIENCY	4		Ongoing	No	Moderate	Not related	None/not applicable	No /No
					0 mg	1	嘔吐	VOMITIING	3	7	Resolved	No	Moderate	Not related	None/not applicable	No /No
					0 mg	15	潰瘍性大腸炎	ULCERATIVE COLITIS FLARE	87	7	Resolved	Yes	Moderate	Not related	None/not applicable	Yes/No

表 2.7.6.3-8 重篤な有害事象を発現した症例の一覧 （続き）

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/ Injection-site Reaction[c,d]
					0 mg	15	口腔カンジダ症	ORAL THRUSH	88		Ongoing	No	Mild	Not related	None/not applicable	No /No
		7775-00001	5[redacted]/F	UNITED STATES/Black	0 mg	1	注射部位疼痛	LOWER LEFT QUADRENT PAIN AT WEEK 0 INJECTION SITE	3	11	Resolved	No	Mild	Unlikely	None/not applicable	No /Yes
					0 mg	15	直腸ポリープ	RECTAL PSEUDOPOLYPS	41	1	Resolved	No	Mild	Possible	None/not applicable	No /No
					0 mg	15	ブドウ球菌感染	STAPHYLOCOCCUS AUREUS ON LEFT BREAST	37		Ongoing	No	Moderate	Probable	None/not applicable	Yes/No
					0 mg	15	甲状腺癌	HURTHLE CELL CARCINOMA	41		Ongoing	Yes	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	腹痛	ABDOMINAL PAIN	32	35	Resolved	No	Mild	Not related	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	便秘	CONSTIPATION	45	31	Resolved	No	Mild	Not related	None/not applicable	No /No
					0 mg	15	潮紅	HECTIC FLUSH	57		Ongoing	No	Mild	Not related	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	心拍数増加	INCREASE IN PULSE RATE	56	9	Resolved	No	Mild	Not related	None/not applicable	No /No
					0 mg	15	多汗症	POLYHIDROSIS	58		Ongoing	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.3-8 重篤な有害事象を発現した症例の一覧 （続き）

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/ Injection-site Reaction[c,d]
					0 mg	15	筋痙縮	LEG CRAMPS	72		Ongoing	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	悪心	NAUSEA	38	1	Resolved	No	Mild	Not related	None/not applicable	No /No
					0 mg	15	口腔咽頭痛	PHARYNGEAL PAIN	106	4	Resolved	No	Mild	Not related	None/not applicable	Yes/No
					0 mg	15	動悸	PALPITATION	58		Ongoing	No	Mild	Not related	None/not applicable	No /No
					0 mg	15	腫脹	SWELLIN	58		Ongoing	No	Mild	Not related	None/not applicable	No /No
					0 mg	15	上気道の炎症	ACUTE UPPER RESPIRATORY INFLAMMATIO N	48	20	Resolved	No	Mild	Not related	None/not applicable	Yes/No
					0 mg	15	体重増加	INCREASE IN BODY WEIGHT	47		Ongoing	No	Mild	Not related	None/not applicable	No /No
		7807-00004	2[redacted]/F	JAPAN/Asia n	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
					0 mg	12	痔瘻	ANAL FISTULA	50	176	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
					0 mg	12	結節性紅斑	ERYTHEMA NODOSUM	47	38	Resolved	No	Mild	Unlikely	None/not applicable	No /No
					0 mg	12	口腔咽頭痛	PHARYNGEAL PAIN	63	3	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
					0 mg	12	壊疽性膿皮症	PYODERMA GANGRENOSU M	51	34	Resolved	No	Severe	Unlikely	None/not applicable	No /No
		7820-00001	1[redacted]/M	JAPAN/Asia n	0 mg	12	感染性小腸結腸炎	INFECTIOUS COLITIS	32	6	Resolved	No	Severe	Unlikely	None/not applicable	Yes/No

表 2.7.6.3-8 重篤な有害事象を発現した症例の一覧 （続き）

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/ Injection-site Reaction[c,d]
					0 mg	12	感染性小腸結腸炎	INFECTIOUS COLITIS	37	8	Resolved	Yes	Severe	Unlikely	None/not applicable	Yes/No
100 mg -> 50 mg	Part 1	7327-00001	2[redacted]/M	LITHUANIA /Caucasian	50 mg	14	貧血	ANEMIA	59		Ongoing	No	Moderate	Unlikely	None/not applicable	No /No
					50 mg	14	サイトメガロウイルス感染	CYTOMEGALOVIRUS INFECTION	47	36	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
					50 mg	14	口腔ヘルペス	HERPES LABIALIS	22	9	Resolved	No	Mild	Possible	None/not applicable	Yes/No
					100 mg	1	発熱	FEVER	4	2	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
	Part 2a	7127-00001	2[redacted]/M	DENMARK/ Caucasian	100 mg	1	潰瘍性大腸炎	WORSENING OF UC SYMPTOMS	15	41	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
		7716-00011	4[redacted]/F	UNITED STATES/Caucasian	50 mg	16	足関節部骨折	RIGHT ANKLE FRACTURE	21	13	Resolved	Yes	Severe	Not related	None/not applicable	No /No
					50 mg	16	下痢	INCREASED DIARRHEA	29		Ongoing	No	Moderate	Unlikely	None/not applicable	No /No
					50 mg	16	転倒	MECHANICAL FALL	21	13	Resolved	Yes	Severe	Not related	None/not applicable	No /No
					100 mg	1	便秘	CONSTIPATION	2	8	Resolved	No	Mild	Not related	None/not applicable	No /No
					100 mg	1	疼痛	ACHES/PAINS	9	2	Resolved	No	Severe	Possible	None/not applicable	No /No
200 mg -> 100 mg	Part 1	7277-00003	3[redacted]/M	ISRAEL/Caucasian	100 mg	22	毛包炎	FOLLICULITIS	22		Ongoing	No	Mild	Possible	None/not applicable	Yes/No
					100 mg	22	胃腸炎	ACUTE GASTROENTERITIS	39	11	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
	Part 2a	7706-00004	4[redacted]/F	UNITED STATES/Caucasian	200 mg	1	発熱	FEVER OF UNKNOWN ORIGIN	8	2	Resolved	Yes	Mild	Unlikely	None/not applicable	No /No

表 2.7.6.3-8 重篤な有害事象を発現した症例の一覧 （続き）

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/ Injection-site Reaction[c,d]
	Part 2b	6115-00004	4[redacted]/F	CANADA/Caucasian	100 mg	14	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	28	7	Resolved	Yes	Severe	Not related	None/not applicable	No /No
		6233-00002	2[redacted]/M	HUNGARY/ Caucasian	100 mg	15	貧血	ANAEMIA	37	3	Resolved	Yes	Severe	Not related	None/not applicable	No /No
					200 mg	1	貧血	ANAEMIA	15	23	Resolved	No	Moderate	Not related	None/not applicable	No /No
		7002-00006	3[redacted]/M	AUSTRALIA/Caucasian	200 mg	1	気管支炎	BRONCHITIS	27		Ongoing	No	Moderate	Unlikely	None/not applicable	Yes/No
					200 mg	1	クロストリジウム感染	CLOSTRIDIUM DIFFICILINE	13	15	Resolved	No	Mild	Not related	Permanent discontinuation of study agent	Yes/No
					200 mg	1	潰瘍性大腸炎	WORSENING SYMPTOMS OF UC	11	17	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
		7204-00006	5[redacted]/M	GERMANY/ Caucasian	100 mg	11	貧血	SEVERE ANEMIA	11	12	Resolved	No	Severe	Not related	None/not applicable	No /No
					100 mg	11	貧血	SEVERE ANEMIA	51	4	Resolved	Yes	Severe	Not related	None/not applicable	No /No
					100 mg	11	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	19	105	Resolved	No	Severe	Not related	None/not applicable	No /No
		7207-00020	2[redacted]/F	GERMANY/ Caucasian	100 mg	14	貧血	ANEMIA	26	14	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
					100 mg	14	クロストリジウム感染	CLOSTRIDIUM DIFFICILE	27		Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
					100 mg	14	悪心	NAUSEA	36	1	Resolved	No	Mild	Unlikely	None/not applicable	No /No
		7735-00004	2[redacted]/M	UNITED STATES/Caucasian	100 mg	10	上腹部痛	STOMACH PAIN	38	6	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
					100 mg	10	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	38		Ongoing	No	Moderate	Not related	None/not applicable	No /No

表 2.7.6.3-8 重篤な有害事象を発現した症例の一覧 （続き）

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/ Injection-site Reaction[c,d]
					100 mg	10	ヘモグロビン減少	WORSENING OF LOW HEMOGLOBIN	38	6	Resolved	Yes	Moderate	Not related	None/not applicable	No /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
					100 mg	15	紅斑	REDNESS	57	19	Resolved	No	Mild	Not related	None/not applicable	No /No
					100 mg	15	頭痛	HEADACHE	50	2	Resolved	No	Mild	Not related	None/not applicable	No /No
					100 mg	15	そう痒症	ITCH SENSATION	57	50	Resolved	No	Mild	Not related	None/not applicable	No /No
		7815-00001	5[redacted]/M	JAPAN/Asian	100 mg	15	結膜炎	CONJUNCTIVITIS	78	50	Resolved	No	Mild	Not related	None/not applicable	No /No
					100 mg	15	サイトメガロウイルス感染	CYTOMEGALOVIRUS INFECTION	45		Ongoing	No	Mild	Not related	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
					100 mg	15	鼻咽頭炎	COMMON COLD	78	15	Resolved	No	Mild	Not related	None/not applicable	Yes/No
					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	足部白癬	TINEA PEDIS	93		Ongoing	No	Mild	Not related	None/not applicable	Yes/No
400 mg -> 200 mg	Part 1	7720-00001	2[redacted]/M	UNITED STATES/Caucasian	200 mg	15	蜂巣炎	CELLULITIS	77	7	Resolved	Yes	Moderate	Unlikely	None/not applicable	Yes/No
					200 mg	15	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	29		Ongoing	Yes	Severe	Unlikely	None/not applicable	No /No

表 2.7.6.3-8 重篤な有害事象を発現した症例の一覧 （続き）

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/ Injection-site Reaction[c,d]
					200 mg	15	肝腫大	HEPATOMEGALY	69			No				No /
					200 mg	15	口腔カンジダ症	ORAL CANDIASIS	52			No	Mild	Possible	None/not applicable	Yes/No
					200 mg	15	骨硬化症	SUBTLE SACROILIAC JOINT SCLEROSIS	15		Ongoing	No	Mild	Unlikely	None/not applicable	No /No
					400 mg	1	筋肉痛	RIGHT LOWER EXTREMITY MYALGIA	1	82	Resolved	No	Moderate	Not related	None/not applicable	No /No
	Part 2a	7081-00001	4[redacted]/M	BULGARIA/ Caucasian	200 mg	18	潰瘍性大腸炎	UC EXACERBATION	64	8	Resolved	Yes	Severe	Not related	None/not applicable	No /No
					200 mg	18	発熱	FEVER-39.5 DEGREE C	64	3	Resolved	Yes	Severe	Possible	None/not applicable	Yes/No
					200 mg	18	発熱	PERSISTENT FEVER 37.5 C	43	19	Resolved	No	Mild	Unlikely	None/not applicable	No /No
		7743-00004	4[redacted]/M	UNITED STATES/Caucasian	200 mg	16	脳膿瘍	BRAIN ABCESS ON MRI	102	47	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
					200 mg	16	脱髄	DEMYELINATING BRAIN LESION ON MRI	205		Ongoing	Yes	Mild	Possible	None/not applicable	No /No
					200 mg	16	上気道感染	UPPER RESPIRATORY INFECTION	20	11	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
					400 mg	1	上気道感染	UPPER RESPIRATORY INFECTION	11	20	Resolved	No	Moderate	Not related	None/not applicable	Yes/
	Part 2b	6179-00008	3[redacted]/M	FRANCE/Caucasian	200 mg	13	浮動性めまい	DIZZYNESS	33	3	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
					200 mg	13	頭痛	HEADACHE	33	3	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No

表 2.7.6.3-8 重篤な有害事象を発現した症例の一覧 （続き）

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/ Injection-site Reaction[c,d]
					200 mg	13	鉄欠乏性貧血	FERRIPRIVE ANEMIA	21		Ongoing	No	Moderate	Possible	None/not applicable	No /No
					200 mg	13	嘔吐	VOMITING	33	3	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
		6705-00013	6[redacted]/M	UNITED STATES/Caucasian	200 mg	12	気管支炎	ACUTE BRONCHITIS	21	4	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
					200 mg	12	慢性閉塞性肺疾患	EXACERBATION COPD	21	4	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
		7008-00006	3[redacted]/M	AUSTRALIA/Caucasian	200 mg	15	ウイルス性胃腸炎	VIRAL GASTROENTERITIS	21	5	Resolved	Yes	Moderate	Unlikely	None/not applicable	Yes/No
		7008-00023	3[redacted]/F	AUSTRALIA/Caucasian	200 mg	17	潰瘍性大腸炎	FLARE OF ULCERATIVE COLITIS	67	6	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
					200 mg	17	疲労	FATIGUE	67		Ongoing	No	Mild	Unlikely	None/not applicable	No /No
					200 mg	17	肺浸潤	BILATERAL PULMONARY INFLITRATES (HUMAN METAPNEUMO VIRUS)	67	15	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
					200 mg	17	栄養障害	MALNUTRITIAN	67		Ongoing	No	Mild	Unlikely	None/not applicable	No /No
					200 mg	17	上気道感染	UPPER RESPIRATORY TRACT INFECTION	25	57	Resolved	No	Mild	Not related	None/not applicable	Yes/No
		7207-00024	5[redacted]/F	GERMANY/ Caucasian	400 mg	1	上皮内癌	CARCINOMA IN SITU	2	27	Resolved	Yes	Moderate	Not related	Permanent discontinuation of study agent	No /No
					400 mg	1	結腸癌	ADENOCARCINOMA OF THE COLON	2	27	Resolved	Yes	Moderate	Not related	Permanent discontinuation of study agent	No /No

表 2.7.6.3-8 重篤な有害事象を発現した症例の一覧 （続き）

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/ Injection-site Reaction[c,d]
		7279-00010	2[redacted]/M	ISRAEL/Caucasian	200 mg	16	肛門膿瘍	PERIANAL ABSCESS	79	3	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
					200 mg	16	肛門膿瘍	PERIANAL ABSCESS RECURRENCE	91	52	Resolved	Yes	Severe	Possible	None/not applicable	Yes/No
					200 mg	16	潰瘍性大腸炎	ULCERATIVE COLITIS EXACERBATION	44	19	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
					400 mg	1	腹痛	ABDOMINAL PAIN(RIGHT SIDE)	10	2	Resolved	No	Mild	Unlikely	None/not applicable	No /No
					400 mg	1	アフタ性口内炎	APHTE	14		Ongoing	No	Mild	Unlikely	None/not applicable	No /No
					400 mg	1	発熱	FEVER	10		Ongoing	No	Mild	Unlikely	None/not applicable	No /No
		7413-00006	2[redacted]/F	POLAND/Caucasian	200 mg	16	悪心	NAUSEA	37	1	Resolved	No	Mild	Unlikely	None/not applicable	No /No
					200 mg	16	循環血液量低下	HYPOHYDRAEMIA	42	12	Resolved	Yes	Mild	Unlikely	None/not applicable	No /No
					200 mg	16	嘔吐	VOMITUS	37	1	Resolved	No	Mild	Unlikely	None/not applicable	No /No
					400 mg	1	腹痛	ABDOMINAL PAIN	6	9	Resolved	No	Moderate	Not related	None/not applicable	No /No
					400 mg	1	潰瘍性大腸炎	UC WORSENING	12	19	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
		7417-00006	6[redacted]/M	POLAND/Caucasian	200 mg	16	良性前立腺肥大症	PROSTATIC HYPERTROPHY	57		Ongoing	No	Mild	Not related	None/not applicable	No /No
					200 mg	16	潰瘍性大腸炎	UC EXACERBATION	34	24	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
					200 mg	16	十二指腸炎	CHRONIC DUODENITIS	37		Ongoing	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.3-8 重篤な有害事象を発現した症例の一覧 （続き）

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/ Injection-site Reaction[c,d]
					200 mg	16	虚血性脳卒中	ISCHEMIC STROKE	47	11	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
					400 mg	1	慢性閉塞性肺疾患	COPD EXACERBATION	10		Ongoing	No	Moderate	Not related	None/not applicable	No /No
		7586-00015	5[redacted]/M	UKRAINE/Caucasian	200 mg	15	高熱	HYPERTHERMIA	32	3	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
					200 mg	15	骨髄球数増加	INCREASE MYELOCYTES	29		Ongoing	No	Moderate	Not related	None/not applicable	Yes/No
					200 mg	15	肛門周囲痛	PAIN IN THE ANARECTAL AREA	29		Ongoing	No	Moderate	Not related	None/not applicable	Yes/No
					200 mg	15	直腸膿瘍	ABSCESS ISCHIORECTAL	33		Ongoing	Yes	Severe	Not related	Temporary interruption/dose modification	Yes/No
		7791-00001	2[redacted]/F	UNITED STATES/Black	200 mg	15	腹痛	ABDOMINAL CRAMPING	20	3	Resolved	Yes	Severe	Not related	None/not applicable	No /No
					200 mg	15	末梢性浮腫	SWOLLEN HANDS AND FEET	27	2	Resolved	No	Mild	Possible	None/not applicable	No /No
					400 mg	1	筋痙縮	CRAMPS	8	8	Resolved	No	Moderate	Possible	None/not applicable	No /No
					400 mg	1	末梢性浮腫	RIGHT LOWER ARM SWOLLEN	13	3	Resolved	No	Mild	Unlikely	None/not applicable	No /No
		7801-00003	3[redacted]/M	JAPAN/Asian	200 mg	15	ざ瘡	ACNE	71	12	Resolved	No	Mild	Not related	None/not applicable	No /No
					200 mg	15	背部痛	LOIN PAIN	93	3	Resolved	No	Mild	Not related	None/not applicable	No /No
					200 mg	15	潰瘍性大腸炎	WORSENING OF UC	82	25	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
					200 mg	15	頭痛	HEADACHE	89	7	Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.3-8 重篤な有害事象を発現した症例の一覧 （続き）

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/ Injection-site Reaction[c,d]
					200 mg	15	注射部位疼痛	INJECTION SITE PAIN	91	5	Resolved	No	Mild	Not related	None/not applicable	No /No
					200 mg	15	頚部痛	NECK PAIN	93	3	Resolved	No	Mild	Not related	None/not applicable	No /No
					200 mg	15	気道感染	RESPIRATORY INFECTION	29	29	Resolved	No	Mild	Possible	None/not applicable	Yes/No
					400 mg	1	鼻咽頭炎	COMMON COLD	4	3	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
		7801-00006	2[redacted]/F	JAPAN/Asian	200 mg	15	クロストリジウム感染	CLOSTRIDIUM DIFFICILE INFECTION	74	17	Resolved	No	Moderate	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
					200 mg	15	百日咳	WHOOPING COUGH	39	23	Resolved	No	Mild	Possible	None/not applicable	Yes/No
					200 mg	15	偽膜性大腸炎	PSEUDOMEMBRANOUS COLITIS	73	13	Resolved	No	Moderate	Not related	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.

以下に，ゴリムマブの投与開始後に死亡及び重篤な有害事象を発現した症例のうち，重篤な有害事象により治験薬投与を中止した症例及び治験担当医師により重篤な有害事象が感染症と判断された症例の詳細を示す。

被験者識別コード：7586-00015

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
Died/ SAE/ Serious infection	直腸膿瘍 (Abscess ischiorectal)	Not related	30 Aug 2010 Ongoing
Demographic information: 5[redacted]-year-old (DOB: 26 Jan [redacted]) Caucasian male. Weight: 72.6 kg; height: 170 cm.			
Relevant medical history at baseline: 報告なし			
Baseline smoking status: Not provided.			
Ulcerative colitis history: Date of diagnosis: September 2009. UC disease duration: 0.8 years.			

Prior/concomitant medication, route	Start date	End date
Prednisolone, oral	21 Apr 2010	Ongoing
Mesalazine, oral	21 Apr 2010	Ongoing
Iron, oral	19 Jul 2010	26 Aug 2010
Iron, intramuscular	26 Aug 2010	Ongoing

Randomized treatment group: Golimumab 400 mg to 200 mg.
Actual treatment group: Golimumab 400 mg to 200 mg.

Treatment received:

Visit, Date (Study Day)	Admin. No. /Inj. No.	Agent	Dose/Unit
Week 0, 29 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0, 29 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0, 29 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0, 29 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2, 12 Aug 2010 (Study Day 15)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2, 12 Aug 2010 (Study Day 15)	Admin. 2/ Inj. 6	Golimumab	100 mg

Treatment status:
Study treatment discontinuation? No.
Date of last study agent administration: 12 Aug 2010.
Last scheduled study treatment visit: Week 2.

Study status:
Study participation discontinuation? Yes.
Date of study discontinuation: 22 Sep 2010.
Reason for noncompletion: Other.
Other reason for noncompletion/details: According to the PI decision.
Subject entered into maintenance study: No.
Date of disposition status: 22 Sep 2010.

被験者識別コード：7327-00001

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
Related SAE/ Serious infection/ Opportunistic infection	サイトメガロウイルス感染 (Cytomegalovirus infection)	Possible	09 Jun 2008 14 Jul 2008 (36 days)
Demographic information: 2[redacted]-year-old (DOB: 14 Dec [redacted]) Caucasian male. Weight: 74 kg; height: 180 cm.			
Relevant medical history at baseline: 報告なし			
Baseline smoking status: Not provided.			
Ulcerative colitis history: Date of diagnosis: 01 Jul 2006. UC disease duration: 1.8 years.			

Prior/concomitant medication, route	Start date	End date
Azathioprine, oral	11 Jul 2007	Ongoing
Mesalazine, oral	18 Jul 2006	Ongoing
Aciclovir, topical	15 May 2008	23 May 2008
Ganciclovir, intravenous	28 Jun 2008	08 Jul 2008
Prednisolone, oral	28 Jun 2008	Ongoing
Saccharated iron oxide, intravenous	10 Jul 2008	11 Jul 2008
Ranitidine, oral	24 Jun 2008	10 Jul 2008

Randomized treatment group: Golimumab 100 mg to 50 mg.
Actual treatment group: Golimumab 100 mg to 50 mg.

Treatment received:

Visit, Date (Study Day)	Admin. No. /Inj. No.	Agent	Dose/Unit
Week 0, 24 Apr 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0, 24 Apr 2008 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0, 24 Apr 2008 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0, 24 Apr 2008 (Study Day 1)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2, 07 May 2008 (Study Day 14)	Admin. 2/ Inj. 5	Golimumab	50 mg
Week 2, 07 May 2008 (Study Day 14)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2, 07 May 2008 (Study Day 14)	Admin. 2/ Inj. 7	Placebo	0 mg

Treatment status:
Study treatment discontinuation? No.
Date of last study agent administration: 07 May 2008.
Last scheduled study treatment visit: Week 2.

Study status:
Study participation discontinuation? No.
Subject entered into maintenance study: No.
Date of disposition status: 27 Aug 2008.

被験者識別コード：7127-00001

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of UC symptoms)	Not related	06 Feb 2009 18 Mar 2009 (41 days)

Demographic information: 2[redacted]-year-old (DOB: 11 Dec [redacted]) Caucasian male. Weight: 90 kg; height: 195 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not provided.

Ulcerative colitis history:
Date of diagnosis: 28 Jan 2008.
UC disease duration: 1.0 year.

Prior/concomitant medication, route	Start date	End date
Mesalazine, oral	Prior	Ongoing
Infliximab, intravenous	06 Feb 2009	20 Feb 2009

Randomized treatment group: Golimumab 100 mg to 50 mg.
Actual treatment group: Golimumab 100 mg to 50 mg.

Treatment received:

Visit, Date (Study Day)	Admin. No. /Inj. No.	Agent	Dose/Unit
Week 0, 23 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0, 23 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0, 23 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0, 23 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 4	Placebo	0 mg

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Adverse event.
Date of last study agent administration: 23 Jan 2009.
Last scheduled study treatment visit: Week 0.

Study status:	
Study participation discontinuation?	Yes.
Date of study discontinuation:	06 Feb 2009.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	Worsening of colitis ulcerosa.
Subject entered into maintenance study:	No.
Date of disposition status:	06 Feb 2009.

被験者識別コード：7002-00006

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening symptoms of UC)	Not related	08 Oct 2009 24 Oct 2009 (17 days)
Permanent discontinuation of study agent due to AE	クロストリジウム感染 (Clostridium difficile)	Not related	10 Oct 2009 24 Oct 2009 (15 days)

Demographic information: 3[redacted]-year-old (DOB: 06 Mar [redacted]) Caucasian male. Weight: 67.8 kg; height: 178 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 25 Sep 2007.
UC disease duration: 2.0 years.

Prior/concomitant medication, route	**Start date**	**End date**
Azathioprine, oral	24 Apr 2009	Ongoing
Mesalazine, oral	January 2008	Ongoing
Prednisolone, oral	January 2008	Ongoing
Fleet enema /00129701/, rectal	25 Sep 2009	25 Sep 2009
Paracetamol, oral	24 Oct 2000	28 Oct 2009
Sodium chloride, intravenous	08 Oct 2009	23 Oct 2009
Blood cells, packed human, intravenous	10 Oct 2009	10 Oct 2009
Glucose, intravenous	21 Oct 2009	21 Oct 2009
Flebobag ring lact, intravenous	24 Oct 2009	24 Oct 2009
Gelofusine /00523001/, intravenous	24 Oct 2009	24 Oct 2009
Temazepam, oral	19 Oct 2009	28 Oct 2009
Hydrocortisone, intravenous	08 Oct 2009	15 Oct 2009
Calcium w/vitamin d nos, oral	08 Oct 2009	29 Oct 2009
Enoxaparin, subcutaneous	08 Oct 2009	27 Oct 2009
Mesalazine, rectal	12 Oct 2009	14 Oct 2009
Metronidazole, oral	14 Oct 2009	23 Oct 2009
Saccharated iron oxide, intravenous	13 Oct 2009	13 Oct 2009
Potassium, oral	15 Oct 2009	28 Oct 2009
Tramadol, oral	24 Oct 2009	28 Oct 2009
Ceftriaxone, intravenous	21 Oct 2009	23 Oct 2009
Morphine, intramuscular	27 Oct 2009	28 Oct 2009
Ondansetron, intravenous	24 Oct 2009	24 Oct 2009
Dexamethasone, intravenous	24 Oct 2009	24 Oct 2009
Midazolam, intravenous	24 Oct 2009	24 Oct 2009
Propofol, intravenous	24 Oct 2009	24 Oct 2009
Atracurium, intravenous	24 Oct 2009	24 Oct 2009
Metoprolol, intravenous	24 Oct 2009	24 Oct 2009
Glucose, intravenous	25 Oct 2009	25 Oct 2009

Randomized treatment group: Golimumab 200 mg to 100 mg.
Actual treatment group: Golimumab 200 mg to 100 mg.

Treatment received:			
Visit, Date (Study Day)	**Admin. No. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0, 28 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0, 28 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0, 28 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0, 28 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 4	Golimumab	100 mg
Treatment status:			
Study treatment discontinuation?	Yes.		
Reason for treatment discontinuation:	Adverse event.		
Date of last study agent administration:	28 Sep 2009.		
Last scheduled study treatment visit:	Week 0.		
Study status:			
Study participation discontinuation?	Yes.		
Date of study discontinuation:	24 Oct 2009.		
Reason for noncompletion:	Other.		
Other reason for noncompletion/details:	Worsening of UC.		
Subject entered into maintenance study:	No.		
Date of disposition status:	24 Oct 2009.		

被験者識別コード：7815-00001

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
Related SAE/ Serious infection	肺炎 (Pneumonia)	Probable	23 Nov 2009 03 Dec 2009 (11 days)
Opportunistic infection	サイトメガロウイルス感染 (Cytomegalovirus infection)	Not related	18 Dec 2009 Ongoing
Demographic information: 5[redacted]-year-old (DOB: 09 Jul [redacted]) Asian male. Weight: 54.2 kg; height: 152 cm.			
Relevant medical history at baseline: ブドウ膜炎，喫煙（過去），回腸炎			
Baseline smoking status: Prior smoker (stopped > 1 year ago).			
Ulcerative colitis history: Date of diagnosis: November 2002. UC disease duration: 6.9 years.			

Prior/concomitant medication, route	**Start date**	**End date**
Levofloxacin, ophthalmic	18 Aug 2009	06 Oct 2009
Betamethasone, ophthalmic	03 Oct 2007	Ongoing
Carteolol, ophthalmic	14 Jan 2009	17 Nov 2009
Brinzolamide, ophthalmic	04 Feb 2009	20 Oct 2009
Diclofenac, ophthalmic	18 Aug 2009	03 Nov 2009
Travoprost, ophthalmic	01 Apr 2009	Ongoing
Prednisolone, ophthalmic	04 Nov 2009	Ongoing
Tropicamide, ophthalmic	03 Oct 2007	Ongoing
Lactobacillus bifidus, lyophilized, oral	06 Nov 2002	Ongoing
Ecabet, oral	06 Nov 2002	Ongoing
Atorvastatin, oral	26 Apr 2003	Ongoing
Risedronic acid, oral	28 Aug 2008	Ongoing
Prednisolone, oral	22 Nov 2002	Ongoing
Mesalazine, oral	06 Nov 2002	Ongoing
Prednisolone, rectal	24 Dec 2003	06 Oct 2009
Glycerol, rectal	21 Oct 2009	21 Oct 2009
Lidocaine, topical	21 Oct 2009	21 Oct 2009
Cefcapene, oral	21 Nov 2009	22 Nov 2009
Paracetamol, oral	21 Nov 2009	26 Nov 2009
Ceftriaxone, intravenous	23 Nov 2009	28 Nov 2009
Solutions for parenteral nutrition, intravenous	23 Nov 2009	25 Nov 2009
Osmosal /00501801/, intravenous	23 Nov 2009	25 Nov 2009
Glycerol, rectal	16 Dec 2009	26 Dec 2009
Lidocaine, topical	16 Dec 2009	16 Dec 2009

Pl gran., oral	21 Jan 2010	26 Jan 2010
Serrapeptase, oral	21 Jan 2010	26 Jan 2010
Cefdinir, oral	21 Jan 2010	26 Jan 2010
Levofloxacin, ophthalmic	27 Jan 2010	10 Mar 2010
Liranaftate, other	04 Feb 2010	Ongoing

Randomized treatment group: Golimumab 200 mg to 100 mg.
Actual treatment group: Golimumab 200 mg to 100 mg.

Treatment received:

Visit, Date (Study Day)	Admin. No. /Inj. No.	Agent	Dose/Unit
Week 0, 04 Nov 2009 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0, 04 Nov 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0, 04 Nov 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0, 04 Nov 2009 (Study Day 1)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2, 18 Nov 2009 (Study Day 15)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2, 18 Nov 2009 (Study Day 15)	Admin. 2/ Inj. 6	Placebo	0 mg

Treatment status:
Study treatment discontinuation? No.
Date of last study agent administration: 18 Nov 2009.
Last scheduled study treatment visit: Week 2.

Study status:
Study participation discontinuation? No.
Subject entered into maintenance study: No.
Date of disposition status: 10 Mar 2010.

被験者識別コード：7720-00001

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Unlikely	10 Oct 2007 Ongoing
SAE/ Serious infection	蜂巣炎 (Cellulitis)	Unlikely	27 Nov 2007 03 Dec 2007 (7 days)

Demographic information: 2[redacted]-year-old (DOB: 05 Apr [redacted]) Caucasian male. Weight: 67.4 kg; height: 182.88 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not provided.

Ulcerative colitis history:
Date of diagnosis: 15 Mar 2007.
UC disease duration: 0.5 years.

Prior/concomitant medication, route	Start date	End date
Mesalazine, oral	15 Mar 2007	20 Jul 2007
Azathioprine, oral	14 May 2007	20 Jul 2007
Levofloxacin, oral	13 Jul 2007	02 Aug 2007
Promethazine, oral	16 Jul 2007	26 Jul 2007
Hydromorphone, oral	13 Jul 2007	20 Jul 2007
Oxycocet, oral	20 Jul 2007	24 Oct 2007
Sulfamethizole, oral	20 Jul 2007	30 Jul 2007
Mesalazine, oral	20 Jul 2007	10 Oct 2007
Azathioprine, oral	20 Jul 2007	Ongoing
Hydrocodone, oral	20 Jul 2007	20 Aug 2007
Midazolam, intravenous	10 Sep 2007	10 Sep 2007
Propofol, intravenous	10 Sep 2007	10 Sep 2007
Tramadol, oral	14 Sep 2007	Ongoing
Prednisone, oral	10 Oct 2007	Ongoing
Rifaximin, oral	10 Oct 2007	Ongoing
Mesalazine, oral	10 Oct 2007	Ongoing
Prednisone, oral	10 Oct 2007	Ongoing
Methylprednisolone, intravenous	24 Oct 2007	04 Nov 2007

Mesalazine, oral	24 Oct 2007	Ongoing
Hydrocortisone, rectal	24 Oct 2007	Ongoing
Mesalazine, rectal	24 Oct 2007	Ongoing
Methylprednisolone, intravenous	04 Nov 2007	25 Nov 2007
Fluconazole, oral	02 Nov 2007	Ongoing
Hydromorphone, intravenous	04 Nov 2007	25 Nov 2007
Indometacin, oral	25 Nov 2007	Ongoing
Cefalexin, oral	25 Nov 2007	30 Nov 2007
Gabapentin, oral	25 Nov 2007	Ongoing
Prednisone, oral	25 Nov 2007	08 Dec 2007
Prednisone, oral	09 Dec 2007	22 Dec 2007
Prednisone, oral	23 Dec 2007	05 Jan 2008
Prednisone, oral	06 Jan 2008	19 Jan 2008
Infliximab, intravenous	25 Oct 2007	25 Oct 2007
Hyoscyamine, sublingual	26 Oct 2007	Ongoing
Oxycocet, oral	24 Oct 2007	Ongoing
Insulin human, subcutaneous	03 Nov 2007	03 Nov 2007
Morphine, intravenous	03 Nov 2007	03 Nov 2007
Morphine, intravenous	03 Nov 2007	03 Nov 2007
Morphine, intravenous	03 Nov 2007	04 Nov 2007
Insulin human, subcutaneous	02 Nov 2007	02 Nov 2007
Insulin human, subcutaneous	30 Oct 2007	01 Nov 2007
Fentanyl, intravenous	06 Nov 2007	06 Nov 2007
Midazolam, intravenous	06 Nov 2007	06 Nov 2007
Midazolam, intravenous	18 Oct 2007	18 Oct 2007
Propofol, intravenous	18 Oct 2007	18 Oct 2007

Randomized treatment group: Golimumab 400 mg to 200 mg.
Actual treatment group: Golimumab 400 mg to 200 mg.

Treatment received:

Visit, Date (Study Day)	Admin. No. /Inj. No.	Agent	Dose/Unit
Week 0, 12 Sep 2007 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0, 12 Sep 2007 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0, 12 Sep 2007 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0, 12 Sep 2007 (Study Day 1)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2, 26 Sep 2007 (Study Day 15)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2, 26 Sep 2007 (Study Day 15)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2, 26 Sep 2007 (Study Day 15)	Admin. 2/ Inj. 7	Golimumab	100 mg

Treatment status:
Study treatment discontinuation? No.
Date of last study agent administration: 26 Sep 2007.
Last scheduled study treatment visit: Week 2.

Study status:
Study participation discontinuation? Yes.
Date of study discontinuation: 03 Dec 2007.
Reason for noncompletion: Other.
Other reason for noncompletion/details: Lack of efficacy/worsening of ulcerative colitis.
Subject entered into maintenance study: No.
Date of disposition status: 03 Dec 2007.

被験者識別コード：7081-00001

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
Related SAE/ Serious infection	発熱 (Fever—39.5 degree C)	Possible	13 Feb 2009 15 Feb 2009 (3 days)
SAE	潰瘍性大腸炎 (Worsening ulcerative colitis)	Not related	13 Feb 2009 20 Feb 2009 (8 days)

Demographic information: 4[redacted]-year-old (DOB: 01 Nov [redacted]) Caucasian male. Weight: 60 kg; height: 170 cm.

Relevant medical history at baseline: 報告なし			
Baseline smoking status: Not provided.			
Ulcerative colitis history: Date of diagnosis: 20 Jan 2007. UC disease duration: 1.9 years.			
Prior/concomitant medication, route	**Start date**	**End date**	
Prednisone, oral	07 Aug 2008	Ongoing	
Azathioprine, oral	07 Aug 2008	Ongoing	
Mesalazine, oral	17 Oct 2008	Ongoing	
Omeprazole, oral	07 Aug 2008	Ongoing	
Paracetamol, oral	23 Jan 2009	10 Feb 2009	
Ciprofloxacin, intravenous	14 Feb 2009	20 Feb 2009	
Metronidazole, intravenous	14 Feb 2009	20 Feb 2009	
Randomized treatment group: Golimumab 400 mg to 200 mg. **Actual treatment group:** Golimumab 400 mg to 200 mg.			
Treatment received:			
Visit, Date (Study Day)	**Admin. No. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0, 12 Dec 2008 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0, 12 Dec 2008 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0, 12 Dec 2008 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0, 12 Dec 2008 (Study Day 1)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2, 29 Dec 2008 (Study Day 18)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2, 29 Dec 2008 (Study Day 18)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 2, 29 Dec 2008 (Study Day 18)	Admin. 2/ Inj. 7	Golimumab	100 mg
Treatment status: Study treatment discontinuation? No. Date of last study agent administration: 29 Dec 2008. Last scheduled study treatment visit: Week 2.			
Study status: Study participation discontinuation? No. Subject entered into maintenance study: No. Date of disposition status: 14 May 2009.			

被験者識別コード：7743-00004

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
Related SAE/ Serious infection	脳膿瘍 (Brain abscess on MRI)	Possible	02 Apr 2009 18 May 2009 (47 days)
Related SAE/ Neurologic event of interest	脱髄 (Demyelinating brain lesion on MRI)	Possible	14 Jul 2009 Ongoing
Demographic information: 4[redacted]-year-old (DOB: 28 Jan [redacted]) Caucasian male. Weight: 136.1 kg; height: 191 cm.			
Relevant medical history at baseline: 関節炎， 関節痛， 喫煙（過去）			
Baseline smoking status: Prior smoker (stopped > 1 year ago).			
Ulcerative colitis history: Date of diagnosis: 1995. UC disease duration: 13 years.			
Prior/concomitant medication, route	**Start date**	**End date**	
Mesalazine, oral	28 Mar 2008	Ongoing	
Azathioprine, oral	04 Jun 2008	Ongoing	
Metoprolol, oral	February 2000	Ongoing	
Propofol, intravenous	08 Dec 2008	08 Dec 2008	
Glycopyrronium, intravenous	08 Dec 2008	08 Dec 2008	
Phosphates, oral	07 Dec 2008	07 Dec 2008	
Cefalexin, oral	09 Dec 2008	18 Dec 2008	
Azithromycin, oral	12 Jan 2009	16 Jan 2009	

Randomized treatment group: Golimumab 400 mg to 200 mg. **Actual treatment group:** Golimumab 400 mg to 200 mg.			
Treatment received:			
Visit, Date (Study Day)	**Admin. No. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0, 22 Dec 2008 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0, 22 Dec 2008 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0, 22 Dec 2008 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0, 22 Dec 2008 (Study Day 1)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2, 06 Jan 2009 (Study Day 16)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2, 06 Jan 2009 (Study Day 16)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2, 06 Jan 2009 (Study Day 16)	Admin. 2/ Inj. 7	Golimumab	100 mg
Treatment status: Study treatment discontinuation? No. Date of last study agent administration: 06 Jan 2009. Last scheduled study treatment visit: Week 2			
Study status: Study participation discontinuation? No. Subject entered into maintenance study: Yes. Date of disposition status: 05 Feb 2009.			

被験者識別コード：6705-00013

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
Related SAE/ Serious infection	気管支炎 (Acute bronchitis)	Possible	16 Aug 2009 19 Aug 2009 (4 days)
Demographic information: 6[redacted]-year-old (DOB: 17 Jan [redacted]) Caucasian male. Weight: 78 kg; height: 163 cm.			
Relevant medical history at baseline: 喫煙（現在）			
Baseline smoking status: Current smoker.			
Ulcerative colitis history: Date of diagnosis: 2007. UC disease duration: 1.6 years.			

Prior/concomitant medication, route	**Start date**	**End date**
Simvastatin, oral	Prior	Ongoing
Mesalazine, oral	Prior	Ongoing
Citalopram, oral	Prior	Ongoing
Isosorbide, oral	Prior	Ongoing
Fluticasone, inhalation	Prior	Ongoing
Tiotropium, inhalation	Prior	Ongoing
Doxazosin, oral	Prior	Ongoing
Varenicline, oral	Prior	Ongoing
Fenofibrate, oral	Prior	Ongoing
Lisinopril, oral	Prior	Ongoing
Isoniazid, oral	06 Jul 2009	Ongoing
Pyridoxine, oral	06 Jul 2009	Ongoing
Bisacodyl, oral	20 Jul 2009	20 Jul 2009
Macrogol, oral	20 Jul 2009	20 Jul 2009
Levofloxacin, oral	19 Aug 2009	01 Sep 2009
Paracetamol, oral	17 Aug 2009	17 Aug 2009
Sodium chloride, intravenous	17 Aug 2009	17 Aug 2009
Heparin, intramuscular	17 Aug 2009	17 Aug 2009
Salbutamol w/ipratropium, inhalation	17 Aug 2009	17 Aug 2009
Levofloxacin, intravenous	17 Aug 2009	17 Aug 2009
Methylprednisolone, intravenous	17 Aug 2009	17 Aug 2009
Calcium carbonate, oral	18 Aug 2009	18 Aug 2009
Asasantin, oral	18 Aug 2009	18 Aug 2009
Prednisone, oral	19 Aug 2009	28 Aug 2009
Propofol, intravenous	08 Sep 2009	08 Sep 2009

Macrogol, oral	07 Sep 2009	07 Sep 2009
Bisacodyl, oral	07 Sep 2009	07 Sep 2009
Lidocaine, intravenous	08 Sep 2009	08 Sep 2009

Randomized treatment group: Golimumab 400 mg to 200 mg.
Actual treatment group: Golimumab 400 mg to 200 mg.

Treatment received:

Visit, Date (Study Day)	Admin. No. /Inj. No.	Agent	Dose/Unit
Week 0, 27 Jul 2009 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0, 27 Jul 2009 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0, 27 Jul 2009 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0, 27 Jul 2009 (Study Day 1)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2, 07 Aug 2009 (Study Day 12)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2, 07 Aug 2009 (Study Day 12)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 2, 07 Aug 2009 (Study Day 12)	Admin. 2/ Inj. 7	Golimumab	100 mg

Treatment status:
Study treatment discontinuation? No.
Date of last study agent administration: 07 Aug 2009.
Last scheduled study treatment visit: Week 2.

Study status:
Study participation discontinuation? No.
Subject entered into maintenance study: No.
Date of disposition status: 30 Nov 2009.

被験者識別コード：7008-00006

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Serious infection	ウイルス性胃腸炎 (Viral gastroenteritis)	Unlikely	28 Apr 2009 02 May 2009 (5 days)

Demographic information: 3[redacted]-year-old (DOB: 17 Mar [redacted]) Caucasian male. Weight: 83.3 kg; height: 178 cm.

Relevant medical history at baseline: 関節痛, アフタ性口内炎, 喫煙（過去）

Baseline smoking status: Prior smoker (stopped ≤ 1 year ago).

Ulcerative colitis history:
Date of diagnosis: September 1992.
UC disease duration: 16.5 years.

Prior/concomitant medication, route	Start date	End date
Mesalazine, oral	1997	Ongoing
Warfarin, oral	April 2007	17 Mar 2009
Prednisone, oral	22 Feb 2007	Ongoing
Enoxaparin, subcutaneous	18 Mar 2009	30 Mar 2009
Warfarin, oral	31 Mar 2009	29 Apr 2009
Fentanyl, intravenous	25 Mar 2009	25 Mar 2009
Propofol, intravenous	25 Mar 2009	25 Mar 2009
Enoxaparin, subcutaneous	30 Apr 2009	02 May 2009
Warfarin, oral	03 May 2009	Ongoing
Fentanyl, intravenous	01 May 2009	01 May 2009
Midazolam, intravenous	01 May 2009	01 May 2009
Propofol, intravenous	01 May 2009	01 May 2009
Metoclopramide, oral	28 Apr 2009	30 Apr 2009
Paracetamol, oral	28 Apr 2009	29 Apr 2009
Oxycodone, oral	29 Apr 2009	29 Apr 2009
Morphine, intravenous	28 Apr 2009	30 Apr 2009
Hydrocortisone, intravenous	28 Apr 2009	28 Apr 2009

Randomized treatment group: Golimumab 400 mg to 200 mg.
Actual treatment group: Golimumab 400 mg to 200 mg.

Treatment received:			
Visit, Date (Study Day)	**Admin. No. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0, 08 Apr 2009 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0, 08 Apr 2009 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0, 08 Apr 2009 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0, 08 Apr 2009 (Study Day 1)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2, 22 Apr 2009 (Study Day 15)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2, 22 Apr 2009 (Study Day 15)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2, 22 Apr 2009 (Study Day 15)	Admin. 2/ Inj. 7	Golimumab	100 mg
Treatment status:			
Study treatment discontinuation?	No.		
Date of last study agent administration:	22 Apr 2009.		
Last scheduled study treatment visit:	Week 2.		
Study status:			
Study participation discontinuation?	No.		
Subject entered into maintenance study:	Yes.		
Date of disposition status:	22 May 2009.		

被験者識別コード：7008-00023

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
Related SAE/ Serious infection	肺浸潤 (Bilateral pulmonary infiltrates [human metapneumovirus])	Possible	09 Sep 2010 23 Sep 2010 (15 days)

Demographic information: 3[redacted]-year-old (DOB: 31 Mar [redacted]) Caucasian female. Weight: 43 kg; height: 157 cm.

Relevant medical history at baseline: 硬化性胆管炎

Baseline smoking status: Nonsmoker.

Ulcerative colitis history:
Date of diagnosis: 24 May 2007.
UC disease duration: 3.1 years.

Prior/concomitant medication, route	**Start date**	**End date**
Mercaptopurine, oral	01 Mar 2010	Ongoing
Seretide, oral	Prior	Ongoing
Salbutamol, oral	Prior	Ongoing
Doxycycline, oral	01 Jul 2010	07 Jul 2010
Fentanyl, intravenous	05 Jul 2010	05 Jul 2010
Midazolam, intravenous	05 Jul 2010	05 Jul 2010
Dexchlorpheniramine, oral	17 Jul 2010	Ongoing
Fexofenadine, oral	17 Jul 2010	Ongoing
Doxycycline, oral	02 Aug 2010	09 Aug 2010
Panadeine co, oral	29 Jul 2010	Ongoing
Cough and cold preparations, oral	29 Jul 2010	02 Aug 2010
Temazepam, oral	10 Sep 2010	12 Sep 2010
Metoclopramide, intravenous	09 Sep 2010	09 Sep 2010
Heparin, subcutaneous	09 Sep 2010	13 Sep 2010
Spironolactone, oral	11 Sep 2010	14 Sep 2010
Hydrocortisone, intravenous	09 Sep 2010	14 Sep 2010
Prednisone, oral	14 Sep 2010	Ongoing
Fentanyl, intravenous	07 Sep 2010	07 Sep 2010
Glycopyrronium, intravenous	07 Sep 2010	07 Sep 2010
Rocuronium, nasogastric	07 Sep 2010	07 Sep 2010
Midazolam, intravenous	07 Sep 2010	07 Sep 2010
Neostigmine, intravenous	07 Sep 2010	07 Sep 2010

Randomized treatment group: Golimumab 400 mg to 200 mg.
Actual treatment group: Golimumab 400 mg to 200 mg.

Treatment received:			
Visit, Date (Study Day)	**Admin. No. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0, 05 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0, 05 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0, 05 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0, 05 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2, 21 Jul 2010 (Study Day 17)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2, 21 Jul 2010 (Study Day 17)	Admin. 2/ Inj. 6	Golimumab	100 mg
Treatment status: Study treatment discontinuation? No. Date of last study agent administration: 21 Jul 2010. Last scheduled study treatment visit: Week 2.			
Study status: Study participation discontinuation? No. Subject entered into maintenance study: No. Date of disposition status: 03 Nov 2010.			

被験者識別コード：7207-00024

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE/ Event of interest: Malignancy	結腸癌 (Adenocarcinoma of the colon)	Not related	15 Jul 2010 10 Aug 2010 (27 days)
SAE/ Permanent discontinuation of study agent due to AE/ Event of interest: Malignancy	上皮内癌 (Carcinoma in situ)	Not related	15 Jul 2010 10 Aug 2010 (27 days)

Demographic information: 5[redacted]-year-old (DOB: 01 Jun [redacted]) Caucasian female. Weight: 78.3 kg; height: 167 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not provided.

Ulcerative colitis history:
Date of diagnosis: 2003.
UC disease duration: 6.5 years.

Prior/concomitant medication, route	**Start date**	**End date**
Mesalazine, oral	03 Jun 2010	Ongoing
Omeprazole, oral	March 2010	Ongoing

Randomized treatment group: Golimumab 400 mg to 200 mg.
Actual treatment group: Golimumab 400 mg to 200 mg.

Treatment received:			
Visit, Date (Study Day)	**Admin. No. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0, 14 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0, 14 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0, 14 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0, 14 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 4	Golimumab	100 mg
Treatment status: Study treatment discontinuation? Yes. Reason for treatment discontinuation: Adverse event. Date of last study agent administration: 14 Jul 2010. Last scheduled study treatment visit: Week 0.			
Study status: Study participation discontinuation? Yes. Date of study discontinuation: 20 Jul 2010. Reason for noncompletion: Other. Other reason for noncompletion/details: AE#1. Subject entered into maintenance study: No. Date of disposition status: 20 Jul 2010.			

被験者識別コード：7279-00010

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE	潰瘍性大腸炎 (Ulcerative colitis exacerbation)	Not related	03 Jun 2009 21 Jun 2009 (19 days)
Related SAE/ Serious infection	肛門膿瘍 (Perianal abscess)	Possible	08 Jul 2009 10 Jul 2009 (3 days)
Related SAE/ Serious infection	肛門膿瘍 (Perianal abscess recurrence)	Possible	20 Jul 2009 09 Sep 2009 (52 days)

Demographic information: 2[redacted]-year-old (DOB: 21 Feb [redacted]) Caucasian male. Weight: 63.5 kg; height: 172 cm.

Relevant medical history at baseline: 喫煙（現在）

Baseline smoking status: Current smoker (still smoking).

Ulcerative colitis history:
Date of diagnosis: 2003.
UC disease duration: 5.3 years.

Prior/concomitant medication, route	Start date	End date
Azathioprine, oral	2005	Ongoing
Aminosalicylic acid, oral	01 Feb 2009	Ongoing
Aminosalicylic acid, rectal	01 Feb 2009	01 Apr 2009
Paracetamol, oral	30 Apr 2009	05 May 2009
Prednisone, oral	10 May 2009	Ongoing
Hydrocortisone, intravenous	21 Jul 2009	23 Jul 2009
Hydrocortisone, intravenous	27 Aug 2009	29 Aug 2009
Azathioprine, oral	21 Jul 2009	12 Aug 2009
Metronidazole, intravenous	21 Jul 2009	03 Aug 2009
Metronidazole, intravenous	27 Aug 2009	29 Aug 2009
Amikacin, intravenous	25 Aug 2009	28 Aug 2009
Ampicillin, intravenous	25 Aug 2009	29 Aug 2009
Enoxaparin, subcutaneous	23 Aug 2009	25 Aug 2009
Ranitidine, intravenous	28 Aug 2009	02 Sep 2009
Ranitidine, intravenous	22 Jul 2009	25 Jul 2009
Hydrocortisone, intravenous	03 Jun 2009	16 Jun 2009
Azathioprine, oral	03 Jun 2009	21 Jun 2009
Ciprofloxacin, intravenous	04 Jun 2009	13 Jun 2009
Metronidazole, intravenous	04 Jun 2009	13 Jun 2009
Ranitidine, intravenous	04 Jun 2009	16 Jun 2009
Potassium, oral	10 Jun 2009	20 Jun 2009
Clindamycin, oral	12 Jun 2009	16 Jun 2009
Ensure /06360301/, oral	18 Jun 2009	20 Jun 2009

Randomized treatment group: Golimumab 400 mg to 200 mg.
Actual treatment group: Golimumab 400 mg to 200 mg.

Treatment received:

Visit, Date (Study Day)	Admin. No. /Inj. No.	Agent	Dose/Unit
Week 0, 21 Apr 2009 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0, 21 Apr 2009 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0, 21 Apr 2009 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0, 21 Apr 2009 (Study Day 1)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2, 06 May 2009 (Study Day 16)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2, 06 May 2009 (Study Day 16)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 2, 06 May 2009 (Study Day 16)	Admin. 2/ Inj. 7	Golimumab	100 mg

Treatment status:
Study treatment discontinuation? No.
Date of last study agent administration: 06 May 2009.
Last scheduled study treatment visit: Week 2.

Study status:	
Study participation discontinuation?	Yes.
Date of study discontinuation:	09 Sep 2009.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	UC exacerbation.
Subject entered into maintenance study:	No.
Date of disposition status:	09 Sep 2009.

2.7.6.4　臨床第 III 相試験（C0524T18）

本試験は治験薬投与後 54 週までの寛解維持試験とそれに続く 228 週までの継続投与試験から構成される。寛解維持試験の結果を 2.7.6.4.1 項に，継続投与試験の結果を【2.7.6.4.2 項】に示す。

2.7.6.4.1　C0524T18 試験（寛解維持試験，54 週まで）（評価資料：5.3.5.1.3-1, 5.3.5.1.4）

標題：

中等症から重症の活動期潰瘍性大腸炎（以下 UC）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を評価する第 III 相，多施設共同，ランダム化，プラセボ対照，二重盲検試験

実施期間：2007 年 9 月 ■日～2011 年 11 月 ■日（54 週データカットオフ）

地域：　5 地域　アジア，オセアニア，北米，ヨーロッパ，アフリカ

参加国：　25 ヵ国　日本，インド，オーストラリア，ニュージーランド，米国，カナダ，ブルガリア，ハンガリー，ポーランド，ルーマニア，セルビア，スロバキア，ウクライナ，ラトビア，ロシア，チェコ共和国，オーストリア，ベルギー，フランス，オランダ，デンマーク，スウェーデン，ドイツ，イスラエル，南アフリカ

実施施設：　251 施設（日本 21 施設）

開発の相：第 III 相

試験の目的：

主目的

1. 寛解導入試験である C0524T16 試験（以下 T16 試験）又は C0524T17 試験（T17 試験）でゴリムマブにより clinical response が認められた中等症から重症の活動期 UC 患者を対象とした，54 週までの clinical response 維持を指標とする 2 用量のゴリムマブを皮下投与したときの有効性の評価
2. 中等症から重症の活動期 UC 患者を対象とした，2 用量のゴリムマブを皮下投与したときの寛解維持療法での安全性の評価

副次目的

1. 30 週及び 54 週の clinical remission 維持を指標とするゴリムマブの有効性の評価
2. 30 週及び 54 週の mucosal healing 維持を指標とするゴリムマブの有効性の評価
3. 本試験の 0 週で clinical remission が認められた被験者を対象とした，30 週及び 54 週の clinical remission 維持を指標とするゴリムマブの有効性の評価

4. 本試験の 0 週でコルチコステロイドを併用していた被験者を対象とした，54 週の clinical remission 達成及びコルチコステロイド使用の減少を指標とするゴリムマブの有効性の評価

試験方法：

試験デザイン及び対象患者集団

本試験は第 III 相，多施設共同，プラセボ対照，二重盲検，並行群間，randomized withdrawn 試験である。本試験は寛解維持試験及び継続投与試験から構成され，寛解維持試験では 52 週まで治験薬を投与し，54 週まで有効性及び安全性を評価した。

T16 試験又は T17 試験の 6 週にゴリムマブにより clinical response が認められた被験者は，本試験の 0 週にプラセボ（以下プラセボ群），ゴリムマブ 50 mg 又は 100 mg（以下それぞれ 50 mg 群，100 mg 群）のいずれかの投与群へ 1：1：1 の比でランダムに割り付けられ（Target population，以下ランダム割付けされた被験者），52 週まで 4 週ごとに治験薬が皮下投与された。

T16 試験又は T17 試験の 6 週にプラセボにより clinical response が認められた被験者（以下プラセボ寛解導入 responder），プラセボにより clinical response を認めなかった被験者（以下プラセボ寛解導入 non-responder），及びゴリムマブにより clinical response を認めなかった被験者（以下ゴリムマブ寛解導入 non-responder）は，ランダムに割り付けることなく本試験への登録を可能とし，用法・用量は以下のとおりとした。

- プラセボ寛解導入 responder：プラセボを 52 週まで 4 週ごとに皮下投与
- プラセボ寛解導入 non-responder：ゴリムマブ 100 mg を 52 週まで 4 週ごとに皮下投与
- ゴリムマブ寛解導入 non-responder：ゴリムマブ 100 mg を 52 週まで 4 週ごとに皮下投与

なお，52 週までの投与を完了し，54 週の有効性及び安全性の評価を完了した被験者のうち，治験担当医師により継続投与で効果が得られると判断された被験者は，継続投与試験に参加可能とした。継続投与試験は 54 週から開始し 228 週まで，ゴリムマブの UC に対する製造販売承認が取得されるまで，又は UC の適応を取得しないと決定されるまでのいずれか早い時点までとした。

用量調節

ランダム割付けされた被験者の clinical response が試験期間中に消失した場合，以下の方法で治験薬の用量を調節した。

- プラセボ群：ゴリムマブ 100 mg を 4 週ごとに皮下投与した
- 50 mg 群：再度ランダムに 2 群に割り付け，ゴリムマブ 50 mg 又は 100 mg のいずれかを 4 週ごとに皮下投与した
- 100 mg 群：
  - 治験実施計画書 改訂 3 版の発行以前は，再度ランダムに 2 群に割り付け，ゴリムマブ 100 mg 又は 200 mg のいずれかを 4 週ごとに皮下投与した。

- その後，関節リウマチに長期罹患した患者に対するゴリムマブの投与でリンパ腫が報告されたため計画を変更（治験実施計画書 改訂 3 版を発行）し，200 mg への増量はせず 100 mg を 4 週ごとに皮下投与することとした。なお，治験実施計画書 改訂 3 版の発行以前に 200 mg を皮下投与されていた被験者は，100 mg へ減量した。

ランダム割付けされなかった被験者のうち，プラセボ寛解導入 responder の clinical response が試験期間中に消失した場合，ゴリムマブ 100 mg を 4 週ごとに皮下投与することとした。プラセボ寛解導入 non-responder 及びゴリムマブ寛解導入 non-responder は用量調節の対象外とした。

被験者は，52 週までに用量調節を 1 回だけ行うことができることとした。用量調節後の初回投与後 16 週までに UC の疾患活動性に改善が認められないと治験担当医師が判断した場合は，当該被験者の治験薬投与を中止した。

被験者数：

1228 例が本試験に組み入れられた。組み入れられた被験者の内訳は，以下のとおりである。

・ ランダム割付けされた被験者［寛解導入試験（T16 試験又は T17 試験）の結果，6 週にゴリムマブにより clinical response が認められランダム割付けされた被験者］：464 例

- プラセボ群：156 例
- 50 mg 群：154 例
- 100 mg 群：154 例

・ ランダム割付けされなかった被験者：764 例

- プラセボ寛解導入 responder でありプラセボを継続して投与された被験者：129 例
- プラセボ寛解導入 non-responder でありゴリムマブ 100 mg を投与された被験者：230 例
- ゴリムマブ寛解導入 non-responder でありゴリムマブ 100 mg を投与された被験者：405 例

診断及び主な組入れ基準：

寛解導入試験（T16 試験又は T17 試験）で，治験薬の投与をすべて受け，6 週の Mayo スコアの評価が完了している被験者で，寛解導入試験の 6 週の来院と寛解維持試験の 0 週の来院が同日に完了した被験者を，本試験へ参加可能とした。なお，medical monitor の承認がある場合は，6 週の来院から 7 日以内に 0 週の来院を完了することとした。

寛解導入試験の 0 週以降に併用 UC 治療薬の投与量を増量した被験者，併用 UC 治療薬の投与を開始した被験者，結腸切除（部分切除又は全体切除）又は造瘻術（一時的な結腸造瘻術，永久的な結腸造瘻術，回腸造瘻術又はその他の腸造瘻術）を施行された被験者は除外した。肉芽腫性感染症（結核を含む），非結核性のマイコバクテリア感染症又は日和見感染症，並びに HIV 感染，B 型肝炎感染又は C 型肝炎感染の徴候及び症状がある被験者は除外した。何らかの悪性腫瘍

の徴候及び症状がある被験者，リンパ増殖性疾患の可能性を示唆する徴候及び症状がある被験者は除外した。うっ血性心不全，全身性エリテマトーデス又は脱髄疾患の徴候及び症状のある被験者は除外した。また，寛解導入試験の 0 週以降に臨床的に重要な感染症に罹患した被験者，寛解導入試験中に臨床的に重要な過敏症反応を発現した被験者は除外した。

被験薬：

ゴリムマブは単回使用プレフィルドシリンジ（以下 PFS）の皮下注射用滅菌液として供給された。各 PFS には，ヒスチジン，ソルビトール及びポリソルベート 80 が含まれた pH が 5.5 の水溶性媒体に，ゴリムマブ 50 mg（0.5 mL）又は 100 mg（1 mL）のいずれかが充填された。防腐剤は添加されていなかった。

対照薬：

プラセボは被験薬と同じ単回使用 PFS に 0.5 mL 又は 1.0 mL の皮下注射用滅菌液として治験依頼者より供給された。各 PFS にはヒスチジン，ソルビトール及びポリソルベート 80 が pH 5.5 で充填された。防腐剤は添加されていなかった。

投与期間：

本試験の投与期間は 52 週であった。

評価：

薬物動態等　54 週までの血清中ゴリムマブ濃度，免疫原性（抗ゴリムマブ抗体及び中和抗体）

有効性

評価項目：Mayo スコア，partial Mayo スコア，内視鏡検査，C-反応性たん白（以下 CRP），糞便中ラクトフェリン及びカルプロテクチン

評価基準：54 週までの clinical response（Mayo スコアが T16 試験又は T17 試験の 0 週から，30%以上かつ 3 ポイント以上減少するとともに，rectal bleeding サブスコアが 1 点以上減少するか，rectal bleeding サブスコアが 0 又は 1 になった場合），clinical remission（Mayo スコアが 2 点以下であり，1 を超えるサブスコアがない状態）及び mucosal healing（Mayo スコアの内視鏡検査サブスコアが 0 又は 1 の場合）

患者報告アウトカム：Inflammatory Bowel Disease Questionnaire（以下 IBDQ），36-item short form health survey（以下 SF-36）及び Euro QOL（以下 EQ）-5D

医療経済評価：雇用形態，日々の生産性に対する疾患の影響，患者及び介護者の離職期間，医療資源利用度，UC による入院，結腸切除等を含む手術

安全性　有害事象及び臨床検査［血液学的検査，血液生化学検査，抗核抗体（ANA）及び抗 dsDNA 抗体］

なお，有害事象名は MedDRA ver.14.0 を用いてコーディングした。また，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」又は不明の有害事象を治験薬の使用と関連性のある有害事象とした。

症例数設計の根拠：

本試験開始時には，潰瘍性大腸炎患者を対象としたゴリムマブのデータは得られていなかったため，ゴリムマブ 100 mg 群で 54 週まで clinical response が認められる被験者の割合は，中等症から重症の活動期の潰瘍性大腸炎患者を対象としたインフリキシマブの臨床試験（Active Ulcerative Colitis Trial：ACT 1 試験）の結果から，プラセボ群で 54 週まで clinical response が認められる被験者の割合は，クローン病患者を対象としたインフリキシマブの臨床試験（A Crohn's disease Clinical study Evaluating infliximab in a New long term Treatment regimen：ACCENT 1 試験）の結果から推定した。54 週まで clinical response が認められる被験者の割合を，ゴリムマブ 100 mg 群で 55%，プラセボ群で 35%と仮定した場合，各群に約 128 名（合計 384 名）の被験者がいれば，有意水準 0.05（両側）で 90%の検出力が得られると考えられた。

本試験の登録被験者数は，寛解導入試験の C0524T16 及び C0524T17 試験から組み入れられる被験者数に依存する。また，主要解析対象集団の被験者数は，寛解導入試験でゴリムマブに clinical response を示し，さらに本試験への参加に同意した被験者数に依存する。

主要解析対象集団に必要な被験者数を確保するために，IVRS（interactive voice response system）を用いて C0524T17 試験への登録被験者を増加できることとした。

統計手法：

被験者背景

寛解維持試験のすべての被験者は，寛解導入試験より参加した。

ランダム割付けされた被験者及びランダム割付けされなかった被験者について，寛解導入試験の 0 週からの人口統計学的特性及びベースラインの疾患特性を要約した。

薬物動態等

54 週までの血清中ゴリムマブ濃度，免疫原性（抗ゴリムマブ抗体及び中和抗体）は，寛解維持試験の全投与被験者の用量ごと，ランダム割付けされた被験者の投与群ごとに要約した。

有効性

主要解析対象集団：

寛解維持試験の 0 週にランダム割付けされた被験者［すなわち IVRS（interactive voice response system）で決定された，ゴリムマブの寛解導入によって寛解維持試験の 0 週に clinical response が認められた被験者］とした。ランダム割付けされなかった被験者の有効性評価を除き，すべての有効性の解析は主要解析対象集団を対象とした。なお，T16 試験及び T17 試験で有効性の解析対象から除外した治験実施医療機関（施設番号：6706，7257 及び 7407）の被験者のデータは，本試験でも有効性の解析対象から除外した。

主要評価項目：

主要評価項目は 54 週までの clinical response とした。54 週までに clinical response が認められた被験者の割合を集計し，本試験の 0 週における clinical remission（あり，なし）及び寛解導入試験での用量を層別因子とした Cochran-Mantel-Haenszel（以下 CMH）カイ二乗検定を用いて，各ゴリムマブ群とプラセボ群を比較した。第 1 種の過誤確率を 0.05 のレベルにコントロールするた

め，固定順序による逐次的な検定手順を使用した。この検定手順では，最初に 100 mg 群とプラセボ群の比較を両側有意水準 0.05 で実施した。この検定結果が有意な場合にのみ，50 mg 群とプラセボ群の比較を両側有意水準 0.05 で実施することとした。50 mg 群の検定結果によらず，100 mg 群の検定結果が有意な場合に本試験の結果を有意とみなすこととした。

主な副次評価項目：

主要評価項目である 54 週までの clinical response について，プラセボ群に対し 100 mg 群で統計学的に有意な差が認められた場合にのみ，以下の主な副次評価項目について解析した。

1. 30 週及び 54 週に clinical remission が認められた被験者の割合を集計し，各ゴリムマブ群とプラセボ群を比較した。
2. 30 週及び 54 週に mucosal healing が認められた被験者の割合を集計し，各ゴリムマブ群とプラセボ群を比較した。
3. 本試験の 0 週に clinical remission が認められた被験者のうち，30 週及び 54 週に clinical remission が認められた被験者の割合を集計し，各ゴリムマブ群とプラセボ群を比較した。
4. 本試験の 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 週で併用しておらず clinical remission が認められた被験者の割合を集計し，各ゴリムマブ群とプラセボ群を比較した。

上記の主な副次評価項目「3.」以外の解析には，本試験の 0 週における clinical remission（あり，なし）及び寛解導入試験での用量を層別因子とした CMH カイ二乗検定を用いた。主な副次評価項目「3.」の解析には，寛解導入試験での用量を層別因子とした CMH カイ二乗検定を用いた。第 1 種の過誤確率を両側有意水準 0.05 にコントロールするため，主な副次評価項目それぞれについて固定順序による逐次的な検定手順を使用し，階層的な方法で検定した。この検定手順では，50 mg 群の検定結果にかかわらず，先立つ副次評価項目の検定結果が 100 mg 群でプラセボ群に対し有意な場合にのみ，次の評価項目について 100 mg 群の検定を実施した。50 mg 群の検定は，同項目の 100 mg 群での検定結果が有意な場合でかつ先立つ副次評価項目の 50 mg 群での検定結果が有意な場合に，該当副次評価項目の検定を開始できることとした。

その他の副次評価項目：

2 値データの評価項目は，特に規定のない限り，本試験の 0 週における clinical remission（あり，なし）及び寛解導入試験での用量を層別因子とした CMH カイ二乗検定を用いて，プラセボ群と各ゴリムマブ群を比較した。連続量の評価項目は，共分散分析又は本試験の 0 週の値，本試験の 0 週における clinical remission（あり，なし），寛解導入試験での用量及び投与群を共変量とした Van der Waerden 正規スコアに基づく共分散分析を適宜用いた。

患者報告アウトカム：

連続量の評価項目は，本試験の 0 週の値，本試験の 0 週における clinical remission（あり，なし），寛解導入試験での用量及び投与群を共変量とした Van der Waerden 正規スコアに基づく共分散分析を用いた。

安全性

安全性は，以下に示す集団ごとに要約した。

- ランダム割付けされた被験者
- ランダム割付けされなかった被験者（プラセボ寛解導入 responder，プラセボ寛解導入 non-responder，ゴリムマブ寛解導入 non-responder）
- ランダム割付けされた被験者及びランダム割付けされなかった被験者を含む全投与被験者

試験結果：

被験者及び投与状況

1228 例が本試験に組み入れられた。このうちランダム割付けされた被験者は 464 例であり，50 mg 群及び 100 mg 群にそれぞれ 154 例，プラセボ群に 156 例がランダムに割り付けられた。ランダム割付けされなかった被験者は 764 例で，その内訳は，プラセボ寛解導入 responder 129 例，プラセボ寛解導入 non-responder 230 例，ゴリムマブ寛解導入 non-responder 405 例であった。ランダム割付けされなかった被験者の 1 例を除き，すべての被験者で割り当てられた用法・用量で治験薬が投与された。このランダム割付けされなかった被験者の 1 例は，プラセボ寛解導入 responder であったためプラセボが割り当てられたが，32 週にゴリムマブ 100 mg が投与された。

ランダム割付けされた被験者の 464 例では，28.2%（131/464 例）が 52 週までに治験薬投与を中止した。治験薬投与を中止した被験者の割合は各投与群間で同様であった［プラセボ群及び併合ゴリムマブ群でそれぞれ 27.6%（43/156 例）及び 28.6%（88/308 例），以下同順］。最も高頻度にみられた治験薬投与中止理由は，「効果不十分」［12.2%（19/156 例）及び 12.7%（39/308 例）］，「有害事象」［10.9%（17/156 例）及び 7.8%（24/308 例）］であった。ランダム割付けされた被験者では，12.3%（57/464 例）が 54 週時点で試験を中止した。試験を中止した被験者の割合は各投与群間でおおむね同様であった［11.5%（18/156 例）及び 12.7%（39/308 例）］。プラセボ群及び併合ゴリムマブ群で最も高頻度にみられた試験中止理由は「その他」及び「同意撤回」であった。

ランダム割付けされなかった被験者の 764 例で治験薬投与を中止した被験者の割合は，プラセボ寛解導入 responder［31.8%（41/129 例）］に比べプラセボ寛解導入 non-responder［44.8%（103/230 例）］及びゴリムマブ寛解導入 non-responder［53.3%（216/405 例）］で多く，最も高頻度にみられた治験薬投与中止理由は「効果不十分」であった。ランダム割付けされなかった被験者のうち 154 例が 54 週時点で試験を中止し，最も高頻度にみられた試験中止理由は「その他」及び「同意撤回」であった。

被験者の内訳を表 2.7.6.4-1 に示す。

表 2.7.6.4-1 被験者の内訳（全投与被験者，54 週）

	Randomized Subjects					Nonrandomized Subjects			
		Golimumab					Golimumab 100 mg		
	Placebo[a]	50 mg	100 mg	Combined	Total	Placebo[b]	Placebo Nonresponders (Induction)	Golimumab Nonresponders (Induction)	Total
Subjects enrolled	156	154	154	308	464	129	230	405	1228
Subjects who did not end study participation as of Week 54	115 (73.7%)	120 (77.9%)	116 (75.3%)	236 (76.6%)	351 (75.6%)	95 (73.6%)	131 (57.0%)	201 (49.6%)	778 (63.4%)
Subjects who entered study extension	104 (66.7%)	101 (65.6%)	102 (66.2%)	203 (65.9%)	307 (66.2%)	78 (60.5%)	113 (49.1%)	174 (43.0%)	672 (54.7%)
Subjects who did not enter study extension	11 (7.1%)	19 (12.3%)	14 (9.1%)	33 (10.7%)	44 (9.5%)	17 (13.2%)	18 (7.8%)	27 (6.7%)	106 (8.6%)
Subjects who were being followed for safety	10 (6.4%)	15 (9.7%)	13 (8.4%)	28 (9.1%)	38 (8.2%)	13 (10.1%)	18 (7.8%)	25 (6.2%)	94 (7.7%)
Subjects who discontinued study agent prior to Week 52	3 (1.9%)	9 (5.8%)	8 (5.2%)	17 (5.5%)	20 (4.3%)	7 (5.4%)	5 (2.2%)	13 (3.2%)	45 (3.7%)
Subjects who completed study agent through Week 52	7 (4.5%)	6 (3.9%)	5 (3.2%)	11 (3.6%)	18 (3.9%)	6 (4.7%)	13 (5.7%)	12 (3.0%)	49 (4.0%)
Subjects who did not complete safety follow-up	1 (0.6%)	4 (2.6%)	1 (0.6%)	5 (1.6%)	6 (1.3%)	4 (3.1%)	0 (0.0%)	2 (0.5%)	12 (1.0%)
Subjects who ended study participation as of Week 54	41 (26.3%)	34 (22.1%)	38 (24.7%)	72 (23.4%)	113 (24.4%)	34 (26.4%)	99 (43.0%)	204 (50.4%)	450 (36.6%)
Subjects who discontinued study agent prior to Week 52 and completed safety follow-up	23 (14.7%)	16 (10.4%)	17 (11.0%)	33 (10.7%)	56 (12.1%)	15 (11.6%)	52 (22.6%)	116 (28.6%)	239 (19.5%)
Subjects who terminated study participation prior to Week 54	18 (11.5%)	18 (11.7%)	21 (13.6%)	39 (12.7%)	57 (12.3%)	19 (14.7%)	47 (20.4%)	88 (21.7%)	211 (17.2%)
Reason for termination									
Withdrawal of consent	5 (3.2%)	10 (6.5%)	11 (7.1%)	21 (6.8%)	26 (5.6%)	7 (5.4%)	19 (8.3%)	34 (8.4%)	86 (7.0%)
Lost to follow-up	3 (1.9%)	2 (1.3%)	2 (1.3%)	4 (1.3%)	7 (1.5%)	1 (0.8%)	6 (2.6%)	9 (2.2%)	23 (1.9%)
Death	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)	2 (0.2%)
Other	10 (6.4%)	6 (3.9%)	8 (5.2%)	14 (4.5%)	24 (5.2%)	11 (8.5%)	22 (9.6%)	43 (10.6%)	100 (8.1%)

[a] Subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study.
[b] Subjects who were in clinical response to placebo induction dosing and received placebo on entry into this maintenance study.

RE309:[P_SS_4_A_CC], 02FEB2012 9:05

(8) 参照元：C0524T18 Clinical Study Report Attachment 1.2

人口統計学的特性，ベースラインの疾患特性及び他の UC 治療薬（コルチコステロイド，免疫調整薬及びアミノサリチル酸）を併用していた被験者の割合は，ランダム割付けされた被験者のいずれの投与群でもおおむね同様であった。ランダム割付けされなかった被験者の結果では，性別で男性の割合，Mayo スコアが 11 又は 12 の重症の被験者の割合及び CRP の中央値が高いことを除きランダム割付けされた被験者の結果ともおおむね一致していた。

被験者の人口統計学的特性を表 2.7.6.4-2 に示す。

表 2.7.6.4-2 人口統計学的特性（全投与被験者）

	Randomized Subjects					Nonrandomized Subjects			
		Golimumab					Golimumab 100 mg		
	Placebo[a]	50 mg	100 mg	Combined	Total	Placebo[b]	Placebo Nonresponders (Induction)	Golimumab Nonresponders (Induction)	Total
Subjects enrolled	156	154	154	308	464	129	230	405	1228
Sex									
n	156	154	154	308	464	129	230	405	1228
Male	75 (48.1%)	77 (50.0%)	89 (57.8%)	166 (53.9%)	241 (51.9%)	61 (47.3%)	131 (57.0%)	267 (65.9%)	700 (57.0%)
Female	81 (51.9%)	77 (50.0%)	65 (42.2%)	142 (46.1%)	223 (48.1%)	68 (52.7%)	99 (43.0%)	138 (34.1%)	528 (43.0%)
p-value					0.194				
Race									
n	156	154	154	308	464	129	230	405	1228
Caucasian	137 (87.8%)	138 (89.6%)	130 (84.4%)	268 (87.0%)	405 (87.3%)	106 (82.2%)	181 (78.7%)	320 (79.0%)	1012 (82.4%)
Black	1 (0.6%)	2 (1.3%)	5 (3.2%)	7 (2.3%)	8 (1.7%)	6 (4.7%)	4 (1.7%)	7 (1.7%)	25 (2.0%)
Asian	12 (7.7%)	12 (7.8%)	14 (9.1%)	26 (8.4%)	38 (8.2%)	15 (11.6%)	37 (16.1%)	61 (15.1%)	151 (12.3%)
Other	6 (3.8%)	2 (1.3%)	5 (3.2%)	7 (2.3%)	13 (2.8%)	2 (1.6%)	8 (3.5%)	17 (4.2%)	40 (3.3%)
p-value					0.497				
Age (yrs)									
n	156	154	154	308	464	129	230	405	1228
Mean ± SD	40.2 ± 14.05	41.4 ± 13.84	39.1 ± 13.11	40.2 ± 13.51	40.2 ± 13.68	38.0 ± 13.27	40.3 ± 12.67	41.2 ± 13.60	40.3 ± 13.44
Median	38.0	41.0	37.0	39.0	39.0	35.0	39.5	40.0	39.0
IQ range	(29.0, 49.5)	(30.0, 53.0)	(28.0, 49.0)	(29.0, 50.5)	(29.0, 50.0)	(27.0, 49.0)	(30.0, 48.0)	(30.0, 51.0)	(29.0, 50.0)
Range	(18, 77)	(18, 79)	(18, 72)	(18, 79)	(18, 79)	(18, 72)	(19, 71)	(18, 78)	(18, 79)
p-value					0.330				

表 2.7.6.4-2 人口統計学的特性（全投与被験者）（続き）

	Randomized Subjects					Nonrandomized Subjects			
		Golimumab					Golimumab 100 mg		
	Placebo[a]	50 mg	100 mg	Combined	Total	Placebo[b]	Placebo Nonresponders (Induction)	Golimumab Nonresponders (Induction)	Total
Weight (kg)									
n	156	154	154	308	464	128	230	405	1227
Mean ± SD	72.18 ± 19.120	72.43 ± 17.571	74.18 ± 17.211	73.30 ± 17.386	72.93 ± 17.975	72.51 ± 19.195	72.74 ± 16.795	75.03 ± 18.605	73.54 ± 18.112
Median	70.00	71.75	72.15	72.05	71.95	70.95	71.00	74.00	72.00
IQ range	(57.15, 83.45)	(60.00, 81.80)	(62.10, 85.00)	(60.00, 83.95)	(59.55, 83.75)	(58.00, 83.25)	(60.00, 83.00)	(61.00, 85.50)	(60.00, 84.40)
Range	(40.0, 136.1)	(35.0, 137.0)	(37.4, 137.8)	(35.0, 137.8)	(35.0, 137.8)	(37.9, 133.6)	(40.0, 140.0)	(33.0, 150.0)	(33.0, 150.0)
p-value					0.568				
Height (cm)									
n	156	154	154	308	464	129	230	404	1227
Mean ± SD	169.8 ± 9.28	169.5 ± 9.19	171.3 ± 9.81	170.4 ± 9.53	170.2 ± 9.44	169.6 ± 10.28	170.7 ± 9.75	171.8 ± 10.16	170.8 ± 9.85
Median	170.0	170.0	171.0	170.0	170.0	168.0	170.0	172.0	170.0
IQ range	(163.0, 177.0)	(162.0, 176.0)	(163.0, 178.0)	(163.0, 178.0)	(163.0, 178.0)	(163.0, 177.0)	(164.0, 178.0)	(165.0, 178.0)	(164.0, 178.0)
Range	(147, 193)	(150, 196)	(149, 194)	(149, 196)	(147, 196)	(145, 194)	(142, 196)	(136, 205)	(136, 205)
p-value					0.212				

[a] Subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study.
[b] Subjects who were in clinical response to placebo induction dosing and received placebo on entry into this maintenance study.

RE309:[P DEM 49 A CC], 29NOV2011 17:35

参照元：C0524T18 Clinical Study Report Attachment 1.8

ランダム割付けされた被験者のうち 37.1%（172/464 例）が用量調整の対象となり，以下のように投与された。

・ プラセボ群では 48.7%（76/156 例）が用量調整の対象となった。
  － すべての被験者がゴリムマブ 100 mg へ増量した。
・ 50 mg 群では 34.4%（53/154 例）が用量調整の対象となった。
  － 28 例がゴリムマブ 50 mg を継続した。
  － 25 例が 100 mg へ増量した。
・ 100 mg 群では 27.9%（43/154 例）が用量調整の対象となった。
  － 29 例が 100 mg を継続した。
  － 14 例が 200 mg へ増量した。200 mg へ増量した 14 例のうち，治験実施計画書 改訂 3 版の発行時点で 200 mg を投与されていた 3 例では，計画の変更に伴い 100 mg へ減量した。

プラセボ寛解導入 responder のうち 55 例では，試験期間中に clinical response が消失し，ゴリムマブ 100 mg が投与された。

薬物動態及び免疫原性

・ ランダム割付けされた被験者では，ゴリムマブ 50 mg 又は 100 mg の 4 週ごとの皮下投与による寛解維持療法において，約 8 週で定常状態に到達した。8 週以降，定常状態時の血清中ゴリムマブのトラフ濃度の中央値は 50 mg 群で 0.69～0.83 μg/mL，100 mg 群で 1.33～1.58 μg/mL であった。
・ ランダム割付けされた被験者では，ゴリムマブ 50 mg 又は 100 mg の 4 週ごとの皮下投与による寛解維持療法において，54 週までの血清中ゴリムマブ濃度は，ほぼすべての被験者で定量可能であり用量に比例していた。20 週から 44 週の投与前に血清中ゴリムマブ濃度が定量限界未満であった被験者の割合は，100 mg 群［0.9%（1/106 例）～2.2%（2/90 例）］の方が 50 mg 群［1.1%（1/92 例）～11.2%（11/98 例）］と比べ低かった。
・ 寛解導入療法が皮下投与（T17 試験）又は静脈内投与（T16 試験）のいずれの場合も，血清中ゴリムマブ濃度は，寛解維持療法の投与開始後約 8 週で定常状態に到達し，定常状態到達までの期間は同程度であった。
・ 寛解導入療法が皮下投与又は静脈内投与のいずれの場合も，100 mg 群では，寛解導入療法時の用量によらず，皮下投与による寛解維持療法後 8 週の血清中ゴリムマブ濃度は同程度であった。50 mg 群では，寛解導入療法が皮下投与の場合，寛解導入療法時の用量によらず，皮下投与による寛解維持療法後 8 週の血清中ゴリムマブ濃度は同程度であったが，静脈内投与の場合，2 mg/kg 群の値は，1 mg/kg 及び 4 mg/kg 群と比較して高かった。

・ ランダム割付けされた被験者では，いずれの投与群でも体重別の血清中ゴリムマブ濃度の中央値は 75 kg 未満の被験者で 75 kg 以上の被験者と比べやや高かった。

・ ゴリムマブを投与され抗ゴリムマブ抗体評価用の検体が適切に得られた 1103 例のうち，54 週までに抗ゴリムマブ抗体が陽性であった被験者は 32/1103 例（2.9%）であり，その大半で抗体価は低かった（< 1:640）。抗ゴリムマブ抗体が陽性であり中和抗体評価用の検体が適切に得られた被験者 31 例のうち，21/31 例（67.7%）が中和抗体陽性であった。

・ ゴリムマブを増量しなかった被験者における抗ゴリムマブ抗体が陽性の被験者の割合は 50 mg を投与された被験者［1.6%（2/127 例）］及び 100 mg を投与された被験者［2.1%（15/726 例）］で同程度であった。ゴリムマブを増量した被験者のうち，100 mg から 200 mg へ増量した被験者では，抗ゴリムマブ抗体が陽性の被験者はいなかったが，50 mg から 100 mg へ増量した被験者における抗ゴリムマブ抗体が陽性の被験者の割合は 8%（2/25 例）であった。

・ 抗ゴリムマブ抗体が陽性の被験者の血清中ゴリムマブ濃度の中央値は，抗ゴリムマブ抗体が陰性の被験者と比べ低かった。しかしながら，抗ゴリムマブ抗体が陽性の被験者数は限られていたため，解釈には注意が必要である。

有効性

主要解析対象集団を対象に実施した有効性の解析結果を以下に示す。

主要評価項目は 54 週までの clinical response とした。54 週まで clinical response が維持された被験者の割合は，100 mg 群及び 50 mg 群［それぞれ 49.7%（75/151 例）及び 47.0%（71/151 例）］でプラセボ群［31.2%（48/154 例）］と比較し高く，100 mg 群及び 50 mg 群のプラセボ群に対する統計学的に有意な差が認められた（それぞれ p<0.001 及び p=0.010）。本試験では 100 mg 群のプラセボ群に対する統計学的な有意差が示され，本剤の有効性が確認された。人口統計学的特性，UC 疾患特性，併用 UC 治療薬，UC に関する病歴など被験者背景で層別した部分集団解析では，100 mg 群及び 50 mg 群のプラセボ群に対する効果は主要解析対象集団の結果とおおむね同様であった。主要評価項目の解析結果について，事前に設定された感度分析で頑健性が示された。すなわち，感度分析でも 54 週まで clinical response の維持に 100 mg 群及び 50 mg 群のプラセボ群に対する統計学的に有意な差が認められた（100 mg 群対プラセボ群ではいずれも p<0.010，50 mg 群対プラセボ群ではいずれも p<0.050）。

主な副次評価項目の結果を以下に示す。

・ 30 週及び 54 週ともに clinical remission が認められた被験者の割合は 100 mg 群及び 50 mg 群［それぞれ 27.8%（42/151 例）及び 23.2%（35/151 例）］でプラセボ群［15.6%（24/154 例）］と比較し高く，100 mg 群のプラセボ群に対する統計学的に有意な差が認められた（p=0.004）。

・ 30 週及び 54 週ともに mucosal healing が認められた被験者の割合は 100 mg 群及び 50 mg 群［それぞれ 42.4%（64/151 例）及び 41.7%（63/151 例）］でプラセボ群［26.6%（41/154 例）］と比較し高く，100 mg 群のプラセボ群に対する統計学的に有意な差が認められた（p=0.002）。

・ 約 35%（160/456 例）の被験者が寛解維持試験の 0 週に clinical remission が認められた。このうち 30 週及び 54 週に clinical remission が認められた被験者の割合は 100 mg 群及び 50 mg 群［それぞれ 38.9%（21/54 例）及び 36.5%（19/52 例）］でプラセボ群［24.1%（13/54 例）］と比較し高かった。

・ 約 54%（247/456 例）の被験者が寛解維持試験の 0 週にコルチコステロイドを併用していた。このうち 54 週に clinical remission が認められたが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［23.2%（19/82 例）］ではプラセボ群［18.4%（16/87 例）］と同程度であったが，50 mg 群［28.2%（22/78 例）］はプラセボ群［18.4%（16/87 例）］と比較し高かった。

その他の臨床効果及びバイオマーカーの結果を以下に示す。なお，以下に示す他の副次評価項目の解析では多重性を調整せず，nominal p 値に基づき記載した。

・ 事後解析で，clinical remission が消失するまでの時間は 100 mg 群及び 50 mg 群でプラセボ群と比較し長かった（プラセボ群に対し 100 mg 群及び 50 mg 群で p=0.017 及び p=0.207）。

・ 30 週まで clinical remission を維持した被験者の割合は，100 mg 群及び 50 mg 群［53.7%（29/54 例）及び 53.8%（28/52 例）］でプラセボ群［33.3%（18/54 例）］と比較し高く，100 mg 群において統計学的に有意な差が認められた（プラセボ群に対し 100 mg 群で p=0.037）。

・ 30 週及び 54 週ともに mucosal healing を維持した被験者の割合は，100 mg 群及び 50 mg 群［44.6%（50/112 例）及び 45.8%（54/118 例）］でプラセボ群［31.1%（33/106 例）］と比較し高く，100 mg 群において統計学的に有意な差が認められた（プラセボ群に対し 100 mg 群で p=0.037）。

・ 寛解維持試験の 0 週に減少していた Mayo スコアは，30 週又は 54 週において 100 mg 群及び 50 mg 群でプラセボ群と比較し減少が維持された。

・ 寛解維持試験の 0 週に減少していた partial Mayo スコアは，54 週において 100 mg 群及び 50 mg 群でプラセボ群と比較し減少が維持された。

・ 寛解維持試験の 0 週に減少していた CPR 濃度は，100 mg 群でプラセボ群と比較し減少が維持された。50 mg 群では同様の傾向はみられなかった。

・ 寛解維持試験の 0 週に減少していた糞便中ラクトフェリン濃度及び糞便中カルプロテクチン濃度（対数変換値）は，30 週及び 54 週において 100 mg 群でプラセボ群と比較し減少が維持された。50 mg 群では同様の傾向はみられなかった。

患者報告アウトカム（健康に関する QOL）の結果を以下に示す。なお，これらの解析では多重性を調整せず，nominal p 値に基づき記載した。

・ 寛解維持試験の 0 週の IBDQ が寛解導入試験の 0 週から 20 ポイント超改善していた被験者のうち，54 週までその改善が維持された被験者の割合は 100 mg 群［40.0%（46/115 例）］及び 50 mg 群［44.5%（57/128 例）］でプラセボ群［27.8%（30/108 例）］と比較し高く，

50 mg 群において統計学的に有意な差が認められた（プラセボ群に対し 50 mg 群で p=0.026，100 mg 群で p=0.051）。

・ 寛解維持試験の 0 週の SF-36 は，身体的側面の QOL サマリースコアが 100 mg 群及び 50 mg 群で 54 週まで維持された。

・ 寛解維持試験の 0 週の EQ-5D スコア及び EQ VAS（Visual Analogue Scale）は，100 mg 群及び 50 mg 群で 54 週まで維持された。

有効性と薬物動態及び抗ゴリムマブ抗体の関係について以下に示す。

・ いずれかのゴリムマブ群にランダム割付けされた被験者では，血清中ゴリムマブ濃度の上昇と，54 週までの clinical response の維持並びに 30 週及び 54 週の clinical remission の維持に関連性が認められた。

・ いずれかのゴリムマブ群にランダム割付けされた被験者では，抗ゴリムマブ抗体が陽性であった被験者の clinical response は，抗ゴリムマブ抗体が陰性であった被験者と比較して見かけ上低い傾向が認められた。しかしながら，抗ゴリムマブ抗体が陽性の被験者数は限られていたため，明確な結論には至らなかった。

安全性

54 週までのゴリムマブ 50 mg 又は 100 mg の 4 週ごとの皮下投与による寛解維持療法では，おおむね良好な忍容性が認められた。

ランダム割付けされた被験者：

・ 有害事象を発現した被験者の割合は，いずれのゴリムマブ群でも同様であったが，プラセボ群と比較してやや高かった。しかしながら，試験デザインが randomized withdrawn であることから，プラセボ群の追跡期間は顕著に短かった。被験者の追跡期間 100 人年あたりの有害事象の発現割合はいずれの投与群でもおおむね同様であると考えられた。

・ 治験担当医師により感染症と判断された有害事象及び重篤な有害事象，治験薬の投与中止に至った有害事象の発現割合についても同様の傾向が認められた。

・ 重篤な有害事象が認められた被験者の割合は，プラセボ群及び 50 mg 群と比較し 100 mg 群で高かったが，被験者の追跡期間で補正すると特筆すべき差ではなかった。

・ 各投与群で最も高頻度に認められた重篤な有害事象は UC であり，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。

・ 体重別では，75 kg 未満の被験者と 75 kg 以上の被験者で，ゴリムマブの安全性プロファイルはおおむね一致していた。

ランダム割付けされなかった被験者：

・ 全投与被験者で認められた UC に関する有害事象の大部分はランダム割付けされなかった被験者が占めていた。

全投与被験者：

・ 全投与被験者での安全性プロファイルはランダム割付けされた被験者と同様であった。

- 死亡は 54 週までに 3 例認められ，すべてゴリムマブ 100 mg を投与された被験者であった。その 3 例の内訳は，1 例が栄養障害及び敗血症性ショック，1 例が心不全（被験者は血栓症の既往があった），1 例が播種性結核（被験者は潜伏結核を認めており，イソニアジドの治療を受けていた）であった。このうち，播種性結核の 1 例はゴリムマブの使用と関連性のある死亡であった。
- 悪性腫瘍は 54 週までにゴリムマブ 100 mg を投与された被験者の 3 例に認められた。3 例のうち，直腸癌及び甲状腺癌の各 1 例は，寛解導入試験のプラセボ投与中にその徴候を示していた。肺腺癌の 1 例は，寛解維持療法でゴリムマブ 100 mg を投与された被験者であったが 40 年の喫煙歴があり慢性閉塞性肺疾患（COPD）を合併していた。更に，寛解導入療法及び維持療法のいずれでもプラセボのみの投与であった被験者の 1 例に乳癌が認められた。
- 結核は 54 週までに 4 例に認められ，すべてゴリムマブを投与された被験者であった（うち 1 例は寛解維持試験ではプラセボのみの投与）。4 例のうち 3 例は播種性結核であり，いずれも重篤で，ゴリムマブ 100 mg を投与された被験者の 2 例（うち 1 例が死亡），プラセボを投与された被験者の 1 例に認められた。残りの 1 例の結核はゴリムマブ 100 mg を投与された被験者であり，重篤ではなかった。
- 重篤な日和見感染症は 54 週までにゴリムマブを投与された被験者の 2 例に認められた。その 2 例の内訳は，サイトメガロウイルス感染（寛解維持試験ではプラセボのみの投与），ノカルジア感染により悪化した脳腫瘍であった。
- 脱髄はゴリムマブを投与された被験者の 1 例に認められた。
- ゴリムマブによる注射部位反応を認めた被験者の割合は低く，重症度は軽度又は中等度であり，重篤な事象は認められなかった。遅発性の 4 型過敏症が 1 例に認められたが，重篤ではなく重症度は中等度であった。
- 抗ゴリムマブ抗体の発現と注射部位反応に関連性はなかった。
- 血液学的検査及び血液生化学検査の顕著な異常変動はほとんど認められず，用量にかかわらず特筆すべき差は認められなかった。

試験の限界（Study limitations）

発現割合の低い有害事象に関して，各用量を投与された被験者数の総数に不均衡（ゴリムマブ 100 mg を投与された被験者数と 50 mg を投与された被験者数の比はおよそ 6:1，ゴリムマブ 100 mg を投与された被験者数とプラセボ群の被験者数の比はおよそ 3:1）が生じていることにより，寛解維持試験での安全性の評価は限定された。更に，ゴリムマブ 100 mg を投与された被験者には，ゴリムマブ寛解導入 responder で 100 mg 群にランダム割付けされた被験者（154 例），プラセボ寛解導入 non-responder でゴリムマブ 100 mg を投与された被験者（230 例），ゴリムマブ寛解導入 non-responder でゴリムマブ 100 mg を投与された被験者（405 例）及び clinical response が消失しゴリムマブ 100 mg を投与された被験者（157 例）が含まれることから，多様性に富んでおり，全投与被験者の安全性の評価が複雑になった。対照的に，ゴリムマブ 50 mg 群はゴリムマブ寛解導入 responder で 50 mg 群にランダム割付けされた被験者（154 例）のみであり，プラセボ群はプラセボ寛解導入 responder でありプラセボを継続して投与された被験者（129 例）

及びゴリムマブ寛解導入 responder でプラセボ群にランダム割付けされた被験者（156 例）であった。

結論

- ゴリムマブ 100 mg 又は 50 mg を 4 週ごとに皮下投与する寛解維持療法では，寛解導入療法で clinical response が認められた後も UC の疾患活動性の改善が維持された。ゴリムマブ 100 mg の 4 週ごと投与の臨床的有効性は，clinical remission 及び mucosal healing の長期維持を含む副次的な有効性の評価において，50 mg の 4 週ごと投与と比べてより一貫して認められた。
- ゴリムマブを 4 週ごとに皮下投与する寛解維持療法では，ゴリムマブの薬物動態特性はこれまでの試験結果と同様，血清中ゴリムマブ濃度の用量比例性がみられた。高用量の血清中ゴリムマブの曝露量は，54 週までの clinical response の維持，clinical remission の長期維持につながると考えられた。
- 中等症から重症の活動期 UC 成人患者に対する安全性プロファイルは，本剤の他の適応症及び他の抗 TNF（tumor necrosis factor）薬と同様であった。本試験の有効性及び安全性の結果は，寛解導入療法でゴリムマブにより clinical response が認められた中等症から重症の活動期 UC 成人患者に対する，ゴリムマブの皮下投与による寛解維持療法の良好なベネフィット・リスクプロファイルを支持するものであった。

表 2.7.6.4-3 すべての有害事象（ランダム割付けされた被験者，54 週）

SOC PT	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]
Treated subjects who were randomized	156	154	154	308	76	25	14	384
Avg duration of follow-up (weeks)	32.7	44.3	46.3	45.3	32.1	25.9	27.5	45.4
Avg exposure (number of administrations)	8.2	11.1	11.3	11.2	7.6	5.5	6.9	11.1
Subjects with 1 or more adverse events	103 (66.0%)	112 (72.7%)	113 (73.4%)	225 (73.1%)	54 (71.1%)	16 (64.0%)	9 (64.3%)	285 (74.2%)
胃腸障害	50 (32.1%)	50 (32.5%)	57 (37.0%)	107 (34.7%)	36 (47.4%)	8 (32.0%)	4 (28.6%)	151 (39.3%)
潰瘍性大腸炎	29 (18.6%)	27 (17.5%)	24 (15.6%)	51 (16.6%)	13 (17.1%)	4 (16.0%)	1 (7.1%)	69 (18.0%)
腹痛	4 (2.6%)	11 (7.1%)	11 (7.1%)	22 (7.1%)	3 (3.9%)	2 (8.0%)	0 (0.0%)	26 (6.8%)
悪心	3 (1.9%)	7 (4.5%)	7 (4.5%)	14 (4.5%)	1 (1.3%)	2 (8.0%)	1 (7.1%)	18 (4.7%)
下痢	7 (4.5%)	4 (2.6%)	5 (3.2%)	9 (2.9%)	4 (5.3%)	2 (8.0%)	1 (7.1%)	15 (3.9%)
痔核	2 (1.3%)	3 (1.9%)	3 (1.9%)	6 (1.9%)	2 (2.6%)	1 (4.0%)	1 (7.1%)	10 (2.6%)
上腹部痛	1 (0.6%)	4 (2.6%)	1 (0.6%)	5 (1.6%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	6 (1.6%)
便秘	1 (0.6%)	2 (1.3%)	3 (1.9%)	5 (1.6%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	6 (1.6%)
消化不良	2 (1.3%)	3 (1.9%)	2 (1.3%)	5 (1.6%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	6 (1.6%)
血便排泄	2 (1.3%)	1 (0.6%)	5 (3.2%)	6 (1.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (1.6%)
嘔吐	5 (3.2%)	2 (1.3%)	2 (1.3%)	4 (1.3%)	1 (1.3%)	1 (4.0%)	0 (0.0%)	6 (1.6%)
裂肛	0 (0.0%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	5 (1.3%)
腹部不快感	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	4 (1.0%)
下腹部痛	1 (0.6%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	4 (1.0%)
胃食道逆流性疾患	1 (0.6%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	4 (1.0%)
腹部膨満	2 (1.3%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
排便回数増加	2 (1.3%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	1 (4.0%)	0 (0.0%)	3 (0.8%)
アフタ性口内炎	1 (0.6%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
結腸ポリープ	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
便意切迫	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
血性下痢	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
胃炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
直腸炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
偽性ポリポーシス	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
直腸ポリープ	1 (0.6%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
歯痛	1 (0.6%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
腹部ヘルニア	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.3%)

表 2.7.6.4-3 すべての有害事象（ランダム割付けされた被験者，54 週）（続き）

SOC PT	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]
肛門の炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
口唇炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
結腸狭窄	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
齲歯	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
小腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
食中毒	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
歯肉炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
痔出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
鼠径ヘルニア	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
食道浮腫	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
口腔内痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
排便痛	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
膵炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
直腸出血	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
歯の知覚過敏	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
腹部硬直	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
大腸炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
鼓腸	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
胃腸の炎症	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
粘液便	1 (0.6%)	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	40 (25.6%)	57 (37.0%)	61 (39.6%)	118 (38.3%)	25 (32.9%)	10 (40.0%)	5 (35.7%)	151 (39.3%)
鼻咽頭炎	11 (7.1%)	14 (9.1%)	21 (13.6%)	35 (11.4%)	7 (9.2%)	4 (16.0%)	3 (21.4%)	46 (12.0%)
上気道感染	4 (2.6%)	8 (5.2%)	9 (5.8%)	17 (5.5%)	6 (7.9%)	3 (12.0%)	1 (7.1%)	26 (6.8%)
咽頭炎	4 (2.6%)	8 (5.2%)	5 (3.2%)	13 (4.2%)	2 (2.6%)	0 (0.0%)	1 (7.1%)	16 (4.2%)
副鼻腔炎	3 (1.9%)	6 (3.9%)	7 (4.5%)	13 (4.2%)	1 (1.3%)	1 (4.0%)	0 (0.0%)	15 (3.9%)
インフルエンザ	5 (3.2%)	7 (4.5%)	2 (1.3%)	9 (2.9%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	10 (2.6%)
気管支炎	3 (1.9%)	6 (3.9%)	1 (0.6%)	7 (2.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	8 (2.1%)
胃腸炎	2 (1.3%)	2 (1.3%)	4 (2.6%)	6 (1.9%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	8 (2.1%)
尿路感染	4 (2.6%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	2 (2.6%)	0 (0.0%)	1 (7.1%)	6 (1.6%)
口腔ヘルペス	3 (1.9%)	2 (1.3%)	2 (1.3%)	4 (1.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	5 (1.3%)
外陰腟真菌感染	1 (0.6%)	3 (1.9%)	1 (0.6%)	4 (1.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	5 (1.3%)
レンサ球菌性咽頭炎	0 (0.0%)	1 (0.6%)	3 (1.9%)	4 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (1.0%)
ウイルス感染	0 (0.0%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	0 (0.0%)	1 (4.0%)	0 (0.0%)	4 (1.0%)
虫垂炎	0 (0.0%)	0 (0.0%)	3 (1.9%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.8%)

表 2.7.6.4-3 すべての有害事象（ランダム割付けされた被験者，54 週）（続き）

SOC PT	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]
膀胱炎	1 (0.6%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
真菌感染	0 (0.0%)	0 (0.0%)	3 (1.9%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
単純ヘルペス	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
肺炎	2 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
歯膿瘍	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	2 (8.0%)	0 (0.0%)	3 (0.8%)
創傷感染	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	1 (4.0%)	0 (0.0%)	3 (0.8%)
急性扁桃炎	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
肛門膿瘍	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
せつ	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
ウイルス性胃腸炎	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
麦粒腫	1 (0.6%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
喉頭炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
爪真菌症	1 (0.6%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
外耳炎	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
気道感染	1 (0.6%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
鼻炎	2 (1.3%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
皮膚感染	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
ブドウ球菌感染	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
癜風	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
扁桃炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
気管炎	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
ウイルス性咽頭炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	1 (7.1%)	2 (0.5%)
膿瘍	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
急性副鼻腔炎	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
ボレリア感染	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
カンジダ症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
慢性副鼻腔炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
クロストリジウム感染	2 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
感染性皮膚炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
憩室炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
感染性小腸結腸炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
丹毒	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
紅色陰癬	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
ブドウ球菌性眼感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)

表 2.7.6.4-3 すべての有害事象（ランダム割付けされた被験者，54 週）（続き）

SOC PT	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]
ロタウイルス胃腸炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
消化管感染	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
ウイルス性消化管感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
ジアルジア症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
帯状疱疹	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
限局性感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
ライム病	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
爪感染	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
口腔真菌感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
中耳炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
爪囲炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
膿疱性皮疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
ウイルス性気道感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
皮膚細菌感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
白癬感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
足部白癬	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
歯感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
結核	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
ウイルス性上気道感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.3%)
外陰部腟カンジダ症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
腹壁膿瘍	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
肛門性器疣贅	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
細菌感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
脳膿瘍	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
蜂巣炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
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%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
サイトメガロウイルス感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
播種性結核	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
耳感染	2 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
毛包炎	3 (1.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
下気道感染	2 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
原発性異型肺炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

表 2.7.6.4-3 すべての有害事象（ランダム割付けされた被験者，54 週）（続き）

SOC PT	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]
皮下組織膿瘍	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
尿道炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ワクチン接種部位感染	1 (0.6%)	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	23 (14.7%)	22 (14.3%)	31 (20.1%)	53 (17.2%)	11 (14.5%)	3 (12.0%)	3 (21.4%)	69 (18.0%)
発疹	3 (1.9%)	9 (5.8%)	7 (4.5%)	16 (5.2%)	1 (1.3%)	0 (0.0%)	1 (7.1%)	18 (4.7%)
そう痒症	2 (1.3%)	1 (0.6%)	4 (2.6%)	5 (1.6%)	2 (2.6%)	1 (4.0%)	0 (0.0%)	8 (2.1%)
皮膚乾燥	0 (0.0%)	3 (1.9%)	2 (1.3%)	5 (1.6%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	6 (1.6%)
脱毛症	3 (1.9%)	0 (0.0%)	4 (2.6%)	4 (1.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	5 (1.3%)
ざ瘡	2 (1.3%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	4 (1.0%)
皮膚炎	3 (1.9%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	1 (1.3%)	1 (4.0%)	0 (0.0%)	4 (1.0%)
アレルギー性皮膚炎	5 (3.2%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	1 (4.0%)	1 (7.1%)	4 (1.0%)
湿疹	3 (1.9%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	1 (1.3%)	0 (0.0%)	1 (7.1%)	4 (1.0%)
紅斑	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
滴状乾癬	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
汗腺炎	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
酒さ	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
皮膚病変	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
日光性角化症	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
接触性皮膚炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
結節性紅斑	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
多汗症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
顔面感覚鈍麻	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
内出血発生の増加傾向	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
嵌入爪	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
脂肪肥大症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
寝汗	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
光線性皮膚症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
痒疹	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
乾癬	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
膿疱性乾癬	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
全身性皮疹	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
斑状皮疹	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
そう痒性皮疹	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
瘢痕	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)

表 2.7.6.4-3 すべての有害事象（ランダム割付けされた被験者，54 週）（続き）

SOC PT	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]
脂漏性皮膚炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
皮膚灼熱感	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
皮膚剥脱	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
皮膚色素減少	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
皮膚刺激	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
蕁麻疹	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
水疱	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
アトピー性皮膚炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
乾癬様皮膚炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
皮脂欠乏性湿疹	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
斑	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
斑状丘疹状皮疹	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
皮膚亀裂	1 (0.6%)	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	27 (17.3%)	23 (14.9%)	25 (16.2%)	48 (15.6%)	11 (14.5%)	0 (0.0%)	3 (21.4%)	62 (16.1%)
関節痛	12 (7.7%)	11 (7.1%)	8 (5.2%)	19 (6.2%)	7 (9.2%)	0 (0.0%)	1 (7.1%)	27 (7.0%)
背部痛	5 (3.2%)	3 (1.9%)	7 (4.5%)	10 (3.2%)	1 (1.3%)	0 (0.0%)	1 (7.1%)	12 (3.1%)
筋肉痛	3 (1.9%)	4 (2.6%)	1 (0.6%)	5 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (1.3%)
四肢痛	4 (2.6%)	3 (1.9%)	1 (0.6%)	4 (1.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	5 (1.3%)
筋骨格痛	3 (1.9%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
変形性関節症	0 (0.0%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
関節炎	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
椎間板突出	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
筋骨格系胸痛	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
骨痛	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
外骨腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
線維筋痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
凧径部痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
関節腫脹	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
筋痙縮	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
頚部痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
重感	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
変形性脊椎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.3%)
脊椎炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
滑液嚢腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)

表 2.7.6.4-3 すべての有害事象（ランダム割付けされた被験者，54 週）（続き）

SOC PT	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]
腱痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
腱鞘炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
筋力低下	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
骨粗鬆症	1 (0.6%)	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	16 (10.3%)	18 (11.7%)	23 (14.9%)	41 (13.3%)	8 (10.5%)	4 (16.0%)	4 (28.6%)	54 (14.1%)
発熱	7 (4.5%)	6 (3.9%)	3 (1.9%)	9 (2.9%)	2 (2.6%)	4 (16.0%)	0 (0.0%)	14 (3.6%)
疲労	3 (1.9%)	4 (2.6%)	6 (3.9%)	10 (3.2%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	12 (3.1%)
注射部位紅斑	1 (0.6%)	1 (0.6%)	4 (2.6%)	5 (1.6%)	3 (3.9%)	0 (0.0%)	1 (7.1%)	8 (2.1%)
末梢性浮腫	1 (0.6%)	3 (1.9%)	4 (2.6%)	7 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (1.8%)
無力症	2 (1.3%)	2 (1.3%)	2 (1.3%)	4 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (1.0%)
胸痛	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	3 (0.8%)
インフルエンザ様疾患	0 (0.0%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
注射部位発疹	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	3 (0.8%)
悪寒	1 (0.6%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
注射部位血腫	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
浮腫	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
投与部位発疹	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
投与部位反応	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
顔面浮腫	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
体温変動感	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
注入部位反応	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
注射部位硬結	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.3%)
注射部位そう痒感	2 (1.3%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
注射部位腫脹	2 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
倦怠感	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
微石症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
疼痛	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
注入部位静脈炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
注射部位疼痛	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
非心臓性胸痛	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
口渇	1 (0.6%)	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	25 (16.0%)	15 (9.7%)	20 (13.0%)	35 (11.4%)	13 (17.1%)	2 (8.0%)	1 (7.1%)	51 (13.3%)
頭痛	14 (9.0%)	12 (7.8%)	12 (7.8%)	24 (7.8%)	8 (10.5%)	2 (8.0%)	1 (7.1%)	35 (9.1%)

表 2.7.6.4-3 すべての有害事象（ランダム割付けされた被験者，54 週）（続き）

SOC PT	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]
浮動性めまい	4 (2.6%)	0 (0.0%)	5 (3.2%)	5 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (1.3%)
片頭痛	1 (0.6%)	3 (1.9%)	0 (0.0%)	3 (1.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	4 (1.0%)
振戦	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
手根管症候群	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
痙攣	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
味覚異常	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
顔面不全麻痺	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
感覚鈍麻	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
筋緊張低下	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
嗜眠	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
錯感覚	3 (1.9%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
坐骨神経痛	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
副鼻腔炎に伴う頭痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
失神	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
脱髄	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
神経圧迫	1 (0.6%)	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	11 (7.1%)	15 (9.7%)	18 (11.7%)	33 (10.7%)	2 (2.6%)	1 (4.0%)	2 (14.3%)	38 (9.9%)
咳嗽	5 (3.2%)	5 (3.2%)	9 (5.8%)	14 (4.5%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	15 (3.9%)
口腔咽頭痛	1 (0.6%)	2 (1.3%)	6 (3.9%)	8 (2.6%)	0 (0.0%)	1 (4.0%)	0 (0.0%)	9 (2.3%)
気道うっ血	0 (0.0%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
鼻漏	0 (0.0%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
呼吸困難	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
鼻閉	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	2 (0.5%)
息詰まり感	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
労作性呼吸困難	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
喀血	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
肺浸潤	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
呼吸時疼痛	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
湿性咳嗽	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
アレルギー性鼻炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
季節性鼻炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
副鼻腔うっ血	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
くしゃみ	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
上気道うっ血	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.3%)

表 2.7.6.4-3 すべての有害事象（ランダム割付けされた被験者，54 週）（続き）

SOC PT	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]
上気道の炎症	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
喘鳴	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
アレルギー性咳嗽	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
鼻出血	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
呼吸障害	1 (0.6%)	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	8 (5.1%)	18 (11.7%)	13 (8.4%)	31 (10.1%)	5 (6.6%)	0 (0.0%)	1 (7.1%)	37 (9.6%)
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%)	2 (1.3%)	7 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (1.8%)
アラニン・アミノトランスフェラーゼ増加	1 (0.6%)	3 (1.9%)	3 (1.9%)	6 (1.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (1.6%)
ヘモグロビン減少	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
肝酵素上昇	3 (1.9%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
白血球数増加	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	3 (0.8%)
好酸球数増加	1 (0.6%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
ヘマトクリット減少	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
好中球数増加	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	2 (0.5%)
血小板数増加	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
白血球数減少	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
血中ビリルビン増加	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
血中カルシウム減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
血中カルシウム増加	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
血中クレアチニン増加	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
血中カリウム減少	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
血圧上昇	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
収縮期血圧上昇	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
血中尿素増加	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
体温上昇	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
胸部X線異常	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
肝機能検査異常	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
単球数減少	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
好中球数減少	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
血小板数減少	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
総蛋白減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
トランスアミナーゼ上昇	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)

表 2.7.6.4-3 すべての有害事象（ランダム割付けされた被験者，54 週）（続き）

SOC PT	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]
体重減少	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
体重増加	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
血中テストステロン減少	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
尿中白血球陽性	1 (0.6%)	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	10 (6.4%)	11 (7.1%)	12 (7.8%)	23 (7.5%)	2 (2.6%)	4 (16.0%)	0 (0.0%)	29 (7.6%)
貧血	1 (0.6%)	4 (2.6%)	5 (3.2%)	9 (2.9%)	2 (2.6%)	2 (8.0%)	0 (0.0%)	13 (3.4%)
白血球減少症	2 (1.3%)	2 (1.3%)	5 (3.2%)	7 (2.3%)	0 (0.0%)	2 (8.0%)	0 (0.0%)	9 (2.3%)
好酸球増加症	1 (0.6%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
白血球増加症	1 (0.6%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
リンパ節症	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
好中球増加症	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
リンパ節痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
リンパ球増加症	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
リンパ球減少症	2 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
単球減少症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
血小板減少症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
血小板増加症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
二血球減少症	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
好中球減少症	1 (0.6%)	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	8 (5.1%)	6 (3.9%)	10 (6.5%)	16 (5.2%)	3 (3.9%)	0 (0.0%)	1 (7.1%)	20 (5.2%)
挫傷	2 (1.3%)	2 (1.3%)	2 (1.3%)	4 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (1.0%)
手骨折	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	2 (0.5%)
関節脱臼	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
肉離れ	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
足関節部骨折	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
節足動物咬傷	2 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
第２度熱傷	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
上顎炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
足骨折	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
裂傷	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
口唇損傷	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
処置による疼痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
橈骨骨折	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
肋骨骨折	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)

表 2.7.6.4-3 すべての有害事象（ランダム割付けされた被験者，54 週）（続き）

SOC PT	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]
脊椎圧迫骨折	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
腱損傷	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
偶発的過量投与	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
節足動物刺傷	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
擦過傷	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
筋損傷	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
処置後合併症	1 (0.6%)	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	4 (2.6%)	6 (3.9%)	11 (7.1%)	17 (5.5%)	2 (2.6%)	0 (0.0%)	1 (7.1%)	20 (5.2%)
うつ病	1 (0.6%)	3 (1.9%)	3 (1.9%)	6 (1.9%)	1 (1.3%)	0 (0.0%)	1 (7.1%)	8 (2.1%)
不安	1 (0.6%)	2 (1.3%)	2 (1.3%)	4 (1.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	5 (1.3%)
不眠症	2 (1.3%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
抑うつ気分	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
神経過敏	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
落ち着きのなさ	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
睡眠障害	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
社会恐怖症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
物質乱用	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
眼障害	4 (2.6%)	6 (3.9%)	5 (3.2%)	11 (3.6%)	1 (1.3%)	1 (4.0%)	1 (7.1%)	14 (3.6%)
結膜炎	1 (0.6%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	1 (4.0%)	1 (7.1%)	4 (1.0%)
白内障	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
加齢黄斑変性	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
複視	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
眼の炎症	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
眼刺激	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
眼部腫脹	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
眼瞼障害	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
眼瞼そう痒症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
眼充血	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
翼状片	1 (0.6%)	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	2 (1.3%)	7 (4.5%)	3 (1.9%)	10 (3.2%)	2 (2.6%)	1 (4.0%)	1 (7.1%)	13 (3.4%)
精巣上体炎	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
バルトリン嚢腫	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (4.0%)	0 (0.0%)	1 (0.3%)
良性前立腺肥大症	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
乳房嚢胞	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)

表 2.7.6.4-3 すべての有害事象（ランダム割付けされた被験者，54 週）（続き）

SOC PT	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]
乳房腫瘤	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
子宮頚部嚢胞	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
子宮頚部出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.3%)
膀胱瘤	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
月経困難症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
月経過多	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
不正子宮出血	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
前立腺炎	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
前立腺腫大	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
精巣痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
子宮ポリープ	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
腟分泌物	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
代謝および栄養障害	1 (0.6%)	4 (2.6%)	4 (2.6%)	8 (2.6%)	1 (1.3%)	1 (4.0%)	0 (0.0%)	10 (2.6%)
脱水	1 (0.6%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	1 (1.3%)	1 (4.0%)	0 (0.0%)	5 (1.3%)
食欲減退	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
糖尿病	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
痛風	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
高カルシウム血症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
低カリウム血症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
耳および迷路障害	2 (1.3%)	4 (2.6%)	3 (1.9%)	7 (2.3%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	8 (2.1%)
耳痛	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	2 (0.5%)
回転性めまい	2 (1.3%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
耳管機能障害	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
乗物酔い	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
耳鳴	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
鼓膜穿孔	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1 (0.6%)	4 (2.6%)	4 (2.6%)	8 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (2.1%)
子宮平滑筋腫	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
乳房の良性新生物	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
唾液腺の良性新生物	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
脂肪腫	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
肺腺癌	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
前立腺腺腫	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)

表 2.7.6.4-3 すべての有害事象（ランダム割付けされた被験者，54 週）（続き）

SOC PT	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]
皮膚乳頭腫	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
腎および尿路障害	4 (2.6%)	3 (1.9%)	4 (2.6%)	7 (2.3%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	8 (2.1%)
腎結石症	2 (1.3%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
腎仙痛	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
排尿困難	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
尿意切迫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.3%)
夜間頻尿	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
頻尿	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.3%)
尿閉	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
水腎症	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
尿道痛	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
尿失禁	1 (0.6%)	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	9 (5.8%)	2 (1.3%)	5 (3.2%)	7 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (1.8%)
高血圧	5 (3.2%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
深部静脈血栓症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
潮紅	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
血腫	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
出血	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
ほてり	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
末梢冷感	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
間欠性跛行	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血管炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
肝胆道系障害	1 (0.6%)	2 (1.3%)	3 (1.9%)	5 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (1.3%)
胆管結石	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
胆石症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
肝嚢胞	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
脂肪肝	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
高ビリルビン血症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
心臓障害	0 (0.0%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
心不全	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
心嚢液貯留	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
心膜炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
免疫系障害	3 (1.9%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	1 (7.1%)	3 (0.8%)
季節性アレルギー	3 (1.9%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	1 (7.1%)	3 (0.8%)

表 2.7.6.4-3 すべての有害事象（ランダム割付けされた被験者，54 週）（続き）

SOC PT	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]
外科および内科処置	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
前頭洞手術	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
副鼻腔手術	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
抜歯	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
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%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
遺伝性フルクトース不耐症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
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%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
妊娠	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
社会環境	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
パートナーの妊娠	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)

[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.

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参照元：C0524T18 Clinical Study Report Attachment 4.1

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）

SOC PT	Placebo[a,b]	Golimumab 50 mg[a]	Golimumab 100 mg[a,c,d]	Golimumab Combined 50 mg and 100 mg	Golimumab 200 mg[d,e]	Golimumab All Golimumab[f]
Subjects treated	285	154	946	1075	14	1075
Avg duration of follow-up (weeks)	34.4	44.3	39.7	41.3	27.5	41.6
Avg exposure (number of administrations)	8.5	11.1	9.2	9.7	6.9	9.8
Subjects with 1 or more adverse events	182 (63.9%)	112 (72.7%)	699 (73.9%)	800 (74.4%)	9 (64.3%)	801 (74.5%)
胃腸障害	93 (32.6%)	50 (32.5%)	352 (37.2%)	400 (37.2%)	4 (28.6%)	402 (37.4%)
潰瘍性大腸炎	48 (16.8%)	27 (17.5%)	175 (18.5%)	202 (18.8%)	1 (7.1%)	203 (18.9%)
腹痛	9 (3.2%)	11 (7.1%)	46 (4.9%)	56 (5.2%)	0 (0.0%)	56 (5.2%)
悪心	9 (3.2%)	7 (4.5%)	31 (3.3%)	38 (3.5%)	1 (7.1%)	39 (3.6%)
下痢	9 (3.2%)	4 (2.6%)	22 (2.3%)	25 (2.3%)	1 (7.1%)	26 (2.4%)
痔核	5 (1.8%)	3 (1.9%)	17 (1.8%)	20 (1.9%)	1 (7.1%)	21 (2.0%)
便秘	3 (1.1%)	2 (1.3%)	15 (1.6%)	17 (1.6%)	0 (0.0%)	17 (1.6%)
上腹部痛	3 (1.1%)	4 (2.6%)	10 (1.1%)	14 (1.3%)	0 (0.0%)	14 (1.3%)
嘔吐	6 (2.1%)	2 (1.3%)	12 (1.3%)	14 (1.3%)	0 (0.0%)	14 (1.3%)
消化不良	5 (1.8%)	3 (1.9%)	9 (1.0%)	12 (1.1%)	0 (0.0%)	12 (1.1%)
血便排泄	7 (2.5%)	1 (0.6%)	10 (1.1%)	11 (1.0%)	0 (0.0%)	11 (1.0%)
胃食道逆流性疾患	1 (0.4%)	1 (0.6%)	9 (1.0%)	10 (0.9%)	0 (0.0%)	10 (0.9%)
腹部不快感	1 (0.4%)	0 (0.0%)	8 (0.8%)	8 (0.7%)	0 (0.0%)	8 (0.7%)
裂肛	0 (0.0%)	1 (0.6%)	7 (0.7%)	8 (0.7%)	0 (0.0%)	8 (0.7%)
歯痛	1 (0.4%)	1 (0.6%)	7 (0.7%)	8 (0.7%)	0 (0.0%)	8 (0.7%)
腹部膨満	3 (1.1%)	1 (0.6%)	6 (0.6%)	7 (0.7%)	0 (0.0%)	7 (0.7%)
結腸ポリープ	0 (0.0%)	0 (0.0%)	7 (0.7%)	7 (0.7%)	0 (0.0%)	7 (0.7%)
口内炎	1 (0.4%)	0 (0.0%)	7 (0.7%)	7 (0.7%)	0 (0.0%)	7 (0.7%)
排便回数増加	3 (1.1%)	0 (0.0%)	5 (0.5%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
直腸ポリープ	1 (0.4%)	0 (0.0%)	5 (0.5%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
下腹部痛	2 (0.7%)	2 (1.3%)	2 (0.2%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
齲歯	0 (0.0%)	1 (0.6%)	3 (0.3%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
鼓腸	1 (0.4%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
アフタ性口内炎	1 (0.4%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
口唇炎	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
血性下痢	3 (1.1%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
口内乾燥	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
過敏性腸症候群	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
口腔内潰瘍形成	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
膵炎	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
肛門周囲痛	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
偽性ポリポーシス	0 (0.0%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
肛門の炎症	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
便意切迫	1 (0.4%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
腸憩室	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
腸炎	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
食中毒	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
胃炎	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
排便痛	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
直腸炎	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (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%)	1 (7.1%)	1 (0.1%)
肛門皮膚垂	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肛門直腸不快感	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
バレット食道	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
便通不規則	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口唇症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
結腸狭窄	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
嚥下障害	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
小腸炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
便失禁	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
萎縮性胃炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
消化器痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胃腸音異常	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
歯肉痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
歯肉炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
痔出血	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胃酸過多	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
イレウス	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
鼠径ヘルニア	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腸管虚血	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
機械的イレウス	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
口腔嚢胞	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口腔内出血	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
食道浮腫	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口腔内痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
急性膵炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肛門周囲炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
直腸出血	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
直腸しぶり	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
歯の知覚過敏	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
小腸閉塞	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
舌腫脹	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
脆弱歯	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
歯の障害	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腹部硬直	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
異常便	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
大腸炎	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
胃腸の炎症	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
粘液便	1 (0.4%)	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	71 (24.9%)	57 (37.0%)	338 (35.7%)	391 (36.4%)	5 (35.7%)	393 (36.6%)
鼻咽頭炎	16 (5.6%)	14 (9.1%)	90 (9.5%)	103 (9.6%)	3 (21.4%)	104 (9.7%)
上気道感染	10 (3.5%)	8 (5.2%)	58 (6.1%)	65 (6.0%)	1 (7.1%)	66 (6.1%)
副鼻腔炎	6 (2.1%)	6 (3.9%)	24 (2.5%)	30 (2.8%)	0 (0.0%)	30 (2.8%)
咽頭炎	4 (1.4%)	8 (5.2%)	20 (2.1%)	28 (2.6%)	1 (7.1%)	29 (2.7%)
インフルエンザ	12 (4.2%)	7 (4.5%)	20 (2.1%)	27 (2.5%)	0 (0.0%)	27 (2.5%)
気管支炎	5 (1.8%)	6 (3.9%)	17 (1.8%)	23 (2.1%)	0 (0.0%)	23 (2.1%)
胃腸炎	4 (1.4%)	2 (1.3%)	15 (1.6%)	17 (1.6%)	0 (0.0%)	17 (1.6%)
口腔ヘルペス	3 (1.1%)	2 (1.3%)	12 (1.3%)	14 (1.3%)	0 (0.0%)	14 (1.3%)
ウイルス感染	1 (0.4%)	2 (1.3%)	11 (1.2%)	13 (1.2%)	0 (0.0%)	13 (1.2%)
尿路感染	8 (2.8%)	2 (1.3%)	8 (0.8%)	10 (0.9%)	1 (7.1%)	11 (1.0%)
ウイルス性胃腸炎	2 (0.7%)	2 (1.3%)	7 (0.7%)	9 (0.8%)	0 (0.0%)	9 (0.8%)
肺炎	2 (0.7%)	0 (0.0%)	8 (0.8%)	8 (0.7%)	0 (0.0%)	8 (0.7%)
鼻炎	2 (0.7%)	1 (0.6%)	7 (0.7%)	8 (0.7%)	0 (0.0%)	8 (0.7%)
膀胱炎	1 (0.4%)	2 (1.3%)	5 (0.5%)	7 (0.7%)	0 (0.0%)	7 (0.7%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
帯状疱疹	1 (0.4%)	1 (0.6%)	6 (0.6%)	7 (0.7%)	0 (0.0%)	7 (0.7%)
真菌感染	0 (0.0%)	0 (0.0%)	6 (0.6%)	6 (0.6%)	0 (0.0%)	6 (0.6%)
せつ	0 (0.0%)	2 (1.3%)	4 (0.4%)	6 (0.6%)	0 (0.0%)	6 (0.6%)
単純ヘルペス	0 (0.0%)	1 (0.6%)	5 (0.5%)	6 (0.6%)	0 (0.0%)	6 (0.6%)
麦粒腫	3 (1.1%)	2 (1.3%)	4 (0.4%)	6 (0.6%)	0 (0.0%)	6 (0.6%)
気道感染	1 (0.4%)	0 (0.0%)	6 (0.6%)	6 (0.6%)	0 (0.0%)	6 (0.6%)
外陰腟真菌感染	1 (0.4%)	3 (1.9%)	3 (0.3%)	6 (0.6%)	0 (0.0%)	6 (0.6%)
喉頭炎	0 (0.0%)	1 (0.6%)	4 (0.4%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
レンサ球菌性咽頭炎	0 (0.0%)	1 (0.6%)	4 (0.4%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
ウイルス性気道感染	1 (0.4%)	0 (0.0%)	5 (0.5%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
扁桃炎	1 (0.4%)	1 (0.6%)	4 (0.4%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
歯膿瘍	1 (0.4%)	0 (0.0%)	5 (0.5%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
外陰部腟カンジダ症	1 (0.4%)	1 (0.6%)	4 (0.4%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
急性扁桃炎	0 (0.0%)	2 (1.3%)	2 (0.2%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
肛門膿瘍	0 (0.0%)	1 (0.6%)	3 (0.3%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
虫垂炎	0 (0.0%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
クロストリジウム感染	2 (0.7%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
外耳炎	0 (0.0%)	1 (0.6%)	3 (0.3%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
歯感染	0 (0.0%)	1 (0.6%)	3 (0.3%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
気管炎	1 (0.4%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
ウイルス性上気道感染	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	1 (7.1%)	4 (0.4%)
慢性副鼻腔炎	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
憩室炎	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
感染性腸炎	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
丹毒	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
毛包炎	3 (1.1%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
爪真菌症	1 (0.4%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
ブドウ球菌感染	0 (0.0%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
創傷感染	0 (0.0%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
膿瘍	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
カンジダ症	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
播種性結核	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
耳感染	2 (0.7%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
感染性小腸結腸炎	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
エンテロウイルス感染	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
ウイルス性消化管感染	0 (0.0%)	0 (0.0%)	2 (0.2%)	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%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
限局性感染	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
口腔カンジダ症	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
爪囲炎	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
膿疱性皮疹	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
皮膚感染	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
皮下組織膿瘍	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
癜風	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
ウイルス性咽頭炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	1 (7.1%)	2 (0.2%)
急性副鼻腔炎	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
真菌性肛門感染	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肛門性器疣贅	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
細菌性敗血症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ブラストシスティス感染	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ボレリア感染	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
脳膿瘍	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
乳房蜂巣炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
蜂巣炎	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
サイトメガロウイルス感染	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
感染性皮膚炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
紅色陰癬	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼感染	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ブドウ球菌性眼感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ロタウイルス胃腸炎	0 (0.0%)	1 (0.6%)	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%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
消化管感染	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ジアルジア症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
鼠径部膿瘍	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
感染性表皮嚢胞	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
感染性皮膚潰瘍	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注射部位膿瘍	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
椎間板炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
迷路炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
下気道感染	2 (0.7%)	0 (0.0%)	1 (0.1%)	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%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ライム病	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
マラリア	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
伝染性軟属腫	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
爪感染	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
食道カンジダ症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口腔真菌感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
精巣炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
中耳炎	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
寄生虫性胃腸炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
歯周感染	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
毛巣嚢胞	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
術後膿瘍	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腎盂腎炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
敗血症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
敗血症性ショック	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚細菌感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
軟部組織感染	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ブドウ球菌性菌血症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
レンサ球菌性敗血症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
白癬感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
足部白癬	1 (0.4%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
結核	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腸チフス熱	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
泌尿生殖器真菌感染	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
水痘	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腹壁膿瘍	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
細菌感染	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
気管支肺炎	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
クロストリジウム・ディフィシレ大腸炎	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ｈ１Ｎ１インフルエンザ	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
細菌の過剰増殖	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
原発性異型肺炎	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
尿道炎	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ワクチン接種部位感染	1 (0.4%)	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	44 (15.4%)	23 (14.9%)	131 (13.8%)	154 (14.3%)	3 (21.4%)	157 (14.6%)
関節痛	19 (6.7%)	11 (7.1%)	58 (6.1%)	69 (6.4%)	1 (7.1%)	70 (6.5%)
背部痛	10 (3.5%)	3 (1.9%)	25 (2.6%)	28 (2.6%)	1 (7.1%)	29 (2.7%)
四肢痛	4 (1.4%)	3 (1.9%)	9 (1.0%)	12 (1.1%)	0 (0.0%)	12 (1.1%)
筋肉痛	4 (1.4%)	4 (2.6%)	5 (0.5%)	9 (0.8%)	0 (0.0%)	9 (0.8%)
筋痙縮	0 (0.0%)	0 (0.0%)	8 (0.8%)	8 (0.7%)	0 (0.0%)	8 (0.7%)
筋骨格痛	4 (1.4%)	2 (1.3%)	5 (0.5%)	7 (0.7%)	0 (0.0%)	7 (0.7%)
関節炎	1 (0.4%)	0 (0.0%)	5 (0.5%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
筋骨格系胸痛	0 (0.0%)	1 (0.6%)	4 (0.4%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
頚部痛	0 (0.0%)	0 (0.0%)	5 (0.5%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
滑液包炎	1 (0.4%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
変形性関節症	0 (0.0%)	2 (1.3%)	1 (0.1%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
骨痛	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
線維筋痛	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
椎間板突出	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
関節腫脹	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
筋骨格不快感	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
腱痛	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
バニオン	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
外骨腫	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
側腹部痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
鼠径部痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
筋骨格硬直	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
骨壊死	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
骨減少症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
骨粗鬆症	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
関節周囲炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
多発性関節炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
仙腸骨炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
重感	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
変形性脊椎症	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%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
滑液嚢腫	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腱性拘縮	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腱鞘炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
狭窄性腱鞘炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
椎間関節症候群	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
瘻孔	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
筋力低下	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
足底筋膜炎	1 (0.4%)	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	38 (13.3%)	22 (14.3%)	129 (13.6%)	150 (14.0%)	3 (21.4%)	153 (14.2%)
発疹	5 (1.8%)	9 (5.8%)	28 (3.0%)	37 (3.4%)	1 (7.1%)	38 (3.5%)
そう痒症	4 (1.4%)	1 (0.6%)	19 (2.0%)	20 (1.9%)	0 (0.0%)	20 (1.9%)
皮膚乾燥	0 (0.0%)	3 (1.9%)	9 (1.0%)	12 (1.1%)	0 (0.0%)	12 (1.1%)
寝汗	1 (0.4%)	0 (0.0%)	9 (1.0%)	9 (0.8%)	0 (0.0%)	9 (0.8%)
脱毛症	4 (1.4%)	0 (0.0%)	8 (0.8%)	8 (0.7%)	0 (0.0%)	8 (0.7%)
ざ瘡	2 (0.7%)	2 (1.3%)	4 (0.4%)	6 (0.6%)	1 (7.1%)	7 (0.7%)
湿疹	6 (2.1%)	1 (0.6%)	5 (0.5%)	6 (0.6%)	1 (7.1%)	7 (0.7%)
接触性皮膚炎	2 (0.7%)	0 (0.0%)	6 (0.6%)	6 (0.6%)	0 (0.0%)	6 (0.6%)
皮膚炎	3 (1.1%)	2 (1.3%)	4 (0.4%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
紅斑	1 (0.4%)	0 (0.0%)	5 (0.5%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
アレルギー性皮膚炎	5 (1.8%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	1 (7.1%)	4 (0.4%)
結節性紅斑	0 (0.0%)	1 (0.6%)	3 (0.3%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
全身性皮疹	1 (0.4%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
皮膚病変	0 (0.0%)	1 (0.6%)	3 (0.3%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
薬疹	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
乾癬	1 (0.4%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
酒さ	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
脂漏性皮膚炎	1 (0.4%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
皮膚変色	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
蕁麻疹	2 (0.7%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
貨幣状湿疹	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
滴状乾癬	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
汗腺炎	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
多汗症	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
膿疱性乾癬	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
そう痒性皮疹	2 (0.7%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
日光性角化症	1 (0.4%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚嚢腫	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ざ瘡様皮膚炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
発汗障害	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮脂欠乏性湿疹	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮下出血	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
顔面感覚鈍麻	0 (0.0%)	1 (0.6%)	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%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
嵌入爪	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
脂肪肥大症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
爪変色	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
爪破損	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
点状出血	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
光線性皮膚症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ばら色粃糠疹	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
痒疹	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
紫斑	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
毛孔性皮疹	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
斑状皮疹	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
斑状丘疹状皮疹	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
瘢痕	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚灼熱感	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚剥脱	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚亀裂	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚色素減少	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
皮膚刺激	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
尋常性白斑	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
水疱	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
アトピー性皮膚炎	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
乾癬様皮膚炎	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
斑状出血	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
扁平苔癬	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
斑	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
皮膚色素脱失	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
顔面腫脹	1 (0.4%)	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	29 (10.2%)	18 (11.7%)	130 (13.7%)	147 (13.7%)	4 (28.6%)	149 (13.9%)
発熱	8 (2.8%)	6 (3.9%)	35 (3.7%)	40 (3.7%)	0 (0.0%)	40 (3.7%)
疲労	7 (2.5%)	4 (2.6%)	21 (2.2%)	25 (2.3%)	0 (0.0%)	25 (2.3%)
無力症	4 (1.4%)	2 (1.3%)	14 (1.5%)	16 (1.5%)	0 (0.0%)	16 (1.5%)
注射部位紅斑	2 (0.7%)	1 (0.6%)	15 (1.6%)	16 (1.5%)	1 (7.1%)	16 (1.5%)
末梢性浮腫	2 (0.7%)	3 (1.9%)	13 (1.4%)	16 (1.5%)	0 (0.0%)	16 (1.5%)
インフルエンザ様疾患	1 (0.4%)	2 (1.3%)	13 (1.4%)	15 (1.4%)	0 (0.0%)	15 (1.4%)
胸痛	0 (0.0%)	0 (0.0%)	6 (0.6%)	6 (0.6%)	1 (7.1%)	7 (0.7%)
悪寒	2 (0.7%)	1 (0.6%)	4 (0.4%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
疼痛	1 (0.4%)	0 (0.0%)	5 (0.5%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
注射部位発疹	0 (0.0%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	1 (7.1%)	4 (0.4%)
注射部位血腫	2 (0.7%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
胸部不快感	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
薬効欠如	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
注射部位疼痛	2 (0.7%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
倦怠感	1 (0.4%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
粘膜の炎症	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
浮腫	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
投与部位発疹	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
投与部位反応	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
適用部位紅斑	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腋窩痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
嚢胞	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
薬物不耐性	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
顔面浮腫	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
体温変動感	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
高熱	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
低体温	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注入部位炎症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注入部位そう痒感	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注入部位反応	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注射部位硬結	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	1 (7.1%)	1 (0.1%)
注射部位腫瘤	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注射部位そう痒感	2 (0.7%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注射部位反応	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注射部位腫脹	2 (0.7%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
限局性浮腫	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
医療機器合併症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
微石症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
偽ポリープ	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
圧迫感	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
軟部組織の炎症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口渇	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注入部位静脈炎	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
非心臓性胸痛	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
神経系障害	38 (13.3%)	15 (9.7%)	104 (11.0%)	119 (11.1%)	1 (7.1%)	120 (11.2%)
頭痛	20 (7.0%)	12 (7.8%)	73 (7.7%)	85 (7.9%)	1 (7.1%)	86 (8.0%)
浮動性めまい	5 (1.8%)	0 (0.0%)	14 (1.5%)	14 (1.3%)	0 (0.0%)	14 (1.3%)
片頭痛	1 (0.4%)	3 (1.9%)	7 (0.7%)	10 (0.9%)	0 (0.0%)	10 (0.9%)
感覚鈍麻	1 (0.4%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
錯感覚	5 (1.8%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
副鼻腔炎に伴う頭痛	1 (0.4%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
失神	1 (0.4%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
振戦	2 (0.7%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
痙攣	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
嗜眠	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
末梢性ニューロパチー	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
坐骨神経痛	1 (0.4%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
手根管症候群	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
頚髄症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
味覚異常	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
顔面不全麻痺	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
筋緊張低下	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
神経圧迫	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
神経根圧迫	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
神経痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
脱髄	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
傾眠	1 (0.4%)	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	22 (7.7%)	15 (9.7%)	95 (10.0%)	110 (10.2%)	2 (14.3%)	112 (10.4%)
咳嗽	10 (3.5%)	5 (3.2%)	43 (4.5%)	48 (4.5%)	0 (0.0%)	48 (4.5%)
口腔咽頭痛	1 (0.4%)	2 (1.3%)	21 (2.2%)	23 (2.1%)	0 (0.0%)	23 (2.1%)
鼻閉	1 (0.4%)	1 (0.6%)	5 (0.5%)	6 (0.6%)	1 (7.1%)	7 (0.7%)
鼻漏	0 (0.0%)	2 (1.3%)	4 (0.4%)	6 (0.6%)	0 (0.0%)	6 (0.6%)
呼吸困難	1 (0.4%)	1 (0.6%)	4 (0.4%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
喘息	0 (0.0%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
気道うっ血	0 (0.0%)	2 (1.3%)	2 (0.2%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
副鼻腔うっ血	2 (0.7%)	1 (0.6%)	3 (0.3%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
鼻出血	1 (0.4%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
呼吸障害	2 (0.7%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
アレルギー性鼻炎	0 (0.0%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
上気道うっ血	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	1 (7.1%)	3 (0.3%)
上気道の炎症	2 (0.7%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
喘鳴	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
労作性呼吸困難	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
湿性咳嗽	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
肺塞栓症	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
慢性気管支炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
息詰まり感	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
咽喉乾燥	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
発声障害	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
喀血	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
上気道分泌増加	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肺浸潤	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
鼻乾燥	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
鼻閉塞	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
呼吸時疼痛	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胸水	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
季節性鼻炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
くしゃみ	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
アレルギー性咳嗽	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
胸膜炎	1 (0.4%)	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	14 (4.9%)	11 (7.1%)	81 (8.6%)	92 (8.6%)	0 (0.0%)	92 (8.6%)
貧血	3 (1.1%)	4 (2.6%)	43 (4.5%)	47 (4.4%)	0 (0.0%)	47 (4.4%)
白血球減少症	3 (1.1%)	2 (1.3%)	14 (1.5%)	16 (1.5%)	0 (0.0%)	16 (1.5%)
好中球減少症	1 (0.4%)	0 (0.0%)	8 (0.8%)	8 (0.7%)	0 (0.0%)	8 (0.7%)
好酸球増加症	1 (0.4%)	2 (1.3%)	5 (0.5%)	7 (0.7%)	0 (0.0%)	7 (0.7%)
リンパ球減少症	2 (0.7%)	0 (0.0%)	7 (0.7%)	7 (0.7%)	0 (0.0%)	7 (0.7%)
好中球増加症	0 (0.0%)	1 (0.6%)	5 (0.5%)	6 (0.6%)	0 (0.0%)	6 (0.6%)
血小板増加症	0 (0.0%)	1 (0.6%)	5 (0.5%)	6 (0.6%)	0 (0.0%)	6 (0.6%)
リンパ節症	0 (0.0%)	2 (1.3%)	3 (0.3%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
単球減少症	0 (0.0%)	1 (0.6%)	4 (0.4%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
白血球増加症	1 (0.4%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
鉄欠乏性貧血	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
リンパ球増加症	1 (0.4%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
血小板減少症	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
溶血性貧血	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
出血性貧血	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
リンパ節痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
小球性貧血	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
単球増加症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
二血球減少症	1 (0.4%)	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	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	Placebo[a,b]	Golimumab 50 mg[a]	Golimumab 100 mg[a,c,d]	Golimumab Combined 50 mg and 100 mg	Golimumab 200 mg[d,e]	Golimumab All Golimumab[f]
臨床検査	17 (6.0%)	18 (11.7%)	64 (6.8%)	82 (7.6%)	1 (7.1%)	83 (7.7%)
アラニン・アミノトランスフェラーゼ増加	4 (1.4%)	3 (1.9%)	15 (1.6%)	18 (1.7%)	0 (0.0%)	18 (1.7%)
アスパラギン酸アミノトランスフェラーゼ増加	3 (1.1%)	5 (3.2%)	8 (0.8%)	13 (1.2%)	0 (0.0%)	13 (1.2%)
肝酵素上昇	3 (1.1%)	2 (1.3%)	4 (0.4%)	6 (0.6%)	0 (0.0%)	6 (0.6%)
好酸球数増加	5 (1.8%)	0 (0.0%)	5 (0.5%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
ヘモグロビン減少	1 (0.4%)	1 (0.6%)	4 (0.4%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
白血球数増加	0 (0.0%)	2 (1.3%)	2 (0.2%)	4 (0.4%)	1 (7.1%)	5 (0.5%)
白血球数減少	1 (0.4%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
血中ビリルビン増加	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
血中カリウム減少	0 (0.0%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
血圧上昇	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
ヘマトクリット減少	1 (0.4%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
肝機能検査異常	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
好中球数減少	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
血小板数増加	1 (0.4%)	2 (1.3%)	1 (0.1%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
体重減少	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
血中アルカリホスファターゼ増加	0 (0.0%)	0 (0.0%)	2 (0.2%)	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%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
血中リン増加	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
血中尿素増加	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
体温上昇	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
リンパ球数増加	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
単球数減少	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
好中球数増加	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	1 (7.1%)	2 (0.2%)
総蛋白減少	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
トランスアミナーゼ上昇	0 (0.0%)	1 (0.6%)	1 (0.1%)	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 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
好塩基球数増加	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
抱合ビリルビン増加	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
乳房生検	0 (0.0%)	0 (0.0%)	1 (0.1%)	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%)	1 (0.1%)	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%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血中カルシウム減少	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
血中カルシウム増加	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血中ブドウ糖増加	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血中鉄減少	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
収縮期血圧上昇	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胸部Ｘ線異常	0 (0.0%)	1 (0.6%)	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%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
心拍数増加	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
心音異常	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ＩＮＲ増加	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
後骨髄球数増加	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
単球数増加	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
好中球数異常	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血小板数減少	1 (0.4%)	1 (0.6%)	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%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
体重増加	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
尿中白血球陽性	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血中コレステロール増加	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血中テストステロン減少	1 (0.4%)	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	12 (4.2%)	6 (3.9%)	49 (5.2%)	55 (5.1%)	1 (7.1%)	56 (5.2%)
挫傷	4 (1.4%)	2 (1.3%)	8 (0.8%)	10 (0.9%)	0 (0.0%)	10 (0.9%)
肉離れ	1 (0.4%)	0 (0.0%)	5 (0.5%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
節足動物咬傷	2 (0.7%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
手骨折	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	1 (7.1%)	3 (0.3%)
関節脱臼	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
関節捻挫	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
裂傷	1 (0.4%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
動物咬傷	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
上顎炎	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
処置後合併症	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
処置による疼痛	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
肋骨骨折	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
偶発的中毒	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
足関節部骨折	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
背部損傷	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
骨亀裂	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
第２度熱傷	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
脳振盪	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
足骨折	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
瘢痕ヘルニア	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
関節損傷	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口唇損傷	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
処置による頭痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
橈骨骨折	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
脊柱損傷	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
脊椎圧迫骨折	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腱損傷	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
歯牙破折	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
創傷	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
手首関節骨折	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
偶発的過量投与	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
節足動物刺傷	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
擦過傷	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
筋損傷	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
鋭的腹部外傷	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
熱傷	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
創合併症	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
精神障害	10 (3.5%)	6 (3.9%)	43 (4.5%)	49 (4.6%)	1 (7.1%)	50 (4.7%)
不眠症	4 (1.4%)	1 (0.6%)	18 (1.9%)	19 (1.8%)	0 (0.0%)	19 (1.8%)
うつ病	5 (1.8%)	3 (1.9%)	11 (1.2%)	14 (1.3%)	1 (7.1%)	15 (1.4%)
不安	3 (1.1%)	2 (1.3%)	8 (0.8%)	10 (0.9%)	0 (0.0%)	10 (0.9%)
錯乱状態	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
抑うつ気分	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
情動障害	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
幻覚	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
精神障害	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
神経過敏	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
落ち着きのなさ	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
睡眠障害	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
社会恐怖症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
物質乱用	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
代謝および栄養障害	3 (1.1%)	4 (2.6%)	35 (3.7%)	39 (3.6%)	0 (0.0%)	39 (3.6%)
脱水	1 (0.4%)	1 (0.6%)	8 (0.8%)	9 (0.8%)	0 (0.0%)	9 (0.8%)
食欲減退	0 (0.0%)	1 (0.6%)	4 (0.4%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
糖尿病	1 (0.4%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
痛風	0 (0.0%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
低カリウム血症	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
鉄欠乏	1 (0.4%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
高カルシウム血症	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
高脂血症	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
低マグネシウム血症	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
異常体重減少	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
高アルブミン血症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
高アミラーゼ血症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
高コレステロール血症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
高血糖	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
高蛋白血症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
低カルシウム血症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
低ナトリウム血症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血液量減少症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
栄養障害	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ビタミンＢ群欠乏	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ビタミンＤ欠乏	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血管障害	11 (3.9%)	2 (1.3%)	34 (3.6%)	36 (3.3%)	0 (0.0%)	36 (3.3%)
高血圧	6 (2.1%)	1 (0.6%)	20 (2.1%)	21 (2.0%)	0 (0.0%)	21 (2.0%)
深部静脈血栓症	1 (0.4%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
潮紅	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
血腫	1 (0.4%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
低血圧	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
大動脈瘤破裂	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
出血	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ほてり	1 (0.4%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
末梢冷感	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
静脈炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血栓性静脈炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
表在性血栓性静脈炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
静脈瘤	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血管脆弱化	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
間欠性跛行	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血管炎	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
眼障害	5 (1.8%)	6 (3.9%)	26 (2.7%)	32 (3.0%)	1 (7.1%)	33 (3.1%)
結膜炎	1 (0.4%)	2 (1.3%)	6 (0.6%)	8 (0.7%)	1 (7.1%)	9 (0.8%)
白内障	0 (0.0%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
霰粒腫	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
眼瞼炎	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
アレルギー性結膜炎	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
上強膜炎	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
眼の炎症	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
加齢黄斑変性	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼精疲労	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
複視	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼乾燥	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼刺激	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼そう痒症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼部腫脹	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼瞼障害	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼瞼そう痒症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
黄斑症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼充血	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼窩浮腫	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
視力障害	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼出血	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
翼状片	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
生殖系および乳房障害	4 (1.4%)	7 (4.5%)	16 (1.7%)	22 (2.0%)	1 (7.1%)	23 (2.1%)
精巣上体炎	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
月経過多	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
良性前立腺肥大症	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
無月経	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
バルトリン嚢腫	0 (0.0%)	1 (0.6%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
乳房嚢胞	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
乳房腫瘤	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
乳房痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
子宮頚部嚢胞	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
子宮頚部出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.1%)
膀胱瘤	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
月経困難症	0 (0.0%)	1 (0.6%)	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%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
女性化乳房	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
不規則月経	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
不正子宮出血	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
前立腺炎	1 (0.4%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
前立腺腫大	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
精巣痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
子宮出血	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
子宮ポリープ	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
外陰腟そう痒症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
卵巣嚢胞	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
卵巣嚢胞破裂	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
頻発月経	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
腟分泌物	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
腎および尿路障害	7 (2.5%)	3 (1.9%)	18 (1.9%)	21 (2.0%)	1 (7.1%)	22 (2.0%)
腎結石症	3 (1.1%)	1 (0.6%)	4 (0.4%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
頻尿	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	1 (7.1%)	4 (0.4%)
腎仙痛	1 (0.4%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
排尿困難	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
血尿	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
夜間頻尿	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
腎嚢胞	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
糸球体腎炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
尿意切迫	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 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
急性腎不全	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
慢性腎不全	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
尿閉	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
水腎症	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
腎不全	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
尿道痛	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
尿失禁	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
耳および迷路障害	2 (0.7%)	4 (2.6%)	16 (1.7%)	20 (1.9%)	1 (7.1%)	21 (2.0%)
回転性めまい	2 (0.7%)	2 (1.3%)	5 (0.5%)	7 (0.7%)	0 (0.0%)	7 (0.7%)
耳痛	0 (0.0%)	1 (0.6%)	3 (0.3%)	4 (0.4%)	1 (7.1%)	5 (0.5%)
耳垢栓塞	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
耳介軟骨膜炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
耳不快感	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
耳管機能障害	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
内耳の炎症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
乗物酔い	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
耳鳴	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
鼓膜穿孔	0 (0.0%)	0 (0.0%)	1 (0.1%)	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）	2 (0.7%)	4 (2.6%)	11 (1.2%)	15 (1.4%)	0 (0.0%)	15 (1.4%)
子宮平滑筋腫	0 (0.0%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
大腸腺腫	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
脂肪腫	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
乳房の良性新生物	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
唾液腺の良性新生物	0 (0.0%)	1 (0.6%)	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%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肺腺癌	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
骨軟骨腫	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
前立腺腺腫	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
直腸癌	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
脂漏性角化症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚乳頭腫	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
甲状腺癌	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
乳癌	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
肝胆道系障害	1 (0.4%)	2 (1.3%)	9 (1.0%)	11 (1.0%)	0 (0.0%)	11 (1.0%)
肝炎	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
高ビリルビン血症	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
胆管結石	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胆嚢炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胆石症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肝嚢胞	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肝不全	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肝機能異常	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
脂肪肝	1 (0.4%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
免疫系障害	6 (2.1%)	1 (0.6%)	9 (1.0%)	10 (0.9%)	1 (7.1%)	11 (1.0%)
季節性アレルギー	3 (1.1%)	1 (0.6%)	6 (0.6%)	7 (0.7%)	1 (7.1%)	8 (0.7%)
過敏症	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
４型過敏症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
金属アレルギー	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
薬物過敏症	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
心臓障害	0 (0.0%)	1 (0.6%)	8 (0.8%)	9 (0.8%)	0 (0.0%)	9 (0.8%)
狭心症	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
不整脈	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
心房細動	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
冠動脈疾患	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
急性心筋梗塞	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
徐脈	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
心不全	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
動悸	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
心嚢液貯留	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
心膜炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-4 すべての有害事象（全投与被験者，54 週）（続き）

SOC PT	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]
妊娠、産褥および周産期の状態	3 (1.1%)	0 (0.0%)	5 (0.5%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
妊娠	3 (1.1%)	0 (0.0%)	5 (0.5%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
自然流産	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
社会環境	0 (0.0%)	1 (0.6%)	4 (0.4%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
パートナーの妊娠	0 (0.0%)	1 (0.6%)	4 (0.4%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
外科および内科処置	0 (0.0%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
前頭洞手術	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
病変部切除	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
副鼻腔手術	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
抜歯	0 (0.0%)	0 (0.0%)	1 (0.1%)	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%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
重複尿管	0 (0.0%)	0 (0.0%)	1 (0.1%)	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%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
静脈奇形	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

[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.

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参照元：C0524T18 Clinical Study Report Attachment 4.7

表 2.7.6.4-5 治験薬の使用と関連性のある有害事象（ランダム割付けされた被験者，54 週）

SOC PT	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]
Treated subjects who were randomized	156	154	154	308	76	25	14	384
Avg duration of follow-up (weeks)	32.7	44.3	46.3	45.3	32.1	25.9	27.5	45.4
Avg exposure (number of administrations)	8.2	11.1	11.3	11.2	7.6	5.5	6.9	11.1
Subjects with 1 or more reasonably related adverse events	44 (28.2%)	39 (25.3%)	55 (35.7%)	94 (30.5%)	16 (21.1%)	6 (24.0%)	4 (28.6%)	114 (29.7%)
感染症および寄生虫症	18 (11.5%)	21 (13.6%)	20 (13.0%)	41 (13.3%)	7 (9.2%)	4 (16.0%)	2 (14.3%)	53 (13.8%)
鼻咽頭炎	3 (1.9%)	5 (3.2%)	6 (3.9%)	11 (3.6%)	2 (2.6%)	1 (4.0%)	1 (7.1%)	15 (3.9%)
上気道感染	2 (1.3%)	2 (1.3%)	3 (1.9%)	5 (1.6%)	2 (2.6%)	2 (8.0%)	0 (0.0%)	9 (2.3%)
副鼻腔炎	0 (0.0%)	2 (1.3%)	3 (1.9%)	5 (1.6%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	6 (1.6%)
気管支炎	1 (0.6%)	3 (1.9%)	0 (0.0%)	3 (1.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	4 (1.0%)
咽頭炎	0 (0.0%)	2 (1.3%)	2 (1.3%)	4 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (1.0%)
口腔ヘルペス	2 (1.3%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
外陰腟真菌感染	0 (0.0%)	3 (1.9%)	0 (0.0%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
急性扁桃炎	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
真菌感染	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
インフルエンザ	1 (0.6%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
爪真菌症	1 (0.6%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
尿路感染	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
ウイルス性咽頭炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	1 (7.1%)	2 (0.5%)
膿瘍	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
虫垂炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
カンジダ症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
慢性副鼻腔炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
膀胱炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
感染性皮膚炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
丹毒	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
紅色陰癬	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
せつ	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
胃腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
消化管感染	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
麦粒腫	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
限局性感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
口腔真菌感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)

表 2.7.6.4-5 治験薬の使用と関連性のある有害事象（ランダム割付けされた被験者，54 週）（続き）

SOC PT	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]
レンサ球菌性咽頭炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
肺炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
気道感染	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
ウイルス性気道感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
鼻炎	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
皮膚細菌感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
皮膚感染	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
白癬感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
結核	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
ウイルス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)	0 (0.0%)	1 (0.3%)
外陰部腟カンジダ症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
腹壁膿瘍	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
急性副鼻腔炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
脳膿瘍	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
クロストリジウム感染	2 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
播種性結核	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
耳感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
毛包炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
帯状疱疹	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
下気道感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
原発性異型肺炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
皮下組織膿瘍	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
足部白癬	1 (0.6%)	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	11 (7.1%)	12 (7.8%)	16 (10.4%)	28 (9.1%)	5 (6.6%)	2 (8.0%)	0 (0.0%)	35 (9.1%)
発疹	2 (1.3%)	7 (4.5%)	4 (2.6%)	11 (3.6%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	12 (3.1%)
そう痒症	0 (0.0%)	0 (0.0%)	4 (2.6%)	4 (1.3%)	1 (1.3%)	1 (4.0%)	0 (0.0%)	6 (1.6%)
皮膚乾燥	0 (0.0%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
脱毛症	2 (1.3%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
紅斑	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
日光性角化症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
皮膚炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)	0 (0.0%)	1 (0.3%)
アレルギー性皮膚炎	3 (1.9%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
湿疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
滴状乾癬	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)

表 2.7.6.4-5 治験薬の使用と関連性のある有害事象（ランダム割付けされた被験者，54 週）（続き）

SOC PT	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]
多汗症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
光線性皮膚症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
乾癬	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
膿疱性乾癬	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
斑状皮疹	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
そう痒性皮疹	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
脂漏性皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
皮膚刺激	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
皮膚病変	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
水疱	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
アトピー性皮膚炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
接触性皮膚炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
乾癬様皮膚炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
斑	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
痒疹	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
蕁麻疹	1 (0.6%)	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	13 (8.3%)	9 (5.8%)	13 (8.4%)	22 (7.1%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	23 (6.0%)
潰瘍性大腸炎	8 (5.1%)	5 (3.2%)	4 (2.6%)	9 (2.9%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	10 (2.6%)
悪心	1 (0.6%)	2 (1.3%)	2 (1.3%)	4 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (1.0%)
腹部膨満	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
血便排泄	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
腹痛	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
下腹部痛	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
結腸ポリープ	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
便秘	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
下痢	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
血性下痢	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
消化不良	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
排便回数増加	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
胃炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
口腔内痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
直腸ポリープ	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
嘔吐	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
アフタ性口内炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

表 2.7.6.4-5 治験薬の使用と関連性のある有害事象（ランダム割付けされた被験者，54 週）（続き）

SOC PT	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]
胃腸の炎症	1 (0.6%)	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	10 (6.4%)	5 (3.2%)	10 (6.5%)	15 (4.9%)	5 (6.6%)	0 (0.0%)	3 (21.4%)	21 (5.5%)
注射部位紅斑	1 (0.6%)	1 (0.6%)	4 (2.6%)	5 (1.6%)	3 (3.9%)	0 (0.0%)	1 (7.1%)	8 (2.1%)
疲労	1 (0.6%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
注射部位発疹	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	3 (0.8%)
末梢性浮腫	1 (0.6%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
インフルエンザ様疾患	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
投与部位発疹	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
投与部位反応	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
無力症	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
顔面浮腫	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
注射部位硬結	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.3%)
注射部位そう痒感	2 (1.3%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
注射部位腫脹	2 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
浮腫	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
発熱	3 (1.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
注射部位疼痛	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
口渇	1 (0.6%)	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 (3.2%)	3 (1.9%)	9 (5.8%)	12 (3.9%)	2 (2.6%)	0 (0.0%)	1 (7.1%)	15 (3.9%)
関節痛	4 (2.6%)	1 (0.6%)	3 (1.9%)	4 (1.3%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	6 (1.6%)
背部痛	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	2 (0.5%)
筋肉痛	1 (0.6%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
関節炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
線維筋痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
単径部痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
四肢痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
腱痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
筋力低下	1 (0.6%)	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 (0.6%)	3 (1.9%)	6 (3.9%)	9 (2.9%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	10 (2.6%)
アラニン・アミノトランスフェラーゼ増加	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
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 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
血中ビリルビン増加	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)

表 2.7.6.4-5 治験薬の使用と関連性のある有害事象（ランダム割付けされた被験者，54 週）（続き）

SOC PT	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]
血中カルシウム増加	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
血圧上昇	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
収縮期血圧上昇	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
好酸球数増加	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
単球数減少	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
好中球数減少	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
トランスアミナーゼ上昇	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
体重減少	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
肝酵素上昇	1 (0.6%)	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	7 (4.5%)	2 (1.3%)	5 (3.2%)	7 (2.3%)	2 (2.6%)	0 (0.0%)	1 (7.1%)	10 (2.6%)
頭痛	4 (2.6%)	2 (1.3%)	3 (1.9%)	5 (1.6%)	1 (1.3%)	0 (0.0%)	1 (7.1%)	7 (1.8%)
手根管症候群	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
浮動性めまい	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
振戦	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
脱髄	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
片頭痛	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
錯感覚	1 (0.6%)	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	1 (0.6%)	6 (3.9%)	4 (2.6%)	10 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	10 (2.6%)
咳嗽	0 (0.0%)	2 (1.3%)	2 (1.3%)	4 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (1.0%)
口腔咽頭痛	0 (0.0%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
呼吸困難	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
喀血	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
気道うっ血	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
喘鳴	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
鼻出血	1 (0.6%)	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	3 (1.9%)	2 (1.3%)	3 (1.9%)	5 (1.6%)	0 (0.0%)	2 (8.0%)	0 (0.0%)	7 (1.8%)
貧血	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	1 (4.0%)	0 (0.0%)	2 (0.5%)
白血球減少症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	1 (4.0%)	0 (0.0%)	2 (0.5%)
好酸球増加症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
リンパ節痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
リンパ節症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
血小板減少症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
リンパ球減少症	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
好中球減少症	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

表 2.7.6.4-5 治験薬の使用と関連性のある有害事象（ランダム割付けされた被験者，54 週）（続き）

SOC PT	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]
精神障害	0 (0.0%)	0 (0.0%)	4 (2.6%)	4 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (1.0%)
抑うつ気分	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
不眠症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
神経過敏	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
落ち着きのなさ	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0 (0.0%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.8%)
脂肪腫	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
肺腺癌	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
皮膚乳頭腫	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
耳および迷路障害	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
耳痛	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
耳鳴	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
傷害、中毒および処置合併症	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
挫傷	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
血管障害	2 (1.3%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
ほてり	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
末梢冷感	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
血腫	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
心臓障害	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
心膜炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
眼障害	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
眼の炎症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
結膜炎	1 (0.6%)	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	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.3%)
尿意切迫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.3%)
頻尿	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.3%)
水腎症	1 (0.6%)	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 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.

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参照元：C0524T18 Clinical Study Report Attachment 4.11

表 2.7.6.4-6 治験薬の使用と関連性のある有害事象（全投与被験者，54 週）

SOC PT	Placebo[a,b]	Golimumab 50 mg[a]	Golimumab 100 mg[a,c,d]	Golimumab Combined 50 mg and 100 mg	Golimumab 200 mg[d,e]	Golimumab All Golimumab[f]
Subjects treated	285	154	946	1075	14	1075
Avg duration of follow-up (weeks)	34.4	44.3	39.7	41.3	27.5	41.6
Avg exposure (number of administrations)	8.5	11.1	9.2	9.7	6.9	9.8
Subjects with 1 or more reasonably related adverse events	71 (24.9%)	39 (25.3%)	274 (29.0%)	310 (28.8%)	4 (28.6%)	311 (28.9%)
感染症および寄生虫症	25 (8.8%)	21 (13.6%)	118 (12.5%)	138 (12.8%)	2 (14.3%)	140 (13.0%)
鼻咽頭炎	3 (1.1%)	5 (3.2%)	22 (2.3%)	27 (2.5%)	1 (7.1%)	28 (2.6%)
上気道感染	6 (2.1%)	2 (1.3%)	24 (2.5%)	26 (2.4%)	0 (0.0%)	26 (2.4%)
副鼻腔炎	2 (0.7%)	2 (1.3%)	12 (1.3%)	14 (1.3%)	0 (0.0%)	14 (1.3%)
気管支炎	1 (0.4%)	3 (1.9%)	7 (0.7%)	10 (0.9%)	0 (0.0%)	10 (0.9%)
咽頭炎	0 (0.0%)	2 (1.3%)	7 (0.7%)	9 (0.8%)	0 (0.0%)	9 (0.8%)
インフルエンザ	2 (0.7%)	1 (0.6%)	7 (0.7%)	8 (0.7%)	0 (0.0%)	8 (0.7%)
口腔ヘルペス	2 (0.7%)	1 (0.6%)	6 (0.6%)	7 (0.7%)	0 (0.0%)	7 (0.7%)
帯状疱疹	1 (0.4%)	0 (0.0%)	5 (0.5%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
真菌感染	0 (0.0%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
麦粒腫	1 (0.4%)	1 (0.6%)	3 (0.3%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
肺炎	0 (0.0%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
尿路感染	1 (0.4%)	1 (0.6%)	3 (0.3%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
急性扁桃炎	0 (0.0%)	2 (1.3%)	1 (0.1%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
せつ	0 (0.0%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
扁桃炎	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
外陰腟真菌感染	0 (0.0%)	3 (1.9%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
カンジダ症	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
クロストリジウム感染	2 (0.7%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
膀胱炎	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
播種性結核	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
感染性腸炎	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
単純ヘルペス	0 (0.0%)	0 (0.0%)	2 (0.2%)	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%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
喉頭炎	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
限局性感染	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
爪真菌症	1 (0.4%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)

表 2.7.6.4-6 治験薬の使用と関連性のある有害事象（全投与被験者，54 週）（続き）

SOC PT	Placebo[a,b]	Golimumab 50 mg[a]	Golimumab 100 mg[a,c,d]	Golimumab Combined 50 mg and 100 mg	Golimumab 200 mg[d,e]	Golimumab All Golimumab[f]
レンサ球菌性咽頭炎	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
気道感染	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
鼻炎	1 (0.4%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
皮下組織膿瘍	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
ウイルス感染	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
ウイルス性咽頭炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	1 (7.1%)	2 (0.2%)
外陰部腟カンジダ症	1 (0.4%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
膿瘍	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肛門性器疣贅	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
虫垂炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
細菌性敗血症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
蜂巣炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
慢性副鼻腔炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
サイトメガロウイルス感染	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
感染性皮膚炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
耳感染	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
丹毒	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
紅色陰癬	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
毛包炎	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胃腸炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ウイルス性胃腸炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
消化管感染	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
感染性表皮嚢胞	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
感染性皮膚潰瘍	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
迷路炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	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%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口腔真菌感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
外耳炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腎盂腎炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
膿疱性皮疹	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ウイルス性気道感染	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
敗血症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚細菌感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚感染	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-6 治験薬の使用と関連性のある有害事象（全投与被験者，54 週）（続き）

SOC PT	Placebo[a,b]	Golimumab 50 mg[a]	Golimumab 100 mg[a,c,d]	Golimumab Combined 50 mg and 100 mg	Golimumab 200 mg[d,e]	Golimumab All Golimumab[f]
軟部組織感染	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ブドウ球菌感染	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
白癬感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
結核	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腸チフス熱	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ウイルス性上気道感染	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腹壁膿瘍	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
急性副鼻腔炎	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
脳膿瘍	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
気管支肺炎	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ｈ１Ｎ１インフルエンザ	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
下気道感染	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
原発性異型肺炎	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
足部白癬	1 (0.4%)	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	19 (6.7%)	12 (7.8%)	62 (6.6%)	74 (6.9%)	0 (0.0%)	74 (6.9%)
発疹	2 (0.7%)	7 (4.5%)	16 (1.7%)	23 (2.1%)	0 (0.0%)	23 (2.1%)
そう痒症	1 (0.4%)	0 (0.0%)	14 (1.5%)	14 (1.3%)	0 (0.0%)	14 (1.3%)
皮膚乾燥	0 (0.0%)	1 (0.6%)	6 (0.6%)	7 (0.7%)	0 (0.0%)	7 (0.7%)
脱毛症	3 (1.1%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
紅斑	1 (0.4%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
寝汗	1 (0.4%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
ざ瘡	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
接触性皮膚炎	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
薬疹	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
結節性紅斑	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
多汗症	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
乾癬	1 (0.4%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
膿疱性乾癬	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
全身性皮疹	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
日光性角化症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚炎	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ざ瘡様皮膚炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
アレルギー性皮膚炎	3 (1.1%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
湿疹	2 (0.7%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-6 治験薬の使用と関連性のある有害事象（全投与被験者，54 週）（続き）

SOC PT	Placebo[a,b]	Golimumab 50 mg[a]	Golimumab 100 mg[a,c,d]	Golimumab Combined 50 mg and 100 mg	Golimumab 200 mg[d,e]	Golimumab All Golimumab[f]
貨幣状湿疹	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
滴状乾癬	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
爪変色	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
点状出血	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
光線性皮膚症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ばら色粃糠疹	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
斑状皮疹	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
斑状丘疹状皮疹	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
そう痒性皮疹	1 (0.4%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
酒さ	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
脂漏性皮膚炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚刺激	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚病変	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
蕁麻疹	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
水疱	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
アトピー性皮膚炎	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
乾癬様皮膚炎	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
斑状出血	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
斑	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
痒疹	1 (0.4%)	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	15 (5.3%)	5 (3.2%)	52 (5.5%)	57 (5.3%)	3 (21.4%)	58 (5.4%)
注射部位紅斑	2 (0.7%)	1 (0.6%)	15 (1.6%)	16 (1.5%)	1 (7.1%)	16 (1.5%)
発熱	3 (1.1%)	0 (0.0%)	12 (1.3%)	12 (1.1%)	0 (0.0%)	12 (1.1%)
無力症	1 (0.4%)	0 (0.0%)	5 (0.5%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
疲労	3 (1.1%)	0 (0.0%)	5 (0.5%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
インフルエンザ様疾患	0 (0.0%)	2 (1.3%)	3 (0.3%)	5 (0.5%)	0 (0.0%)	5 (0.5%)
注射部位発疹	0 (0.0%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	1 (7.1%)	4 (0.4%)
末梢性浮腫	1 (0.4%)	1 (0.6%)	3 (0.3%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
注射部位疼痛	2 (0.7%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
粘膜の炎症	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
投与部位発疹	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
投与部位反応	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
適用部位紅斑	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胸部不快感	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-6 治験薬の使用と関連性のある有害事象（全投与被験者，54 週）（続き）

SOC PT	Placebo[a,b]	Golimumab 50 mg[a]	Golimumab 100 mg[a,c,d]	Golimumab Combined 50 mg and 100 mg	Golimumab 200 mg[d,e]	Golimumab All Golimumab[f]
悪寒	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
顔面浮腫	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
高熱	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注射部位血腫	2 (0.7%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注射部位硬結	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	1 (7.1%)	1 (0.1%)
注射部位腫瘤	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注射部位そう痒感	2 (0.7%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注射部位反応	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注射部位腫脹	2 (0.7%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
限局性浮腫	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
倦怠感	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
浮腫	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
疼痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
圧迫感	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口渇	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
胃腸障害	19 (6.7%)	9 (5.8%)	44 (4.7%)	53 (4.9%)	0 (0.0%)	53 (4.9%)
潰瘍性大腸炎	10 (3.5%)	5 (3.2%)	12 (1.3%)	17 (1.6%)	0 (0.0%)	17 (1.6%)
悪心	3 (1.1%)	2 (1.3%)	6 (0.6%)	8 (0.7%)	0 (0.0%)	8 (0.7%)
腹痛	2 (0.7%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
便秘	0 (0.0%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
腹部膨満	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
下痢	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
排便回数増加	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
血便排泄	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
口腔内潰瘍形成	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
直腸ポリープ	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
嘔吐	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
下腹部痛	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
上腹部痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肛門の炎症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口唇症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
結腸ポリープ	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血性下痢	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
消化不良	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-6 治験薬の使用と関連性のある有害事象（全投与被験者，54 週）（続き）

SOC PT	Placebo[a,b]	Golimumab 50 mg[a]	Golimumab 100 mg[a,c,d]	Golimumab Combined 50 mg and 100 mg	Golimumab 200 mg[d,e]	Golimumab All Golimumab[f]
鼓腸	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胃炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
消化器痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
歯肉痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
痔核	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口腔内痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
アフタ性口内炎	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
胃腸の炎症	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
口内炎	1 (0.4%)	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	7 (2.5%)	3 (1.9%)	33 (3.5%)	36 (3.3%)	1 (7.1%)	37 (3.4%)
関節痛	5 (1.8%)	1 (0.6%)	19 (2.0%)	20 (1.9%)	0 (0.0%)	20 (1.9%)
背部痛	0 (0.0%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	1 (7.1%)	4 (0.4%)
筋肉痛	1 (0.4%)	1 (0.6%)	3 (0.3%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
四肢痛	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
関節炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
滑液包炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
線維筋痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
鼡径部痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
関節腫脹	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
筋痙縮	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
筋骨格痛	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
筋骨格硬直	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
頚部痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
多発性関節炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腱痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
筋力低下	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
神経系障害	9 (3.2%)	2 (1.3%)	31 (3.3%)	33 (3.1%)	1 (7.1%)	34 (3.2%)
頭痛	4 (1.4%)	2 (1.3%)	23 (2.4%)	25 (2.3%)	1 (7.1%)	26 (2.4%)
浮動性めまい	1 (0.4%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
手根管症候群	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
痙攣	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
感覚鈍麻	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
片頭痛	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
末梢性ニューロパチー	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-6 治験薬の使用と関連性のある有害事象（全投与被験者，54 週）（続き）

SOC PT	Placebo[a,b]	Golimumab 50 mg[a]	Golimumab 100 mg[a,c,d]	Golimumab Combined 50 mg and 100 mg	Golimumab 200 mg[d,e]	Golimumab All Golimumab[f]
錯感覚	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
副鼻腔炎に伴う頭痛	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
振戦	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
脱髄	1 (0.4%)	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	3 (1.1%)	6 (3.9%)	25 (2.6%)	31 (2.9%)	0 (0.0%)	31 (2.9%)
咳嗽	1 (0.4%)	2 (1.3%)	14 (1.5%)	16 (1.5%)	0 (0.0%)	16 (1.5%)
口腔咽頭痛	0 (0.0%)	2 (1.3%)	7 (0.7%)	9 (0.8%)	0 (0.0%)	9 (0.8%)
副鼻腔うっ血	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
呼吸困難	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
気道うっ血	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
労作性呼吸困難	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
喀血	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
上気道分泌増加	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
鼻閉	1 (0.4%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
鼻閉塞	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
喘鳴	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
鼻出血	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
湿性咳嗽	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
臨床検査	3 (1.1%)	3 (1.9%)	27 (2.9%)	30 (2.8%)	0 (0.0%)	30 (2.8%)
アラニン・アミノトランスフェラーゼ増加	0 (0.0%)	1 (0.6%)	8 (0.8%)	9 (0.8%)	0 (0.0%)	9 (0.8%)
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 (0.6%)	5 (0.5%)	6 (0.6%)	0 (0.0%)	6 (0.6%)
血中ビリルビン増加	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
好中球数減少	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
肝酵素上昇	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
肝機能検査異常	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
単球数減少	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
トランスアミナーゼ上昇	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
体重減少	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
抱合ビリルビン増加	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血中アルカリホスファターゼ増加	0 (0.0%)	0 (0.0%)	1 (0.1%)	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%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血中カルシウム増加	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-6 治験薬の使用と関連性のある有害事象（全投与被験者，54 週）（続き）

SOC PT	Placebo[a,b]	Golimumab 50 mg[a]	Golimumab 100 mg[a,c,d]	Golimumab Combined 50 mg and 100 mg	Golimumab 200 mg[d,e]	Golimumab All Golimumab[f]
血圧上昇	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
収縮期血圧上昇	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
心エコー像異常	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
好酸球数増加	2 (0.7%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ＩＮＲ増加	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
リンパ球数増加	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
総蛋白減少	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
白血球数減少	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血液およびリンパ系障害	5 (1.8%)	2 (1.3%)	19 (2.0%)	21 (2.0%)	0 (0.0%)	21 (2.0%)
貧血	1 (0.4%)	0 (0.0%)	6 (0.6%)	6 (0.6%)	0 (0.0%)	6 (0.6%)
好中球減少症	1 (0.4%)	0 (0.0%)	6 (0.6%)	6 (0.6%)	0 (0.0%)	6 (0.6%)
白血球減少症	1 (0.4%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
リンパ球減少症	1 (0.4%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
リンパ節症	0 (0.0%)	1 (0.6%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
好酸球増加症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
溶血性貧血	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
リンパ節痛	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
好中球増加症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血小板減少症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
特発性血小板減少性紫斑病	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
眼障害	1 (0.4%)	0 (0.0%)	11 (1.2%)	11 (1.0%)	0 (0.0%)	11 (1.0%)
眼瞼炎	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
霰粒腫	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
結膜炎	1 (0.4%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
眼精疲労	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
アレルギー性結膜炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼乾燥	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼の炎症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼そう痒症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
視力障害	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
精神障害	2 (0.7%)	0 (0.0%)	8 (0.8%)	8 (0.7%)	0 (0.0%)	8 (0.7%)
不眠症	1 (0.4%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
不安	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
抑うつ気分	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

表 2.7.6.4-6 治験薬の使用と関連性のある有害事象（全投与被験者，54 週）（続き）

SOC PT	Placebo[a,b]	Golimumab 50 mg[a]	Golimumab 100 mg[a,c,d]	Golimumab Combined 50 mg and 100 mg	Golimumab 200 mg[d,e]	Golimumab All Golimumab[f]
情動障害	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
神経過敏	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
落ち着きのなさ	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
うつ病	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血管障害	2 (0.7%)	1 (0.6%)	5 (0.5%)	6 (0.6%)	0 (0.0%)	6 (0.6%)
高血圧	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
潮紅	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ほてり	1 (0.4%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
低血圧	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
末梢冷感	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血腫	1 (0.4%)	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 (0.4%)	1 (0.6%)	3 (0.3%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
挫傷	0 (0.0%)	1 (0.6%)	3 (0.3%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
創合併症	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
代謝および栄養障害	0 (0.0%)	0 (0.0%)	4 (0.4%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
食欲減退	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
高カルシウム血症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
鉄欠乏	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ビタミンD欠乏	0 (0.0%)	0 (0.0%)	1 (0.1%)	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 (0.6%)	3 (0.3%)	4 (0.4%)	0 (0.0%)	4 (0.4%)
脂肪腫	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肺腺癌	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚乳頭腫	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
甲状腺癌	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
耳および迷路障害	0 (0.0%)	1 (0.6%)	2 (0.2%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
耳痛	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
耳鳴	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
回転性めまい	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肝胆道系障害	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
肝機能異常	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肝炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
高ビリルビン血症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腎および尿路障害	3 (1.1%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	1 (7.1%)	3 (0.3%)

表 2.7.6.4-6 治験薬の使用と関連性のある有害事象（全投与被験者，54 週）（続き）

SOC PT	Placebo[a,b]	Golimumab 50 mg[a]	Golimumab 100 mg[a,c,d]	Golimumab Combined 50 mg and 100 mg	Golimumab 200 mg[d,e]	Golimumab All Golimumab[f]
頻尿	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	1 (7.1%)	3 (0.3%)
尿意切迫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.1%)
水腎症	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
腎仙痛	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
腎不全	1 (0.4%)	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	0 (0.0%)	0 (0.0%)	3 (0.3%)	3 (0.3%)	0 (0.0%)	3 (0.3%)
精巣上体炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
女性化乳房	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
月経過多	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
心臓障害	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
動悸	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
心膜炎	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
免疫系障害	0 (0.0%)	0 (0.0%)	2 (0.2%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
過敏症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
４型過敏症	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

[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.

RE309:[S_AE_42_5_B_CC], 23NOV2011 10:38

参照元：C0524T18 Clinical Study Report Attachment 4.12

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）

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	TRANSIST ENT ACROPARE STHESIA OF RIGHT ARM	71	43	Resolved	No	Mild	Not related	None/not applicable	No /No
								0	255	胃腸の炎症	GASTROC OLITIS	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	HUNGAR Y/Caucasia n			0	29	うつ病	RECCUREN T DEPRESSIO N	35	16	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								0	141	擦過傷	DIRECT SKIN LESION (ABRASIO N) IN THE RIGHT LEG	155	222	Resolved	No	Moderate	Not related	None/not applicable	No /No
								0	308	うつ病	RECURREN T DEPRESSIO N	331	12	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
								0	308	偶発的過量投与	ACCIDENT AL OVERDOSE	331	12	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
								0	337	高血圧	WORSENIN G OF HYPERTEN SION	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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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]
			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
								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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	1	日光性角化症	WORSENING OF ACTINIC KERATOSES	35		Not Resolved	No	Mild	Not related	None/not applicable	No /No
						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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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]
			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
								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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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]
			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
						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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	注射部位腫脹	SWELLING LEFT UPPER ABDOMEN INJECTION SITE	251	1	Resolved	No	Mild	Probable	None/not applicable	No /Yes
								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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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
						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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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
						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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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
						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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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
						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	HEADACHE	310	7	Resolved	No	Moderate	Not related	None/not applicable	No /No

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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
			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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	175	結膜炎	ACUTE CONJUNCTIVITIS	179	11	Resolved	Yes	Severe	Unlikely	None/not applicable	Yes/No
								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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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]
						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
						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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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]
						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
						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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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]
			7007-00004	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
						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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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	17	33	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	57	発疹	SKIN. 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
			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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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
								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	281	16	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	279	耳管機能障害	INFECTIVE 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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-7 重篤な有害事象を発現した症例の一覧（ランダム割付けされた被験者，54 週）（続き）

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	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

[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.
Maintenance Treatment Group：寛解維持試験での投与群，Induction Treatment Group：寛解導入試験での投与群

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表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）

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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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]
			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
						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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	141	鋭的腹部外傷	PENETRATING WOUND OF EPIGASTRI I	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 WOUNDES R, 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
								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	CONTUSIO N 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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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
						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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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	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 FLARE	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
						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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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]
			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
						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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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								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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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								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
								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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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								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
								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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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			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
								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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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
								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	[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	[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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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
			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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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]
			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
								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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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]
			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
			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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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
								100	279	筋痙縮	NECK SPASM	297	1	Resolved	No	Moderate	Unlikely	None/not applicable	No /No

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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]
			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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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
								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	EPISCLERITITS	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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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
								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	CHRONIC ECZEMA 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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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]
			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
		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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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]
			6052-00001	2[redacted]/M	BELGIUM/ Caucasian			100	1	節足動物咬傷	ALLERGIC SKIN REACTION TO MOSQUITO BITES	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
			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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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]
			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
			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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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]
			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 THROMBOSIS IN THE TRUNCUS BRACHIOCEPHALICUS SINISTER EMBOLI OF THE LUNGS.	89	54	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	30	肺塞栓症		89	11	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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]
			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
								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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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
			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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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]
			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
			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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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
								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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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
			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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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								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
								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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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			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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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

表 2.7.6.4-8 重篤な有害事象を発現した症例の一覧（ランダム割付けされなかった被験者，54 週）（続き）

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	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

[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.
Maintenance Treatment Group：寛解維持試験での投与群，Induction Treatment Group：寛解導入試験での投与群

以下に，ゴリムマブの投与開始後に本試験で死亡及び重篤な有害事象を発現した症例のうち，重篤な有害事象により治験薬投与を中止した症例及び治験担当医師により重篤な有害事象が感染症と判断された症例の詳細を示す。

(1) ゴリムマブの使用と関連性のある死亡の叙述

被験者識別コード： 6407-00031

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
Died/ SAE/ Permanent discontinuation of study agent due to AE/ Serious infection	播種性結核 (Miliary tuberculosis)	Definite	13 Dec 2010 09 Jan 2011 (28 days)
Baseline demographic information: 5[redacted]-year-old (DOB: 14 Jul [redacted]) Caucasian male. Weight: 75.2 kg; height: 175 cm.			
Relevant medical history at baseline: 喫煙（過去）			
Baseline smoking status: Prior smoker (stopped > 1 year ago).			
Ulcerative colitis history: Date of diagnosis: 25 Feb 2009. UC disease duration: 1.2 years.			

Prior/concomitant medication, route	**Start date**	**End date**
Omeprazole	Not reported	Not reported
Potassium	Not reported	Not reported
Sodium chloride	Not reported	Not reported
Potassium	Not reported	Not reported
Methylprednisolone, intravenous	Not reported	Not reported
Augmentin /00756801/	Not reported	Not reported
Loperamide	Not reported	Not reported
Electrolyte solutions	Not reported	Not reported
Paracetamol	Not reported	Not reported
Ciprofloxacin, intravenous	Not reported	Not reported
Metamizole	Not reported	Not reported
Rifinah, oral	Not reported	Not reported
Furosemide	Not reported	Not reported
Enoxaparin	Not reported	Not reported
Calcium gluconate	Not reported	Not reported
Diazepam	Not reported	Not reported
Glucose	Not reported	Not reported
Omeprazole, oral	Not reported	Not reported
Sodium bicarbonate	Not reported	Not reported
Amikacin	Not reported	Not reported
Ranitidine	Not reported	Not reported
Dexamethasone	Not reported	Not reported
Baralgina	Not reported	Not reported
Primaxin	Not reported	Not reported
Corhydron /01932501/	Not reported	Not reported
Ceftriaxone	Not reported	Not reported
Hepa-merz /06109201/	Not reported	Not reported
Calcium	Not reported	Not reported
Vitamin K NOS	Not reported	Not reported
Theophylline	Not reported	Not reported
Metoclopramide	Not reported	Not reported
Midazolam, intravenous	Not reported	Not reported
Morphine, intravenous	Not reported	Not reported
Heparin, intravenous	Not reported	Not reported
Pancuronium, intravenous	Not reported	Not reported
Dopamine, intravenous	Not reported	Not reported
Glyceryl trinitrate, intravenous	Not reported	Not reported

Insulin, subcutaneous	Not reported	Not reported
Cyanocobalamin, intramuscular	Not reported	Not reported
Streptomycin, intramuscular	Not reported	Not reported
Sulfasalazine, oral	Not reported	Not reported
Ethambutol, oral	Not reported	Not reported
Ketoconazole, oral	Not reported	Not reported
Prednisone acetate, oral	05 Mar 2010	Ongoing
Mesalazine, oral	Prior	Ongoing
Azathioprine, oral	Prior	Ongoing
Isosorbide mononitrate, oral	Prior	Ongoing
Indapamide, oral	Prior	Ongoing
Isoniazid, oral	07 May 2010	Ongoing
Prednisone, oral	05 Mar 2010	09 Jan 2011
Mesalazine, oral	Prior	09 Jan 2011
Azathioprine, oral	Prior	09 Jan 2011
Isosorbide, oral	Prior	09 Jan 2011
Indapamide, oral	Prior	09 Jan 2011
Isoniazid, oral	07 May 2010	09 Jan 2011
Treatment group in induction:	200 mg → 100 mg SC.	
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.	
Dose adjusted?	No.	

Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 07 May 2010 (Study Day -42)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 07 May 2010 (Study Day -42)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 07 May 2010 (Study Day -42)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 07 May 2010 (Study Day -42)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 21 May 2010 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 21 May 2010 (Study Day -28)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 18 Jun 2010 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 18 Jun 2010 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 4 (Main), 19 Jul 2010 (Study Day 32)	Admin. 2/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 19 Jul 2010 (Study Day 32)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 8 (Main), 16 Aug 2010 (Study Day 60)	Admin. 3/ Inj. 5	Placebo	0 mg
Week 8 (Main), 16 Aug 2010 (Study Day 60)	Admin. 3/ Inj. 6	Golimumab	100 mg
Week 12 (Main), 10 Sep 2010 (Study Day 85)	Admin. 4/ Inj. 7	Placebo	0 mg
Week 12 (Main), 10 Sep 2010 (Study Day 85)	Admin. 4/ Inj. 8	Golimumab	100 mg
Week 16 (Main), 08 Oct 2010 (Study Day 113)	Admin. 5/ Inj. 9	Placebo	0 mg
Week 16 (Main), 08 Oct 2010 (Study Day 113)	Admin. 5/ Inj. 10	Golimumab	100 mg
Week 20 (Main), 05 Nov 2010 (Study Day 141)	Admin. 6/ Inj. 11	Placebo	0 mg
Week 20 (Main), 05 Nov 2010 (Study Day 141)	Admin. 6/ Inj. 12	Golimumab	100 mg
Week 24 (Main), 03 Dec 2010 (Study Day 169)	Admin. 7/ Inj. 13	Placebo	0 mg
Week 24 (Main), 03 Dec 2010 (Study Day 169)	Admin. 7/ Inj. 14	Golimumab	100 mg

Treatment status:	
Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	03 Dec 2010.
Last scheduled study treatment visit in maintenance:	Week 24 (Main).
Date of study treatment discontinuation:	29 Dec 2010.
Study status:	
Date of study discontinuation:	09 Jan 2011.
Reason for noncompletion:	Death.
Date of disposition status:	09 Jan 2011.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード 6407-00031 は，寛解導入試験（T17 試験）でゴリムマブを投与されたが 6 週に clinical response を示さなかったゴリムマブ寛解導入 non-responder である。本試験（皮下投

与）では，計画に従い寛解維持療法としてゴリムマブ 100 mg を投与された。2010 年 5 月 7 日に寛解導入試験（T17 試験）としてゴリムマブ 200 mg を初回投与され，5 月 21 日に 100 mg を投与された。

上記表以外に，CIOMS で報告されている病歴には，貧血，高血圧，冠動脈疾患，安定狭心症，腎結石症及び裂孔ヘルニアがあった。

治験薬初回投与前の 4 月 9 日（Day -70）に，軽度の潜伏結核を認めた。本事象は，重篤と判断され入院となった。治験担当医師は本事象をイソニアジドによる治療を受けていた感染症（結核）であると判断した。

CIOMS の報告では，本被験者は 3 月 26 日に実施したスクリーニング時の QuantiFERON-TB Gold の結果が陽性であったため，4 月 9 日に呼吸器科に入院した。本被験者には関連する病歴もなく，3 月 24 日に実施した胸部 X 線は正常で，3 月 25 日のスクリーニング時の精製ツベルクリン検査は陰性であり，活動性結核のエビデンスはなかった。過去に，BCG ワクチンを受けたことがあった。更に，4 月 14 日に再度実施した QuantiFERON-TB Gold の結果も陽性で，肺の CT スキャンに異常はなく，気管支鏡検査（検査日不明）では気管支粘膜のうっ血を認め，結核は陰性であった。治療薬としてイソニアジド（商品名 Nidiazid）を 5 月 7 日に開始し 6 カ月間継続した。4 月 15 日には，後遺症なく良好な状態で退院した。

治験薬の投与は変更しなかった。本事象は，4 月 15 日（Day -64）に回復した。治験担当医師は，本事象と治験薬の使用に関連性はないと判断した。

5 月 7 日及び 21 日に寛解導入療法を受けた後，寛解維持試験に組み入れられ 6 月 18 日（Day 1）にゴリムマブ 100 mg を初回投与された。

12 月 3 日（Day 169）のゴリムマブ投与後，12 月 13 日（Day 179）に高度の播種性結核（粟粒結核）と診断された。本事象は，重篤と判断され入院となり，本被験者は 2011 年 1 月 9 日に死亡した。治験担当医師は本事象はイソニアジドによる治療を受けていた感染症（結核）であると判断した。

CIOMS の報告では，発熱及び呼吸困難により 12 月 13 日に入院し，肺炎が疑われた。上記のとおり，潜伏結核の標準治療として 6 カ月間のイソニアジドによる治療を受けており，本試験でも被験者の状態は良好であったが，5-アミノサリチル酸，ステロイド及びアザチオプリンによる治療で著しく免疫が抑制されていた。本被験者は活動性結核患者に接触しておらず，イソニアジドによる治療のコンプライアンスは良好であった。

12 月 13 日から 27 日まで内科病棟に入院した。12 月 27 日の胸部 X 線で横隔膜及び肋骨横隔膜角が認められ，局所性病変や肺浸潤はなかった。肺門から横隔膜まで肺紋理増強が認められた。肺門，中間層及び横隔膜の上部に長期貯溜の徴候を認めた。心肥大を認め，大動脈は拡張していた。気管はずれておらず，胸骨後の甲状腺腫はなかった。胸部 X 線で両肺への病変の広がりを認めたため，12 月 28 日に内科病棟から呼吸器科病棟へ転科した。臨床検査では主に腎機能に高度の機能障害を示した。細菌鏡検で粟粒結核を確認した。

12 月 30 日，呼吸不全の悪化により本被験者は ICU に転科した。同日，気管支鏡検査で抗酸菌の存在が明らかとなり，気管支洗浄液を培養した結果，*Klebsiella pneumonia* 及び *Candida albicans* の増殖を認めた。

2011 年 1 月 9 日に「肺機能不全」により病院にて死亡したことが被験者の家族から報告された。剖検の結果，粟粒結核，小肺血管の血栓塞栓症，粘液性及び化膿性の気管支炎，化膿性の気管支肺炎及び肺の炭粉沈着を認めた。肝臓では局所性乾酪壊死及びびまん性の小結節性及び大結節性脂肪肝を認めた。脾臓では局所性乾酪壊死及び虚血性梗塞を認めた。膵臓の自己消化も認められた。

粟粒結核は *Mycobacterium tuberculosis* により引き起こされた播種性の結核であり，死亡の原因となった。試験開始前の組織病理学的生検において結腸結核感染の徴候はないと治験担当医師により報告された。剖検の結果，気管支鏡検査で検出された *K. pneumonia* 又は *C. albicans* による，死亡の一因であった又は実質的な死亡原因であった播種性疾患の徴候は認められなかった。

2011 年 2 月 23 日に，治験担当医師から追加情報を入手した。入院中の臨床検査値は次のとおりであった［first/last（基準値）］。：白血球数 4.5/2.0 g/L（4-10 g/L），赤血球数 4.54/2.38 T/L（4.5-5.9 T/L），ヘモグロビン 13.4/6.8 g/dL（13.5/17.5 g/dL），ヘマトクリット 40.6%/21.6%（40%-51%），血小板数 24/124 g/L（150-400 g/L），総カルシウム 1.8/1.82 mmol/L（2.2-2.6 mmol/L），マグネシウム 1.12/0.85 mmol/L（0.8-1 mmol/L），ナトリウム 138/133.4 mmol/L （135-145 mmol/L），カリウム 5.75/3.9 mmol/L（3.5-5 mmol/L），クレアチニン 339.3/284.2 µmol/L（62-124 µmol/L），及び BUN 36.4/27.1 mmol/L（2.5-6.4 mmol/L）。

2011 年 3 月 4 日に，治験担当医師から追加情報を入手した。入院中の臨床検査値は次のとおりであった［first/last］。：BUN 8.2/11.6 mmol/L，クレアチニン 139.4/99.8 µmol/L，ヘマトクリット 24.2%/39.9%，ヘモグロビン 7.9/13.0 g/dL，血小板数 131/61 g/L，カリウム 1.89/4.79 mmol/L，赤血球数 2.64/4.42 T/L，ナトリウム 141.6/143.7 mmol/L，白血球数 4.2/6.2 g/L（測定日及び基準値不明）。その他の臨床検査値は次のとおりであった［first/last（基準値）］：アラニン・アミノトランスフェラーゼ 17.9/32.5 U/L（0-32 U/L），アスパラギン酸アミノトランスフェラーゼ 16.7/43.3 U/L（0-32 U/L），ビリルビン 6.9/9.3 µmol/L（0-20 µmol/L）（測定日不明）。

播種性結核により治験薬投与を中止した。本事象の転帰確認日は 2011 年 1 月 9 日（Day 206）であった。治験担当医師は，本事象と治験薬との関連性を「ほぼ確実」と判断した。

(2) ゴリムマブの使用と関連性がないと判断された死亡及びその他の重篤な有害事象の叙述

1) ランダム割付けされた被験者

a) プラセボ群

被験者識別コード：6252-00020

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Serious infection	水腎症 (Lt PUJ stricture with hydronephrosis)	Probable	18 Jan 2009 Ongoing
SAE	腎結石症 (Lt renal calculi)	Unlikely	18 Jan 2009 Ongoing
SAE/ Permanent discontinuation of study agent due to AE/ Serious infection	播種性結核 (Miliary tuberculosis)	Probable	26 Feb 2009 Ongoing

SAE/ Serious infection	発熱 (Recurrent pyrexia)	Probable	09 Mar 2009 Ongoing

Baseline demographic information: 3[redacted]-year-old (DOB: 14 Oct [redacted]) Asian male from India.
Weight: 40 kg; height: 156 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 08 Aug 2002.
UC disease duration: 6.3 years.

Prior/concomitant medication, route	Start date	End date
Azathioprine, oral	13 Jun 2008	Ongoing
Folic acid, oral	13 Jun 2008	Ongoing
Prednisolone, oral	13 Jun 2008	Ongoing
Mesalazine, oral	13 Jun 2008	Ongoing
Pantoprazole, oral	13 Jun 2008	Ongoing
Zevit, oral	13 Jun 2008	Ongoing
Azathioprine, oral	13 Jun 2008	19 Jan 2009
Zevit, oral	13 Jun 2008	22 Jan 2009
Ceftazidime, intravenous	22 Jan 2009	26 Jan 2009
Diclofenac, intramuscular	22 Jan 2009	23 Jan 2009
Ranitidine, intravenous	22 Jan 2009	26 Jan 2009
Hyoscine, intramuscular	26 Jan 2009	26 Jan 2009
Diclofenac, intramuscular	26 Jan 2009	26 Jan 2009
Ceftazidime, intravenous	18 Jan 2009	18 Jan 2009

Treatment group in induction: 4 mg/kg IV.
Treatment group in maintenance: Responder to golimumab induction → randomized to placebo maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 17 Nov 2008 (Study Day -37)	NA	Golimumab	4 mg/kg
Week 0 (Main), 24 Dec 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 24 Dec 2008 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 24 Dec 2008 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 17 Jan 2009 (Study Day 25)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 17 Jan 2009 (Study Day 25)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 17 Jan 2009 (Study Day 25)	Admin. 2/ Inj. 6	Placebo	0 mg
Unscheduled 1 (Main)—dose not done	NA	NA	NA

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Adverse event.
Date of last study agent administration in maintenance: 17 Jan 2009.
Last scheduled study treatment visit in maintenance: Week 4 (Main).
Date of study treatment discontinuation: 08 Apr 2009.

Study status:
Date of study discontinuation: 08 Apr 2009.
Reason for noncompletion: Lost to follow-up.
Date of disposition status: 08 Apr 2009.
Ended study participation as of Week 54? Yes.
Entered extension study? No.

被験者識別コード：6354-00001

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Exacerbation UC)	Not related	29 Apr 2009 14 May 2009 (16 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 29 Sep [redacted]) Caucasian female.
Weight: 110.3 kg; height: 168 cm.

Relevant medical history at baseline: 報告なし		
Baseline smoking status: Not reported.		
Ulcerative colitis history: Date of diagnosis: 1983. UC disease duration: 25.0 years.		
Prior/concomitant medication, route	**Start date**	**End date**
Prednisone, oral	24 Nov 2008	Ongoing
Mesalazine, oral	September 2008	Ongoing
Prednisone, oral	24 Nov 2008	April 2009
Fusidic acid, topical	17 Feb 2009	March 2009
Methylcellulose, ophthalmic	17 Feb 2009	February 2009
Mesalazine, oral	September 2008	13 May 2009
Ibuprofen, oral	14 Feb 2009	16 Feb 2009
Metronidazole, topical	19 Mar 2009	29 Apr 2009
Prednisone, intravenous	04 May 2009	18 May 2009
Vitamin B12 nos, intramuscular	26 Jun 2009	26 Jun 2009
Hydrocortisone, intravenous	14 May 2009	16 May 2009
Methadone, intramuscular	16 May 2009	18 May 2009
Gentamicin, intravenous	06 May 2009	14 May 2009
Cefuroxime, intravenous	06 May 2009	07 May 2009
Metronidazole, intravenous	06 May 2009	15 May 2009
Ciprofloxacin, oral	04 May 2009	05 May 2009
Amoxicillin, intravenous	04 May 2009	05 May 2009
Nadroparin, subcutaneous	05 May 2009	20 May 2009
Prednisone, oral	18 May 2009	Ongoing
Mercaptopurine, oral	04 May 2009	15 May 2009
Betamethasone, rectal	04 May 2009	15 May 2009
Mesalazine, rectal	10 May 2009	29 Jun 2009
Infliximab, intravenous	08 May 2009	08 May 2009
Ondansetron, intravenous	16 May 2009	20 May 2009
Tramadol, oral	18 May 2009	20 May 2009
Treatment group in induction: 4 mg/kg IV. **Treatment group in maintenance:** Responder to golimumab induction → randomized to placebo maintenance. **Dose adjusted?** Yes. **Adjusted treatment group:** Golimumab 100 mg.		

Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 15 Dec 2008 (Study Day -38)	NA	Golimumab	4.0 mg/kg
Week 0 (Main), 22 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 22 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 22 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 19 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 19 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 19 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Unscheduled 1 (Main), 10 Mar 2009 (Study Day 48)	Admin. 1/ Inj. 1	Placebo	0 mg
Unscheduled 1 (Main), 10 Mar 2009 (Study Day 48)	Admin. 1/ Inj. 2	Golimumab	100 mg
Unscheduled 1 (Main), 10 Mar 2009 (Study Day 48)	Admin. 1/ Inj. 3	Placebo	0 mg
Unscheduled 2 (Main)—dose not done	NA	NA	NA

Treatment status:	
Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	10 Mar 2009.
Last scheduled study treatment visit in maintenance:	Week 4 (Main).
Date of study treatment discontinuation:	10 Mar 2009.
Study status:	
Date of disposition status:	29 Jun 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：6426-00006

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Ulcerative colitis flare)	Not related	13 Jul 2009 22 Jul 2009 (10 days)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Ulcerative colitis flare)	Not related	15 Sep 2009 29 Sep 2009 (15 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 31 Jul [redacted]) Caucasian male.
Weight: 64.2 kg; height: 178 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:
Date of diagnosis: 18 Sep 2008.
UC disease duration: 0.2 years.

Prior/concomitant medication, route	Start date	End date
Omeprazole, oral	Prior	Ongoing
Methylprednisolone, oral	18 Sep 2008	Ongoing
Mesalazine, oral	20 Oct 2008	Ongoing
Fortrans /01064301/, oral	07 Dec 2008	08 Dec 2008
Propofol, intravenous	09 Dec 2008	09 Dec 2008
Supradyn /00453001/, oral	11 Dec 2008	Ongoing
Fortrans /01064301, oral	19 Jan 2009	19 Jan 2009
Methylprednisolone, oral	18 Sep 2008	12 Apr 2009
Mesalazine, oral	20 Oct 2008	Ongoing
Omeprazole, oral	Prior	14 Apr 2009
Supradyn /00453001/, oral	11 Dec 2008	01 Feb 2009
Paracetamol, oral	06 May 2009	29 May 2009
Methylprednisolone, intravenous	13 Jul 2009	22 Jul 2009
Glucose, intravenous	13 Jul 2009	20 Jul 2009
Sodium chloride, intravenous	13 Jul 2009	20 Jul 2009
Ranitidine, intravenous	13 Jul 2009	20 Jul 2009
Duocid /00892601, intravenous	14 Jul 2009	20 Jul 2009
Ciprofloxacin, intravenous	14 Jul 2009	20 Jul 2009
Infliximab, intravenous	17 Jul 2009	17 Jul 2009
Loratadine, oral	17 Jul 2009	17 Jul 2009

Treatment group in induction: 4 mg/kg IV.
Treatment group in maintenance: Responder to golimumab induction → randomized to placebo maintenance.
Dose adjusted? Yes.
Adjusted treatment group: Golimumab 100 mg.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 10 Dec 2008 (Study Day -41)	NA	Golimumab	4.0 mg/kg
Week 0 (Main), 20 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 20 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 20 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 17 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 17 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 17 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 17 Mar 2009 (Study Day 57)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 17 Mar 2009 (Study Day 57)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 17 Mar 2009 (Study Day 57)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 14 Apr 2009 (Study Day 85)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 14 Apr 2009 (Study Day 85)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 14 Apr 2009 (Study Day 85)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 12 May 2009 (Study Day 113)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 12 May 2009 (Study Day 113)	Admin. 5/ Inj. 14	Placebo	0 mg

Week 16 (Main), 12 May 2009 (Study Day 113)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 09 Jun 2009 (Study Day 141)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 09 Jun 2009 (Study Day 141)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 20 (Main), 09 Jun 2009 (Study Day 141)	Admin. 6/ Inj. 18	Placebo	0 mg
Unscheduled 1 (Main), 30 Jun 2009 (Study Day 162)	Admin. 1/ Inj. 1	Golimumab	100 mg
Unscheduled 1 (Main), 30 Jun 2009 (Study Day 162)	Admin. 1/ Inj. 2	Placebo	0 mg
Unscheduled 1 (Main), 30 Jun 2009 (Study Day 162)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 24 (Main), 07 Jul 2009 (Study Day 169)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 24 (Main), 07 Jul 2009 (Study Day 169)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 24 (Main), 07 Jul 2009 (Study Day 169)	Admin. 2/ Inj. 6	Golimumab	100 mg
Unscheduled 2 (Main)—dose not done	NA	NA	NA

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	07 Jul 2009.
Last scheduled study treatment visit in maintenance:	Week 24 (Main).
Date of study treatment discontinuation:	16 Jul 2009.

Study status:

Date of study discontinuation:	16 Jul 2009.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	Flare of disease uncontrolled by study medication.
Date of disposition status:	16 Jul 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7801-00002

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of UC)	Unlikely	16 Sep 2009 30 Sep 2009 (15 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 21 May [redacted]) Asian male. Weight: 75 kg; height: 168 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:

Date of diagnosis:	March 1993.
UC disease duration:	16.1 years.

Prior/concomitant medication, route	**Start date**	**End date**
Sulfasalazine, oral	26 Nov 2008	Ongoing
Mercaptopurine, oral	26 Nov 2008	Ongoing
Timepidium bromide, oral	26 Nov 2008	Ongoing
Lactobacillus nos, oral	26 Nov 2008	Ongoing
Prednisolone, oral	11 Mar 2009	Ongoing
Colyte /00751601/, oral	20 Apr 2009	20 Apr 2009
Hyoscine butylbromide, intravenous	20 Apr 2009	20 Apr 2009
Pethidine hydrochloride, intravenous	20 Apr 2009	20 Apr 2009
Naloxone hydrochloride, intravenous	20 Apr 2009	20 Apr 2009
Colyte /00751601/, oral	04 Jun 2009	04 Jun 2009
Hyoscine butylbromide, intravenous	04 Jun 2009	04 Jun 2009
Pethidine hydrochloride, intravenous	04 Jun 2009	04 Jun 2009
Naloxone hydrochloride, intravenous	04 Jun 2009	04 Jun 2009
Prednisolone, oral	11 Mar 2009	05 Oct 2009
Iron, oral	03 Aug 2009	16 Sep 2009
Colyte /00751601/, oral	03 Sep 2009	03 Sep 2009
Hyoscine, intravenous	03 Sep 2009	03 Sep 2009
Pethidine, intravenous	03 Sep 2009	03 Sep 2009
Naloxone, intravenous	03 Sep 2009	03 Sep 2009

Hyoscine, oral	14 Sep 2009	16 Sep 2009
Lactec /00490001/, intravenous	16 Sep 2009	16 Sep 2009
Tacrolimus, oral	16 Sep 2009	Ongoing
Amino acids nos w/electrolytes nos/glucose, intravenous	16 Sep 2009	24 Sep 2009
Glucose w/electrolytes, intravenous	16 Sep 2009	24 Sep 2009
Cefotiam, intravenous	16 Sep 2009	24 Sep 2009
Saccharated iron oxide, intravenous	16 Sep 2009	21 Sep 2009
Omeprazole, intravenous	16 Sep 2009	18 Sep 2009
Glucose, intravenous	16 Sep 2009	21 Sep 2009
Indometacin, topical	23 Sep 2009	25 Sep 2009
Lansoprazole, oral	19 Sep 2009	Ongoing
Colyte /00751601/, oral	18 Dec 2009	18 Dec 2009
Hyoscine, intravenous	18 Dec 2009	18 Dec 2009
Flunitrazepam, intravenous	18 Dec 2009	18 Dec 2009
Pethidine, intravenous	18 Dec 2009	18 Dec 2009
Flumazenil, intravenous	18 Dec 2009	18 Dec 2009
Naloxone, intravenous	18 Dec 2009	18 Dec 2009

Treatment group in induction:	200 mg → 100 mg SC.
Treatment group in maintenance:	Responder to golimumab induction → randomized to placebo maintenance.
Dose adjusted?	Yes.
Adjusted treatment group:	Golimumab 100 mg.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 24 Apr 2009 (Study Day -45)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 24 Apr 2009 (Study Day -45)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 24 Apr 2009 (Study Day -45)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 24 Apr 2009 (Study Day -45)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 11 May 2009 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 11 May 2009 (Study Day -28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 11 May 2009 (Study Day -28)	Admin. 2/ Inj. 7	Golimumab	100 mg
Week 0 (Main), 08 Jun 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 08 Jun 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 08 Jun 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 06 Jul 2009 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 06 Jul 2009 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 06 Jul 2009 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 03 Aug 2009 (Study Day 57)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 03 Aug 2009 (Study Day 57)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 03 Aug 2009 (Study Day 57)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 07 Sep 2009 (Study Day 92)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 12 (Main), 07 Sep 2009 (Study Day 92)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 12 (Main), 07 Sep 2009 (Study Day 92)	Admin. 1/ Inj. 3	Placebo	0 mg
Unscheduled 1 (Main)—dose not done	NA	NA	NA

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	07 Sep 2009.
Last scheduled study treatment visit in maintenance:	Week 12 (Main).
Date of study treatment discontinuation:	16 Sep 2009.

Study status:

Date of disposition status:	28 Dec 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7821-00003

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
Permanent discontinuation of study agent due to AE/ Event of interest: Opportunistic infection	サイトメガロウイルス感染 (Cytomegalovirus infection)	Unlikely	28 Nov 2009 07 Dec 2009 (10 days)
SAE/ Permanent discontinuation of study agent due to AE/ Serious infection/ Event of interest: Opportunistic infection	サイトメガロウイルス感染 (Cytomegalovirus infection)	Unlikely	07 Dec 2009 23 Dec 2009 (17 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 14 Mar [redacted]) Asian male from Japan. Weight: 71 kg; height: 172 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 22 Jun 2007.
UC disease duration: 2.2 years.

Prior/concomitant medication, route	Start date	End date
Azathioprine, oral	27 Mar 2009	Ongoing
Mesalazine, oral	27 Mar 2009	Ongoing
Rabeprazole sodium, oral	27 Mar 2007	Ongoing
Rebamipide, oral	27 Mar 2009	Ongoing
Lactobacillus bifidus, lyophilized, oral	24 Apr 2009	Ongoing
Isoniazid, oral	24 Jul 2009	Ongoing
Pyridoxal phosphate, oral	24 Jul 2009	Ongoing
Cefcapene pivoxil hydrochloride, oral	31 Jul 2009	02 Aug 2009
Povidone-iodine, topical	31 Jul 2009	14 Sep 2009
Loxoprofen sodium, oral	31 Jul 2009	04 Aug 2009
Pl gran., oral	31 Jul 2009	02 Aug 2009
Colyte /00751601, oral	13 Aug 2009	13 Aug 2009
Metoclopramide, oral	13 Aug 2009	13 Aug 2009
Senna alexandrina, oral	12 Aug 2009	12 Aug 2009
Colyte/00751601, oral	01 Oct 2009	01 Oct 2009
Metoclopramide, oral	01 Oct 2009	01 Oct 2009
Senna alexandrina, oral	30 Sep 2009	30 Sep 2009
Hydrocortison med terramycin, topical	05 Oct 2009	Ongoing
Azathioprine, oral	27 Mar 2009	30 Nov 2009
Mesalazine, oral	27 Mar 2009	06 Dec 2009
Rabeprazole, oral	27 Mar 2009	06 Dec 2009
Rebamipide, oral	27 Mar 2009	13 Dec 2009
Lactobacillus bifidus, lyophilized, oral	24 Apr 2009	06 Dec 2009
Isoniazid, oral	24 Jul 2009	04 Dec 2009
Pyridoxal phosphate, oral	24 Jul 2009	04 Dec 2009
Oxytetracycline, topical	05 Oct 2009	30 Nov 2009
Cefcapene, oral	06 Nov 2009	10 Nov 2009
Povidone-iodine, topical	30 Oct 2009	06 Dec 2009
Loxoprofen, oral	03 Nov 2009	03 Nov 2009
Elental, oral	02 Dec 2009	06 Dec 2009
Cefcapene, oral	02 Dec 2009	04 Dec 2009
Loxoprofen, oral	30 Nov 2009	13 Dec 2009
Streptococcus faecalis, oral	02 Dec 2009	06 Dec 2009
Levofloxacin, oral	04 Dec 2009	06 Dec 2009
Soldem 3A, intravenous	07 Dec 2009	16 Dec 2009
Vitamedin /00274301, intravenous	07 Dec 2009	16 Dec 2009
Figiosol 3 go, intravenous	07 Dec 2009	17 Dec 2009
Foscarnet, intravenous	09 Dec 2009	23 Dec 2009
Ethacridine, topical	13 Dec 2009	18 Dec 2009

Mesalazine, oral	09 Dec 2009	Ongoing
Glucose, intravenous	09 Dec 2009	23 Dec 2009
Glycerol, rectal	08 Dec 2009	08 Dec 2009
Oxytetracycline, topical	21 Dec 2009	23 Dec 2009
Lactobacillus bifidus, lyophilized, oral	23 Dec 2009	Ongoing
Rabeprazole, oral	23 Dec 2009	Ongoing
Isoniazid, oral	23 Dec 2009	19 Jan 2010
Pyridoxal phosphate, oral	23 Dec 2009	19 Jan 2010
Lidocaine, topical	08 Dec 2009	08 Dec 2009

Treatment group in induction: 200 mg → 100 mg SC.
Treatment group in maintenance: Responder to golimumab induction → randomized to placebo maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 24 Aug 2009 (Study Day -42)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 24 Aug 2009 (Study Day -42)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 24 Aug 2009 (Study Day -42)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 24 Aug 2009 (Study Day -42)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 07 Sep 2009 (Study Day -28)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 07 Sep 2009 (Study Day -28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 0 (Main), 05 Oct 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 05 Oct 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 05 Oct 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 06 Nov 2009 (Study Day 33)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 06 Nov 2009 (Study Day 33)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 06 Nov 2009 (Study Day 33)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main)—dose not done	NA	NA	NA

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Adverse event.
Date of last study agent administration in maintenance: 06 Nov 2009.
Last scheduled study treatment visit in maintenance: Week 4 (Main).
Date of study treatment discontinuation: 04 Dec 2009.

Study status:
Date of disposition status: 08 Mar 2010.
Ended study participation as of Week 54? Yes.
Entered extension study? No.

被験者識別コード：6578-00008

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Serious infection	肺炎 (Right side focal pneumonia, moderate duration, hyperthermic syndrome)	Not related	09 Dec 2010 22 Dec 2010 (14 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 23 Feb [redacted]) male (race: Other).
Weight: 70.6 kg; height: 168 cm.

Relevant medical history at baseline: 関節痛

Baseline smoking status: Nonsmoker.

Ulcerative colitis history:
Date of diagnosis: 30 Jul 2007.
UC disease duration: 2.4 years.

Prior/concomitant medication, route	Start date	End date
Methylprednisolone, oral	30 Nov 2010	Ongoing
Mesalazine, rectal	30 Nov 2010	08 Dec 2010
Ceftriaxone	09 Dec 2010	Not reported
Levofloxacin	09 Dec 2010	Not reported
Rabeprazole, oral	09 Dec 2010	Not reported

Prednisolone, oral	09 Dec 2010	Ongoing

Treatment group in induction:	400 mg → 200 mg SC.
Treatment group in maintenance:	Responder to golimumab induction → randomized to placebo maintenance.
Dose adjusted?	Yes.
Adjusted treatment group:	Golimumab 100 mg.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 16 Dec 2009 (Study Day -41)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 16 Dec 2009 (Study Day -41)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 16 Dec 2009 (Study Day -41)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 16 Dec 2009 (Study Day -41)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 28 Dec 2009 (Study Day -29)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 28 Dec 2009 (Study Day -29)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 26 Jan 2010 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 26 Jan 2010 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 26 Jan 2010 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 16 Feb 2010 (Study Day 22)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 16 Feb 2010 (Study Day 22)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 16 Feb 2010 (Study Day 22)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 16 Mar 2010 (Study Day 50)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 8 (Main), 16 Mar 2010 (Study Day 50)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 12 (Main)—dose not done	NA	NA	NA
Week 12 (Main), 27 Apr 2010 (Study Day 92)	Admin. 2/ Inj. 3	Placebo	0 mg
Week 12 (Main), 27 Apr 2010 (Study Day 92)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 16 (Main)—dose not done	NA	NA	NA
Week 16 (Main), 18 May 2010 (Study Day 113)	Admin. 3/ Inj. 6	Golimumab	100 mg
Week 16 (Main), 18 May 2010 (Study Day 113)	Admin. 3/ Inj. 5	Placebo	0 mg
Week 20 (Main), 08 Jun 2010 (Study Day 134)	Admin. 4/ Inj. 7	Golimumab	100 mg
Week 20 (Main), 08 Jun 2010 (Study Day 134)	Admin. 4/ Inj. 8	Placebo	0 mg
Week 24 (Main)—dose not done	NA	NA	NA
Week 24 (Main), 06 Jul 2010 (Study Day 162)	Admin. 5/ Inj. 9	Golimumab	100 mg
Week 24 (Main), 06 Jul 2010 (Study Day 162)	Admin. 5/ Inj. 10	Placebo	0 mg
Week 28 (Main), 10 Aug 2010 (Study Day 197)	Admin. 6/ Inj. 11	Golimumab	100 mg
Week 28 (Main), 10 Aug 2010 (Study Day 197)	Admin. 6/ Inj. 12	Placebo	0 mg
Week 32 (Main), 14 Sep 2010 (Study Day 232)	Admin. 7/ Inj. 13	Placebo	0 mg
Week 32 (Main), 14 Sep 2010 (Study Day 232)	Admin. 7/ Inj. 14	Golimumab	100 mg
Week 36 (Main), 05 Oct 2010 (Study Day 253)	Admin. 8/ Inj. 15	Placebo	0 mg
Week 36 (Main), 05 Oct 2010 (Study Day 253)	Admin. 8/ Inj. 16	Golimumab	100 mg
Week 40 (Main), 02 Nov 2010 (Study Day 281)	Admin. 9/ Inj. 17	Placebo	0 mg
Week 40 (Main), 02 Nov 2010 (Study Day 281)	Admin. 9/ Inj. 18	Golimumab	100 mg
Week 44 (Main)—dose not done	NA	NA	NA

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Unsatisfactory therapeutic effect.
Date of last study agent administration in maintenance:	02 Nov 2010.
Last scheduled study treatment visit in maintenance:	Week 40 (Main).
Date of study treatment discontinuation:	30 Nov 2010.

Study status:

Date of study discontinuation:	30 Nov 2010.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	The subject was discontinued from study due to lack of efficacy.
Date of disposition status:	30 Nov 2010.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7006-00006

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Exacerbation of ulcerative colitis)	Not related	30 Aug 2010 06 Sep 2010 (8 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 10 Nov [redacted]) Caucasian female.
Weight: 54.3 kg; height: 166 cm.

Relevant medical history at baseline: 関節痛

Baseline smoking status: Nonsmoker.

Ulcerative colitis history:
Date of diagnosis: May 2005.
UC disease duration: 4.6 years.

Prior/concomitant medication, route	Start date	End date
Budesonide, oral	25 Nov 2009	Ongoing
Mesalazine, oral	01 Dec 2007	Ongoing
Fish oil, oral	31 Dec 2009	Ongoing
Paracetamol, oral	01 May 2005	Ongoing
Calcium carbonate, oral	01 Nov 2006	Ongoing
Ergocalciferol, oral	05 Jan 2010	Ongoing
Fleet /01605601, rectal	01 Mar 2010	01 Mar 2010
Midazolam, intravenous	01 Mar 2010	01 Mar 2010
Fentanyl, intravenous	01 Mar 2010	01 Mar 2010
Propofol, intravenous	01 Mar 2010	01 Mar 2010
Budesonide, oral	25 Nov 2009	15 Jun 2010
Mesalazine, oral	December 2007	Ongoing
Paracetamol, oral	May 2005	Ongoing
Panadeine co, oral	May 2005	Ongoing
Calcium carbonate, oral	November 2006	Ongoing
Hydrocortisone, topical	20 May 2010	Ongoing
Fleet /01605601, rectal	12 Jul 2010	12 Jul 2010
Fentanyl, intravenous	12 Jul 2010	12 Jul 2010
Propofol, intravenous	12 Jul 2010	12 Jul 2010
Hyoscine, oral	03 Aug 2010	Ongoing
Propofol, intravenous	30 Jul 2010	30 Jul 2010
Fentanyl, intravenous	30 Jul 2010	30 Jul 2010
Mebeverine, oral	23 Aug 2010	25 Aug 2010
Loperamide, oral	23 Aug 2010	25 Aug 2010
Hydrocortisone, intravenous	30 Aug 2010	01 Sep 2010
Sodium chloride, intravenous	30 Aug 2010	31 Aug 2010
Fleet /01605601/, rectal	30 Aug 2010	30 Aug 2010
Propofol, intravenous	30 Aug 2010	30 Aug 2010
Prednisolone, oral	01 Sep 2010	Ongoing

Treatment group in induction: 400mg → 200mg SC.
Treatment group in maintenance: Responder to golimumab induction → randomized to placebo maintenance.
Dose adjusted? Yes.
Adjusted treatment group: Golimumab 100 mg.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 18 Jan 2010 (Study Day -42)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 18 Jan 2010 (Study Day -42)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 18 Jan 2010 (Study Day -42)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 18 Jan 2010 (Study Day -42)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 01 Feb 2010 (Study Day -28)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 01 Feb 2010 (Study Day -28)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 01 Mar 2010 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 01 Mar 2010 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 4 (Main), 29 Mar 2010 (Study Day 29)	Admin. 2/ Inj. 3	Placebo	0 mg

Week 4 (Main), 29 Mar 2010 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 8 (Main), 22 Apr 2010 (Study Day 53)	Admin. 3/ Inj. 5	Placebo	0 mg
Week 8 (Main), 22 Apr 2010 (Study Day 53)	Admin. 3/ Inj. 6	Placebo	0 mg
Week 12 (Main), 20 May 2010 (Study Day 81)	Admin. 4/ Inj. 7	Placebo	0 mg
Week 12 (Main), 20 May 2010 (Study Day 81)	Admin. 4/ Inj. 8	Placebo	0 mg
Week 16 (Main), 17 Jun 2010 (Study Day 109)	Admin. 5/ Inj. 9	Placebo	0 mg
Week 16 (Main), 17 Jun 2010 (Study Day 109)	Admin. 5/ Inj. 10	Placebo	0 mg
Unscheduled 1 (Main), 12 Jul 2010 (Study Day 134)	Admin. 1/ Inj. 1	Golimumab	100 mg
Unscheduled 1 (Main), 12 Jul 2010 (Study Day 134)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 20 (Main), 03 Aug 2010 (Study Day 156)	Admin. 2/ Inj. 3	Golimumab	100 mg
Week 20 (Main), 03 Aug 2010 (Study Day 156)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 24 (Main), 23 Aug 2010 (Study Day 176)	Admin. 3/ Inj. 5	Placebo	0 mg
Week 24 (Main), 23 Aug 2010 (Study Day 176)	Admin. 3/ Inj. 6	Golimumab	100 mg
Unscheduled 2 (Main)—dose not done	NA	NA	NA
Treatment status:			
Study treatment discontinuation?	Yes.		
Reason for treatment discontinuation:	Adverse event.		
Date of last study agent administration in maintenance:	23 Aug 2010.		
Last scheduled study treatment visit in maintenance:	Week 24 (Main).		
Date of study treatment discontinuation:	30 Aug 2010.		
Study status:			
Date of disposition status:	16 Mar 2011.		
Ended study participation as of Week 54?	Yes.		
Entered extension study?	No.		

被験者識別コード：7008-00006

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Unlikely	09 Sep 2009 16 Sep 2009 (8 days)
Baseline demographic information: 3[redacted]-year-old (DOB: 17 Mar [redacted]) Caucasian male. Weight: 83.3 kg; height: 178 cm.			
Relevant medical history at baseline: 関節痛，アフタ性口内炎， 喫煙（過去）			
Baseline smoking status: Prior smoker (stopped ≤ 1 year ago)			
Ulcerative colitis history: Date of diagnosis: September 1992. UC disease duration: 16.5 years.			

Prior/concomitant medication, route	**Start date**	**End date**
Mesalazine, oral	1997	Ongoing
Warfarin, oral	April 2007	17 Mar 2009
Prednisone, oral	22 Feb 2007	Ongoing
Enoxaparin sodium, subcutaneous	18 Mar 2009	30 Mar 2009
Warfarin, oral	31 Mar 2009	29 Apr 2009
Fentanyl, intravenous	25 Mar 2009	25 Mar 2009
Propofol, intravenous	25 Mar 2009	25 Mar 2009
Enoxaparin sodium, subcutaneous	30 Apr 2009	02 May 2009
Warfarin, oral	03 May 2009	Ongoing
Fentanyl, intravenous	01 May 2009	01 May 2009
Midazolam, intravenous	01 May 2009	01 May 2009
Propofol, intravenous	01 May 2009	01 May 2009
Metoclopramide, oral	28 Apr 2009	30 Apr 2009
Paracetamol, oral	28 Apr 2009	29 Apr 2009
Oxycodone hydrochloride, oral	29 Apr 2009	29 Apr 2009
Morphine, intravenous	28 Apr 2009	30 Apr 2009
Hydrocortisone, intravenous	28 Apr 2009	28 Apr 2009
Mesalazine, oral	1997	18 Sep 2009
Prednisone, oral	22 Feb 2009	09 Sep 2009

Warfarin, subcutaneous	03 May 2009	Ongoing
Calcium carbonate, oral	08 Jul 2009	09 Sep 2009
Ferric hydroxide polymaltose complex, intravenous	15 Jul 2009	15 Jul 2009
Prednisone, oral	24 Sep 2009	28 Oct 2009
Paracetamol, oral	09 Sep 2009	24 Sep 2009
Oxycodone, oral	17 Sep 2009	21 Sep 2009
Codeine, oral	20 Sep 2009	22 Sep 2009
Loperamide, oral	20 Sep 2009	Ongoing
Psyllium hydrophilic mucilloid, oral	19 Sep 2009	22 Sep 2009
Potassium, oral	14 Sep 2009	20 Sep 2009
Hydrocortisone, intravenous	10 Sep 2009	17 Sep 2009
Metoclopramide, intravenous	15 Sep 2009	15 Sep 2009
Morphine, intravenous	09 Sep 2009	09 Sep 2009
Morphine, subcutaneous	10 Sep 2009	10 Sep 2009
Metoclopramide, intravenous	09 Sep 2009	10 Sep 2009
Hyoscine, intravenous	09 Sep 2009	10 Sep 2009
Oxycodone, intravenous	10 Sep 2009	10 Sep 2009
Magnesium aspartate, oral	14 Sep 2009	15 Sep 2009
Morphine, intravenous	15 Sep 2009	15 Sep 2009
Fentanyl, intravenous	16 Sep 2009	17 Sep 2009
Potassium, oral	16 Sep 2009	18 Sep 2009
Spironolactone, oral	16 Sep 2009	24 Sep 2009
Morphine, oral	17 Sep 2009	17 Sep 2009
Droperidol, intravenous	23 Sep 2009	23 Sep 2009
Granisetron, intravenous	22 Sep 2009	22 Sep 2009
Heparin, intravenous	12 Sep 2009	23 Sep 2009
Metronidazole, intravenous	10 Sep 2009	14 Sep 2009
Ampicillin, intravenous	10 Sep 2009	14 Sep 2009
Hydrocortisone, rectal	03 Nov 2009	Ongoing
Iron, intravenous	09 Dec 2009	09 Dec 2009
Codeine, oral	24 Sep 2009	27 Nov 2009

Treatment group in induction:	400 mg → 200 mg SC.
Treatment group in maintenance:	Responder to golimumab induction → randomized to placebo maintenance.
Dose adjusted?	Yes.
Adjusted treatment group:	Golimumab 100 mg.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 08 Apr 2009 (Study Day -44)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 08 Apr 2009 (Study Day -44)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 08 Apr 2009 (Study Day -44)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 08 Apr 2009 (Study Day -44)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 22 Apr 2009 (Study Day -30)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 22 Apr 2009 (Study Day -30)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 22 Apr 2009 (Study Day -30)	Admin. 2/ Inj. 7	Golimumab	100 mg
Week 0 (Main), 22 May 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 22 May 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 22 May 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 24 Jun 2009 (Study Day 34)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 4 (Main), 24 Jun 2009 (Study Day 34)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 4 (Main), 24 Jun 2009 (Study Day 34)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 8 (Main), 15 Jul 2009 (Study Day 55)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 8 (Main), 15 Jul 2009 (Study Day 55)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 8 (Main), 15 Jul 2009 (Study Day 55)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 12 (Main), 19 Aug 2009 (Study Day 90)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 12 (Main), 19 Aug 2009 (Study Day 90)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 12 (Main), 19 Aug 2009 (Study Day 90)	Admin. 3/ Inj. 9	Golimumab	100 mg

Treatment status:	
Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	19 Aug 2009.
Last scheduled study treatment visit in maintenance:	Week 12 (Main).
Date of study treatment discontinuation:	30 Sep 2009.
Study status:	
Date of disposition status:	11 Dec 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7008-00020

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Unlikely	01 Oct 2010 13 Dec 2010 (74 days)
SAE	潰瘍性大腸炎 (Severe flare of ulcerative colitis in rectal remnant)	Not related	30 Dec 2010 06 Jan 2011 (8 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 22 Jun [redacted]) Caucasian female.
Weight: 110 kg; height: 164 cm.

Relevant medical history at baseline: 関節痛，アフタ性口内炎，喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:
Date of diagnosis: 1993.
UC disease duration: 16.4 years.

Prior/concomitant medication, route	**Start date**	**End date**
Seretide, inhalation	Not reported	Ongoing
Salbutamol, inhalation	Not reported	Ongoing
Folic acid, oral	12 Feb 2010	Ongoing
Omeprazole, oral	August 2009	Ongoing
Mirtazapine, oral	04 May 2010	Ongoing
Oxycodone hydrochloride, oral	January 2008	Ongoing
Cefalexin, oral	02 Jun 2010	08 Jun 2010
Prednisone, oral	21 Apr 2010	Ongoing
Methotrexate, subcutaneous	28 Jan 2010	Ongoing
Balsalazide sodium, oral	September 2008	Ongoing
Prednisone, oral	21 Apr 2010	10 Nov 2010
Methotrexate, subcutaneous	12 Feb 2010	01 Sep 2010
Balsalazide, oral	September 2008	11 Nov 2010
Folic acid, oral	12 Feb 2010	November 2010
Oxazepam, oral	2010	Ongoing
Panadeine co, oral	02 Jun 2010	November 2010
Oxycodone, oral	2010	18 Nov 2010
Methotrexate, subcutaneous	15 Sep 2010	November 2010
Midazolam, intravenous	29 Oct 2010	29 Oct 2010
Fentanyl, intravenous	29 Oct 2010	29 Oct 2010
Propofol, intravenous	29 Oct 2010	29 Oct 2010
Balsalazide, oral	12 Nov 2010	07 Dec 2010
Prednisolone, oral	19 Nov 2010	14 Dec 2010
Prednisolone, oral	03 Jan 2011	Ongoing
Oxycodone, oral	10 Dec 2010	13 Dec 2010
Oxycodone, oral	01 Jan 2011	04 Jan 2011
Hydrocortisone, intravenous	12 Nov 2010	18 Nov 2010
Hydrocortisone, intravenous	07 Dec 2010	08 Dec 2010
Hydrocortisone, intravenous	30 Dec 2010	04 Jan 2011
Fleet enema /00129701, rectal	15 Nov 2010	15 Nov 2010

Osmotically acting laxatives, rectal	17 Nov 2010	17 Nov 2010
Enoxaparin, subcutaneous	13 Nov 2010	19 Nov 2010
Paracetamol, oral	12 Nov 2010	19 Nov 2010
Ensure Plus, oral	18 Nov 2010	19 Nov 2010
Temazepam, oral	12 Nov 2010	18 Nov 2010
Fentanyl, intravenous	17 Nov 2010	17 Nov 2010
Fentanyl, intravenous	07 Dec 2010	07 Dec 2010
Metoclopramide, oral	07 Dec 2010	10 Dec 2010
Alprazolam, oral	08 Dec 2010	Ongoing
Heparin, subcutaneous	07 Dec 2010	13 Dec 2010
Ketamine, intravenous	December 2010	December 2010
Oxycodone, oral	09 Dec 2010	10 Dec 2010
Potassium, oral	10 Dec 2010	Ongoing
Flucloxacillin, oral	14 Dec 2010	19 Dec 2010
Ensure plus, oral	14 Dec 2010	December 2010
Drugs for acid related disorders, oral	03 Jan 2011	03 Jan 2011
Mesalazine, rectal	04 Jan 2011	06j An 2011
Paracetamol, intravenous	30 Dec 2010	31 Dec 2010
Paracetamol, oral	01 Jan 2011	06 Jan 2011
Ondansetron, oral	31 Dec 2010	03 Jan 2011
Heparin, subcutaneous	30 Dec 2010	05 Jan 2011
Metronidazole, oral	30 Dec 2010	04 Jan 2011
Gentamicin, intravenous	31 Dec 2010	03 Jan 2011
Ampicillin, intravenous	30 Dec 2010	04 Jan 2011

Treatment group in induction:	400 mg → 200 mg SC.
Treatment group in maintenance:	Responder to golimumab induction → randomized to placebo maintenance.
Dose adjusted?	Yes.
Adjusted treatment group:	Golimumab 100 mg.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 04 Jun 2010 (Study Day -42)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 04 Jun 2010 (Study Day -42)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 04 Jun 2010 (Study Day -42)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 04 Jun 2010 (Study Day -42)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 16 Jun 2010 (Study Day -30)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 16 Jun 2010 (Study Day -30)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 16 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 16 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 4 (Main), 18 Aug 2010 (Study Day 34)	Admin. 2/ Inj. 3	Placebo	0 mg
Week 4 (Main), 18 Aug 2010 (Study Day 34)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 8 (Main), 15 Sep 2010 (Study Day 62)	Admin. 3/ Inj. 5	Placebo	0 mg
Week 8 (Main), 15 Sep 2010 (Study Day 62)	Admin. 3/ Inj. 6	Placebo	0 mg
Week 12 (Main), 13 Oct 2010 (Study Day 90)	Admin. 4/ Inj. 7	Placebo	0 mg
Week 12 (Main), 13 Oct 2010 (Study Day 90)	Admin. 4/ Inj. 8	Placebo	0 mg
Week 16 (Main), 29 Oct 2010 (Study Day 106)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 16 (Main), 29 Oct 2010 (Study Day 106)	Admin. 1/ Inj. 2	Placebo	0 mg

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	29 Oct 2010.
Last scheduled study treatment visit in maintenance:	Week 16 (Main).
Date of study treatment discontinuation:	12 Nov 2010.

Study status:

Date of study discontinuation:	12 Nov 2010.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	Adverse event.
Date of disposition status:	29 Oct 2010.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No

被験者識別コード：7457-00001

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	アレルギー性皮膚炎 (Toxico-allergic dermatitis)	Possible	16 Oct 2010 08 Dec 2010 (54 days)

Baseline demographic information: 5[redacted]-year-old (DOB: 11 Apr [redacted]) Caucasian female.
Weight: 47 kg; height: 163 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 19 Aug 2007.
UC disease duration: 3.0 years.

Prior/concomitant medication, route	Start date	End date
Methylprednisolone, oral	09 Jun 2010	Ongoing
Sulfasalazine, oral	09 Jun 2010	01 Sep 2010
Mesalazine, oral	09 Jun 2010	Ongoing
Lactobacillus bifidus, oral	09 Jun 2010	Ongoing
Dextriferron, oral	09 Jun 2010	13 Sep 2010
Alfacalcidol, oral	09 Oct 2009	Ongoing
Omeprazole, oral	09 Jun 2010	Ongoing
Isoniazid, oral	04 Aug 2010	Ongoing
Pyridoxine, oral	04 Aug 2010	Ongoing
Drugs for functional gastrointest. disorders, oral	29 Oct 2010	30 Nov 2010
Cetirizine, oral	29 Oct 2010	08 Nov 2010
Levocetirizine, oral	09 Nov 2010	30 Nov 2010
Calcium gluconate, intramuscular	29 Oct 2010	06 Nov 2010
Chloropyramine, intramuscular	30 Oct 2010	07 Nov 2010
Triderm /00998801/, topical	08 Nov 2010	30 Nov 2010

Treatment group in induction: 400 mg → 200 mg SC.
Treatment group in maintenance: Responder to golimumab induction → randomized to placebo maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 04 Aug 2010 (Study Day -40)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 04 Aug 2010 (Study Day -40)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 04 Aug 2010 (Study Day -40)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 04 Aug 2010 (Study Day -40)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 18 Aug 2010 (Study Day -26)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 18 Aug 2010 (Study Day -26)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 13 Sep 2010 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 13 Sep 2010 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 4 (Main), 11 Oct 2010 (Study Day 29)	Admin. 2/ Inj. 3	Placebo	0 mg
Week 4 (Main), 11 Oct 2010 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 8 (Main)—dose not done	NA	NA	NA
Week 12 (Main)—dose not done	NA	NA	NA

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Adverse event.
Date of last study agent administration in maintenance: 11 Oct 2010.
Last scheduled study treatment visit in maintenance: Week 4 (Main).
Date of study treatment discontinuation: 11 Nov 2010.

Study status:
Date of disposition status: 12 Jan 2011.
Ended study participation as of Week 54? Yes.
Entered extension study? No.

被験者識別コード：7743-00004

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE/ Serious infection	脳膿瘍 (Right facial weakness due to brain abscess)	Not related	01 Apr 2009 18 May 2009 (48 days)
SAE/ Serious infection	脳膿瘍 (Brain abscess on MRI)	Possible	02 Apr 2009 18 May 2009 (47 days)
SAE/ Event of interest: Neurologic event	脱髄 (Demyelinating brain lesion on MRI)	Not related	14 Jul 2009 January 2010

Baseline demographic information: 4[redacted]-year-old (DOB: 28 Jan [redacted]) Caucasian male.
Weight: 136.1 kg; height: 191 cm.

Relevant medical history at baseline: 関節炎， 関節痛，喫煙（過去/現在）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:
Date of diagnosis: 1995.
UC disease duration: 13.0 years.

Prior/concomitant medication, route	Start date	End date
Mesalazine, oral	28 Mar 2008	Ongoing
Azathioprine, oral	04 Jun 2008	Ongoing
Metoprolol succinate, oral	February 2000	Ongoing
Propofol, intravenous	08 Dec 2008	08 Dec 2008
Glycopyrronium bromide, intravenous	08 Dec 2008	08 Dec 2008
Fleet/01605601/, oral	07 Dec 2008	07 Dec 2008
Cefalexin monohydrate, oral	09 Dec 2008	18 Dec 2008
Azithromycin, oral	12 Jan 2009	16 Jan 2009
Azathioprine, oral	04 Jun 2008	02 Apr 2009
Metoprolol, oral	February 2000	Ongoing
Fluconazole, intravenous	04 Apr 2009	08 Apr 2009
Vancomycin, intravenous	02 Apr 2009	18 May 2009
Ampicillin, intravenous	04 Apr 2009	18 May 2009
Metronidazole, intravenous	04 Apr 2009	18 May 2009

Treatment group in induction: 400 mg → 200 mg SC.
Treatment group in maintenance: Responder to golimumab induction → randomized to placebo maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 22 Dec 2008 (Study Day -45)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 22 Dec 2008 (Study Day -45)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 22 Dec 2008 (Study Day -45)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 22 Dec 2008 (Study Day -45)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 06 Jan 2009 (Study Day -30)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 06 Jan 2009 (Study Day -30)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 06 Jan 2009 (Study Day -30)	Admin. 2/ Inj. 7	Golimumab	100 mg
Week 0 (Main), 05 Feb 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 05 Feb 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 05 Feb 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 03 Mar 2009 (Study Day 27)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 03 Mar 2009 (Study Day 27)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 03 Mar 2009 (Study Day 27)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 30 Mar 2009 (Study Day 54)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 30 Mar 2009 (Study Day 54)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 30 Mar 2009 (Study Day 54)	Admin. 3/ Inj. 9	Placebo	0 mg
Unscheduled 1 (Main), —dose not done	NA	NA	NA

Treatment status:	
Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	30 Mar 2009.
Last scheduled study treatment visit in maintenance:	Week 8 (Main).
Date of study treatment discontinuation:	02 Apr 2009.
Study status:	
Date of disposition status:	16 Jul 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

b) ゴリムマブ 50 mg 群

被験者識別コード：7203-00002

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Serious infection	ロタウイルス胃腸炎 (Rotavirus enteritis)	Unlikely	20 May 2009 25 May 2009 (6 days)
SAE	腸管虚血 (Mesenteric ischemia)	Unlikely	01 Feb 2010 04 Feb 2010 (4 days)
Died/ SAE	心室機能不全 (Biventricular heart dysfunction)	Not related	04 Feb 2010 04 Feb 2010 (1 day)
Died/ SAE	冠動脈疾患 (Coronary heart disease)	Not related	04 Feb 2010 04 Feb 2010 (1 day)

Baseline demographic information: 7[redacted]-year-old (DOB: 01 Jul [redacted]) Caucasian male.
Weight: 86.5 kg; height: 168 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 27 May 2005.
UC disease duration: 3.5 years.

Prior/concomitant medication, route	**Start date**	**End date**
Mesalazine, oral	21 Oct 2008	Ongoing
Isosorbide mononitrate, oral	2005	Ongoing
Risedronate sodium, oral	2007	Ongoing
Prednisone, oral	21 Oct 2008	Ongoing
Isosorbide, oral	2005	Ongoing
Risedronic acid, oral	2007	Ongoing
Prednisolone, oral	16 Jan 2009	Ongoing
Amoxicillin, oral	11 Nov 2009	18 Nov 2009

Treatment group in induction: 100 mg → 50 mg SC.
Treatment group in maintenance: Responder to golimumab induction → randomized to golimumab 50 mg maintenance.
Dose adjusted? Yes.
Adjusted treatment group: Golimumab 50 mg.

Treatment received:

Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 27 Nov 2008 (Study Day -47)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 27 Nov 2008 (Study Day -47)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 27 Nov 2008 (Study Day -47)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 27 Nov 2008 (Study Day -47)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 11 Dec 2008 (Study Day -33)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 11 Dec 2008 (Study Day -33)	Admin. 2/ Inj. 6	Golimumab	50 mg
Week 2 (Ind), 11 Dec 2008 (Study Day -33)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 13 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 13 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 13 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	50 mg

Week 4 (Main), 10 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 4	Golimumab	50 mg
Week 4 (Main), 10 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 10 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 10 Mar 2009 (Study Day 57)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 10 Mar 2009 (Study Day 57)	Admin. 3/ Inj. 8	Golimumab	50 mg
Week 8 (Main), 10 Mar 2009 (Study Day 57)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 07 Apr 2009 (Study Day 85)	Admin. 4/ Inj. 10	Golimumab	50 mg
Week 12 (Main), 07 Apr 2009 (Study Day 85)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 07 Apr 2009 (Study Day 85)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 05 May 2009 (Study Day 113)	Admin. 5/ Inj. 13	Golimumab	50 mg
Week 16 (Main), 05 May 2009 (Study Day 113)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 05 May 2009 (Study Day 113)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 02 Jun 2009 (Study Day 141)	Admin. 6/ Inj. 16	Golimumab	50 mg
Week 20 (Main), 02 Jun 2009 (Study Day 141)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 20 (Main), 02 Jun 2009 (Study Day 141)	Admin. 6/ Inj. 18	Placebo	0 mg
Unscheduled 1 (Main)—dose not done	NA	NA	NA
Week 24 (Main), 01 Jul 2009 (Study Day 170)	Admin. 7/ Inj. 19	Placebo	0 mg
Week 24 (Main), 01 Jul 2009 (Study Day 170)	Admin. 7/ Inj. 20	Golimumab	50 mg
Week 24 (Main), 01 Jul 2009 (Study Day 170)	Admin. 7/ Inj. 21	Placebo	0 mg
Week 28 (Main), 29 Jul 2009 (Study Day 198)	Admin. 8/ Inj. 22	Placebo	0 mg
Week 28 (Main), 29 Jul 2009 (Study Day 198)	Admin. 8/ Inj. 23	Golimumab	50 mg
Week 28 (Main), 29 Jul 2009 (Study Day 198)	Admin. 8/ Inj. 24	Placebo	0 mg
Week 32 (Main), 26 Aug 2009 (Study Day 226)	Admin. 9/ Inj. 25	Golimumab	50 mg
Week 32 (Main), 26 Aug 2009 (Study Day 226)	Admin. 9/ Inj. 26	Placebo	0 mg
Week 32 (Main), 26 Aug 2009 (Study Day 226)	Admin. 9/ Inj. 27	Placebo	0 mg
Week 36 (Main), 23 Sep 2009 (Study Day 254)	Admin. 10/ Inj. 28	Placebo	0 mg
Week 36 (Main), 23 Sep 2009 (Study Day 254)	Admin. 10/ Inj. 29	Placebo	0 mg
Week 36 (Main), 23 Sep 2009 (Study Day 254)	Admin. 10/ Inj. 30	Golimumab	50 mg
Unscheduled 2 (Main)—dose not done	NA	NA	NA
Week 40 (Main), 21 Oct 2009 (Study Day 282)	Admin. 1/ Inj. 1	Golimumab	50 mg
Week 40 (Main), 21 Oct 2009 (Study Day 282)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 40 (Main), 21 Oct 2009 (Study Day 282)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 44 (Main), 18 Nov 2009 (Study Day 310)	Admin. 2/ Inj. 4	Golimumab	50 mg
Week 44 (Main), 18 Nov 2009 (Study Day 310)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 44 (Main), 18 Nov 2009 (Study Day 310)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 48 (Main), 16 Dec 2009 (Study Day 338)	Admin. 3/ Inj. 7	Golimumab	50 mg
Week 48 (Main), 16 Dec 2009 (Study Day 338)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 48 (Main), 16 Dec 2009 (Study Day 338)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 52 (Main), 13 Jan 2010 (Study Day 366)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 52 (Main), 13 Jan 2010 (Study Day 366)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 52 (Main), 13 Jan 2010 (Study Day 366)	Admin. 4/ Inj. 12	Golimumab	50 mg
Treatment status:			
Study treatment discontinuation?	No.		
Date of last study agent administration in maintenance:	13 Jan 2010.		
Last scheduled study treatment visit in maintenance:	Week 52 (Main).		
Study status:			
Date of disposition status:	27 Jan 2010.		
Ended study participation as of Week 54?	No.		
Entered extension study?	Yes.		

被験者識別コード：7720-00006

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Serious infection	気管支炎 (Hospitalization for chest pain [non-cardiac chest pain] related to bronchitis)	Unlikely	14 Nov 2008 16 Nov 2008 (3 days)

Permanent discontinuation of study agent due to AE	外陰腟真菌感染 (Vaginal yeast infection)	Possible	22 Jun 2009 13 Aug 2009 (53 days)

Baseline demographic information: 5[redacted]-year-old (DOB: 02 Nov [redacted]) Caucasian female.
Weight: 67.5 kg; height: 160 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 1970.
UC disease duration: 37.5 years.

Prior/concomitant medication, route	Start date	End date
Mesalazine, oral	04 Oct 2007	Ongoing
Rosuvastatin calcium, oral	Prior	Ongoing
Fexofenadine, oral	Prior	Ongoing
Potassium chloride, oral	Prior	Ongoing
Estrogens conjugated, oral	Prior	Ongoing
Hydrochlorothiazide, oral	Prior	Ongoing
Triamterene, oral	Prior	Ongoing
Provella-14, oral	Prior	Ongoing
Montelukast sodium, oral	Prior	Ongoing
Dozol /00435101/, oral	Prior	Ongoing
Midazolam hydrochloride, intravenous	09 Jun 2008	09 Jun 2008
Propofol, intravenous	09 Jun 2008	09 Jun 2008
Macrogol, oral	08 Jun 2008	08 Jun 2008
Macrogol, oral	03 Aug 2008	03 Aug 2008
Vitamin D nos, oral	08 Aug 2008	15 Jan 2009
Mesalazine, oral	04 Oct 2007	31 Jul 2009
Rosuvastatin, oral	Prior	Ongoing
Potassium, oral	Prior	2008
Montelukast, oral	Prior	Ongoing
Dozol /00435101/, oral	Prior	28 Oct 2008
Olpidem, oral	30 Sep 2008	20 Feb 2009
Alprazolam, oral	17 Nov 2008	24 Mar 2009
Cefuroxime, oral	17 Nov 2008	27 Nov 2008
Bismuth, oral	24 Nov 2008	24 Nov 2008
Tussionex /00140501/, oral	16 Nov 2008	23 Dec 2008
Fish oil, oral	15 Jan 2009	August 2009
Ramelteon, oral	20 Feb 2009	24 Feb 2009
Fluconazole, oral	03 Mar 2009	23 Mar 2009
Nystatin, topical	03 Mar 2009	28 Mar 2009
Temazepam, oral	03 Mar 2009	15 Sep 2009
Midazolam, intravenous	05 Mar 2009	05 Mar 2009
Propofol, intravenous	05 Mar 2009	05 Mar 2009
Macrogol, oral	04 Mar 2009	04 Mar 2009
Bisacodyl, oral	04 Mar 2009	04 Mar 200
Lorazepam, oral	13 Mar 2009	31 Jul 2009
Terconazole, intravaginal	31 Mar 2009	03 Apr 2009
Lotrisone, topical	31 Mar 2009	10 Jul 2009
Omeprazole, oral	15 Jun 2009	30 Jun 2009
Fluconazole, oral	09 Jul 2009	09 Jul 2009
Nystatin, topical	17 Jul 2009	07 Aug 2009
Mesalazine, oral	31 Jul 2009	12 Oct 2009
Vitamin D nos, oral	13 Aug 2009	Ongoing
Mesalazine, oral	12 Oct 2009	Ongoing

Treatment group in induction: 100 mg → 50 mg SC.
Treatment group in maintenance: Responder to golimumab induction → randomized to golimumab 50 mg maintenance.
Dose adjusted? No.

Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 19 Jun 2008 (Study Day -48)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 19 Jun 2008 (Study Day -48)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 19 Jun 2008 (Study Day -48)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 19 Jun 2008 (Study Day -48)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 08 Jul 2008 (Study Day -29)	Admin. 2/ Inj. 5	Golimumab	50 mg
Week 2 (Ind), 08 Jul 2008 (Study Day -29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 08 Jul 2008 (Study Day -29)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 06 Aug 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 06 Aug 2008 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	50 mg
Week 0 (Main), 06 Aug 2008 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 03 Sep 2008 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 03 Sep 2008 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 03 Sep 2008 (Study Day 29)	Admin. 2/ Inj. 6	Golimumab	50 mg
Week 8 (Main), 30 Sep 2008 (Study Day 56)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 30 Sep 2008 (Study Day 56)	Admin. 3/ Inj. 8	Golimumab	50 mg
Week 8 (Main), 30 Sep 2008 (Study Day 56)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 28 Oct 2008 (Study Day 84)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 28 Oct 2008 (Study Day 84)	Admin. 4/ Inj. 11	Golimumab	50 mg
Week 12 (Main), 28 Oct 2008 (Study Day 84)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 25 Nov 2008 (Study Day 112)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 25 Nov 2008 (Study Day 112)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 25 Nov 2008 (Study Day 112)	Admin. 5/ Inj. 15	Golimumab	50 mg
Week 20 (Main), 23 Dec 2008 (Study Day 140)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 23 Dec 2008 (Study Day 140)	Admin. 6/ Inj. 17	Golimumab	50 mg
Week 20 (Main), 23 Dec 2008 (Study Day 140)	Admin. 6/ Inj. 18	Placebo	0 mg
Week 24 (Main), 22 Jan 2009 (Study Day 170)	Admin. 7/ Inj. 19	Golimumab	50 mg
Week 24 (Main), 22 Jan 2009 (Study Day 170)	Admin. 7/ Inj. 20	Placebo	0 mg
Week 24 (Main), 22 Jan 2009 (Study Day 170)	Admin. 7/ Inj. 21	Placebo	0 mg
Week 28 (Main), 20 Feb 2009 (Study Day 199)	Admin. 8/ Inj. 22	Placebo	0 mg
Week 28 (Main), 20 Feb 2009 (Study Day 199)	Admin. 8/ Inj. 23	Placebo	0 mg
Week 28 (Main), 20 Feb 2009 (Study Day 199)	Admin. 8/ Inj. 24	Golimumab	50 mg
Week 32 (Main), 24 Mar 2009 (Study Day 231)	Admin. 9/ Inj. 25	Golimumab	50 mg
Week 32 (Main), 24 Mar 2009 (Study Day 231)	Admin. 9/ Inj. 26	Placebo	0 mg
Week 32 (Main), 24 Mar 2009 (Study Day 231)	Admin. 9/ Inj. 27	Placebo	0 mg
Week 36 (Main), 21 Apr 2009 (Study Day 259)	Admin. 10/ Inj. 28	Placebo	0 mg
Week 36 (Main), 21 Apr 2009 (Study Day 259)	Admin. 10/ Inj. 29	Golimumab	50 mg
Week 36 (Main), 21 Apr 2009 (Study Day 259)	Admin. 10/ Inj. 30	Placebo	0 mg
Week 40 (Main), 21 May 2009 (Study Day 289)	Admin. 11/ Inj. 31	Placebo	0 mg
Week 40 (Main), 21 May 2009 (Study Day 289)	Admin. 11/ Inj. 32	Placebo	0 mg
Week 40 (Main), 21 May 2009 (Study Day 289)	Admin. 11/ Inj. 33	Golimumab	50 mg
Week 44 (Main), 18 Jun 2009 (Study Day 317)	Admin. 12/ Inj. 34	Placebo	0 mg
Week 44 (Main), 18 Jun 2009 (Study Day 317)	Admin. 12/ Inj. 35	Golimumab	50 mg
Week 44 (Main), 18 Jun 2009 (Study Day 317)	Admin. 12/ Inj. 36	Placebo	0 mg
Week 48 (Main)—dose not done	NA	NA	NA
Week 52 (Main)—dose not done	NA	NA	NA

Treatment status:	
Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	18 Jun 2009.
Last scheduled study treatment visit in maintenance:	Week 44 (Main).
Date of study treatment discontinuation:	31 Jul 2009.
Study status:	
Date of disposition status:	12 Oct 2009.
Ended study participation as of Week 54?	No.
Entered extension study?	No.

被験者識別コード：6501-00014

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Serious infection	帯状疱疹 (Intercostal herpes zoster)	Not related	07 Dec 2009 12 Dec 2009 (6 days)

Baseline demographic information: 4[redacted]-year-old (DOB: 04 Sep [redacted]) Caucasian female.
Weight: 60 kg; height: 164 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 28 Aug 2007.
UC disease duration: 1.9 years.

Prior/concomitant medication, route	Start date	End date
Mesalazine, oral	August 2007	Ongoing
Prednisone, oral	10 Sep 2007	Ongoing
Amoxicillin, oral	21 Sep 2009	27 Sep 2009
Aciclovir, intravenous	07 Dec 2009	12 Dec 2009
Paracetamol, oral	07 Dec 2009	12 Dec 2009

Treatment group in induction: 200 mg → 100 mg SC.
Treatment group in maintenance: Responder to golimumab induction → randomized to golimumab 50 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 15 Jul 2009 (Study Day -42)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 15 Jul 2009 (Study Day -42)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 15 Jul 2009 (Study Day -42)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 15 Jul 2009 (Study Day -42)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 29 Jul 2009 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 29 Jul 2009 (Study Day -28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 29 Jul 2009 (Study Day -28)	Admin. 2/ Inj. 7	Golimumab	100 mg
Week 0 (Main), 26 Aug 2009 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	50 mg
Week 0 (Main), 26 Aug 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 26 Aug 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 23 Sep 2009 (Study Day 29)	Admin. 2/ Inj. 4	Golimumab	50 mg
Week 4 (Main), 23 Sep 2009 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 23 Sep 2009 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 21 Oct 2009 (Study Day 57)	Admin. 3/ Inj. 7	Golimumab	50 mg
Week 8 (Main), 21 Oct 2009 (Study Day 57)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 21 Oct 2009 (Study Day 57)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 19 Nov 2009 (Study Day 86)	Admin. 4/ Inj. 10	Golimumab	50 mg
Week 12 (Main), 19 Nov 2009 (Study Day 86)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 19 Nov 2009 (Study Day 86)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 16 Dec 2009 (Study Day 113)	Admin. 5/ Inj. 13	Golimumab	50 mg
Week 16 (Main), 16 Dec 2009 (Study Day 113)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 16 Dec 2009 (Study Day 113)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 13 Jan 2010 (Study Day 141)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 13 Jan 2010 (Study Day 141)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 20 (Main), 13 Jan 2010 (Study Day 141)	Admin. 6/ Inj. 18	Golimumab	50 mg
Week 24 (Main), 10 Feb 2010 (Study Day 169)	Admin. 7/ Inj. 19	Golimumab	50 mg
Week 24 (Main), 10 Feb 2010 (Study Day 169)	Admin. 7/ Inj. 20	Placebo	0 mg
Week 24 (Main), 10 Feb 2010 (Study Day 169)	Admin. 7/ Inj. 21	Placebo	0 mg
Week 28 (Main), 10 Mar 2010 (Study Day 197)	Admin. 8/ Inj. 22	Placebo	0 mg
Week 28 (Main), 10 Mar 2010 (Study Day 197)	Admin. 8/ Inj. 23	Golimumab	50 mg
Week 32 (Main), 07 Apr 2010 (Study Day 225)	Admin. 9/ Inj. 24	Placebo	0 mg
Week 32 (Main), 07 Apr 2010 (Study Day 225)	Admin. 9/ Inj. 25	Golimumab	50 mg
Week 36 (Main), 05 May 2010 (Study Day 253)	Admin. 10/ Inj. 26	Golimumab	50 mg
Week 36 (Main), 05 May 2010 (Study Day 253)	Admin. 10/ Inj. 27	Placebo	0 mg
Week 40 (Main), 02 Jun 2010 (Study Day 281)	Admin. 11/ Inj. 28	Golimumab	50 mg

Week 40 (Main), 02 Jun 2010 (Study Day 281)	Admin. 11/ Inj. 29	Placebo	0 mg
Week 44 (Main), 30 Jun 2010 (Study Day 309)	Admin. 12/ Inj. 30	Golimumab	50 mg
Week 44 (Main), 30 Jun 2010 (Study Day 309)	Admin. 12/ Inj. 31	Placebo	0 mg
Week 48 (Main), 27 Jul 2010 (Study Day 336)	Admin. 13/ Inj. 32	Golimumab	50 mg
Week 48 (Main), 27 Jul 2010 (Study Day 336)	Admin. 13/ Inj. 33	Placebo	0 mg
Week 52 (Main), 25 Aug 2010 (Study Day 365)	Admin. 14/ Inj. 34	Placebo	0 mg
Week 52 (Main), 25 Aug 2010 (Study Day 365)	Admin. 14/ Inj. 35	Golimumab	50 mg
Treatment status:			
Study treatment discontinuation?	No.		
Date of last study agent administration in maintenance:	25 Aug 2010.		
Last scheduled study treatment visit in maintenance:	Week 52 (Main).		
Study status:			
Date of disposition status:	06 Sep 2010.		
Ended study participation as of Week 54?	No.		
Entered extension study?	Yes.		

被験者識別コード：7007-00007

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE	腹痛 (Abdominal pain)	Unlikely	23 Jan 2010 30 Jan 2010 (8 days)
SAE/ Permanent discontinuation of study agent due to AE/ Serious infection	膿瘍 (Sigmoid abscess)	Possible	26 Jan 2010 27 Jan 2010 (2 days)

Baseline demographic information: 5[redacted]-year-old (DOB: 20 Sep [redacted]) Caucasian female. Weight: 110 kg; height: 161 cm.

Relevant medical history at baseline: 関節炎，喫煙（現在）

Baseline smoking status: Current smoker.

Ulcerative colitis history:
Date of diagnosis: 09 Feb 2007.
UC disease duration: 2.7 years.

Prior/concomitant medication, route	**Start date**	**End date**
Prednisolone, oral	06 Oct 2009	Ongoing
Mesalazine, oral	Prior	Ongoing
Calcium carbonate, oral	Prior	Ongoing
Rabeprazole sodium, oral	Prior	Ongoing
Zolpidem tartrate, oral	Prior	Ongoing
Magnesium, oral	Prior	Ongoing
Paracetamol, oral	Prior	Ongoing
Tramadol, oral	Prior	Ongoing
Trimethoprim, oral	21 Nov 2009	27 Nov 2009
Midazolam, intravenous	17 Dec 2009	17 Dec 2009
Fentanyl, intravenous	17 Dec 2009	17 Dec 2009
Propofol, intravenous	17 Dec 2009	17 Dec 2009
Nystatin, oral	09 Dec 2009	18 Dec 2009
Prednisolone, oral	06 Oct 2009	27 Dec 2009
Mesalazine, oral	Prior	26 Jan 2010
Calcium carbonate, subcutaneous	Prior	Ongoing
Rabeprazole, oral	Prior	Ongoing
Zolpidem, oral	Prior	25 Jan 2010
Magnesium, oral	April 2009	Ongoing
Paracetamol, oral	April 2009	Ongoing
Tramadol, oral	April 2009	Ongoing
Prednisolone, oral	28 Dec 2009	31 Jan 2010
Ceftriaxone, intravenous	26 Jan 2010	05 Feb 2010
Metronidazole, intravenous	26 Jan 2010	05 Feb 2010
Heparin, subcutaneous	26 Jan 2010	05 Feb 2010
Hydrocortisone, intravenous	26 Jan 2010	01 Feb 2010

Esomeprazole, intravenous	27 Jan 2010	01 Feb 2010
Zolpidem, oral	27 Jan 2010	04 Feb 2010
Ondansetron, intravenous	29 Jan 2010	29 Jan 2010
Furosemide, intravenous	27 Jan 2010	27 Jan 2010
Morphine, other	26 Jan 2010	30 Jan 2010
Metoclopramide, other	26 Jan 2010	03 Feb 2010
Phosphate-Sandoz, oral	29 Jan 2010	05 Feb 2010
Prednisolone, oral	01 Feb 2010	Ongoing
Mesalazine, oral	27 Jan 2010	Ongoing
Lactulose, oral	29 Jan 2010	Ongoing
Zinc, oral	03 Feb 2010	Ongoing
Ascorbic acid, oral	03 Feb 2010	Ongoing
Ciprofloxacin, oral	05 Feb 2010	Ongoing
Multivitamin /00831701, oral	04 Feb 2010	Ongoing

Treatment group in induction: 200mg → 100mg SC.
Treatment group in maintenance: Responder to golimumab induction → randomized to golimumab 50 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 10 Nov 2009 (Study Day -41)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 10 Nov 2009 (Study Day -41)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 10 Nov 2009 (Study Day -41)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 10 Nov 2009 (Study Day -41)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 24 Nov 2009 (Study Day -27)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 24 Nov 2009 (Study Day -27)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 21 Dec 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 21 Dec 2009 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	50 mg
Week 0 (Main), 21 Dec 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 19 Jan 2010 (Study Day 30)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 19 Jan 2010 (Study Day 30)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 19 Jan 2010 (Study Day 30)	Admin. 2/ Inj. 6	Golimumab	50 mg

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	19 Jan 2010.
Last scheduled study treatment visit in maintenance:	Week 4 (Main).
Date of study treatment discontinuation:	03 Feb 2010.

Study status:

Date of study discontinuation:	03 Feb 2010.
Reason for noncompletion:	Withdrawal of consent.
Date of disposition status:	03 Feb 2010.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7078-00008

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Ulcerative colitis in relapse)	Not related	15 Apr 2010 04 Jun 2010 (51 days)

Baseline demographic information: 5[redacted]-year-old (DOB: 25 Nov [redacted]) Caucasian male.
Weight: 56.9 kg; height: 168 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:

Date of diagnosis:	16 Dec 2005.
UC disease duration:	4.1 years.

Prior/concomitant medication, route	Start date	End date
Prednisolone, oral	30 Nov 2009	Ongoing
Mesalazine, oral	30 Nov 2009	Ongoing
Bisoprolol fumarate, oral	27 Mar 2008	Ongoing
Mesalazine, oral	30 Nov 2009	15 Apr 2010
Prednisolone, oral	30 Nov 2009	15 Apr 2010
Bisoprolol, oral	27 Mar 2008	15 Apr 2010
Sodium chloride, intravenous	15 Apr 2010	14 May 2010
Ciprofloxacin, intravenous	15 Apr 2010	26 Apr 2010
Ceftriaxone, intravenous	15 Apr 2010	26 Apr 2010
Metronidazole, intravenous	15 Apr 2010	25 Apr 2010
Methylprednisolone, intravenous	15 Apr 2010	17 May 2010
Calcium gluconate, intravenous	16 Apr 2010	21 Apr 2010
Calcium gluconate, intravenous	29 Apr 2010	14 May 2010
Nystatin, oral	29 Apr 2010	09 May 2010
Fluconazole, intravenous	26 Apr 2010	09 May 2010
Metoclopramide, intravenous	26 Apr 2010	28 Apr 2010
Omeprazole, intravenous	05 May 2010	09 May 2010
Famotidine, intravenous	10 May 2010	17 May 2010
Mesalazine, oral	10 May 2010	14 May 2010
Prednisolone, oral	13 May 2010	15 May 2010
Saccharated iron oxide, intravenous	10 May 2010	15 May 2010
Insulin, intravenous	15 May 2010	24 May 2010
Sodium chloride compound injection, intravenous	16 May 2010	02 Jun 2010
Dextrose and sodium chloride injection, intravenous	16 May 2010	18 May 2010
Dextrose and sodium chloride injection, intravenous	25 May 2010	02 Jun 2010
Paracetamol, intravenous	15 May 2010	15 May 2010
Paracetamol, intravenous	18 May 2010	21 May 2010
Oliclinomel/01716901, intravenous	15 May 2010	24 May 2010
Alaglumina, intravenous	15 May 2010	15 May 2010
Alaglumina, intravenous	20 May 2010	24 May 2010
Potassium, intravenous	15 May 2010	25 May 2010
Famotidine, intravenous	15 May 2010	15 May 2010
Famotidine, intravenous	20 May 2010	25 May 2010
Drotaverine, intravenous	15 May 2010	16 May 2010
Albumin human, intravenous	15 May 2010	15 May 2010
Albumin human, intravenous	21 May 2010	21 May 2010
Lactec/00490001, intravenous	15 May 2010	15 May 2010
Lactec/00490001, intravenous	19 May 2010	19 May 2010
Nadroparin, subcutaneous	19 May 2010	03 Jun 2010
Galantamine, subcutaneous	19 May 2010	25 May 2010
Ceftriaxone, intravenous	19 May 2010	27 May 2010
Metronidazole, intravenous	19 May 2010	27 May 2010
Metamizole, intramuscular	16 May 2010	16 May 2010
Metamizole, intramuscular	19 May 2010	19 May 2010
Pethidine, intramuscular	15 May 2010	15 May 2010
Pethidine, intramuscular	18 May 2010	19 May 2010
Pethidine, intramuscular	21 May 2010	21 May 2010
Pethidine, intramuscular	23 May 2010	23 May 2010
Fentanyl, intravenous	21 May 2010	21 May 2010
Tramadol, intramuscular	25 May 2010	25 May 2010
Antidiarrhoeal microorganisms, oral	27 Apr 2010	03 May 2010
Metoclopramide, intravenous	19 May 2010	30 May 2010
Sodium phosphate, rectal	13 May 2010	13 May 2010
Treatment group in induction:	200 mg → 100 mg SC.	
Treatment group in maintenance:	Responder to golimumab induction → randomized to golimumab 50 mg maintenance.	
Dose adjusted?	No.	

Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 19 Jan 2010 (Study Day -42)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 19 Jan 2010 (Study Day -42)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 19 Jan 2010 (Study Day -42)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 19 Jan 2010 (Study Day -42)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 28 Jan 2010 (Study Day -33)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 28 Jan 2010 (Study Day -33)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 02 Mar 2010 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	50 mg
Week 0 (Main), 02 Mar 2010 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 4 (Main), 29 Mar 2010 (Study Day 28)	Admin. 2/ Inj. 3	Placebo	0 mg
Week 4 (Main), 29 Mar 2010 (Study Day 28)	Admin. 2/ Inj. 4	Golimumab	50 mg
Treatment status:			
Study treatment discontinuation?	Yes.		
Reason for treatment discontinuation:	Adverse event.		
Date of last study agent administration in maintenance:	29 Mar 2010.		
Last scheduled study treatment visit in maintenance:	Week 4 (Main).		
Date of study treatment discontinuation:	15 Apr 2010.		
Study status:			
Date of disposition status:	03 Aug 2010.		
Ended study participation as of Week 54?	Yes.		
Entered extension study?	No.		

被験者識別コード：7278-00004

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Serious infection	ウイルス感染 (Viral infection)	Possible	08 Aug 2010 10 Aug 2010 (3 days)

Baseline demographic information: 5[redacted]-year-old (DOB: 08 Oct [redacted]) Caucasian female.
Weight: 67 kg; height: 159 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: February 1995.
UC disease duration: 14.5 years.

Prior/concomitant medication, route	**Start date**	**End date**
Simvastatin, oral	November 2007	Ongoing
Azathioprine, oral	February 1995	Ongoing
Metamizole sodium, oral	Prior	Ongoing
Azathioprine, oral	1997	10 Aug 2010
Metamizole, oral	Prior	Ongoing
Ichthammol, topical	16 Dec 2009	Ongoing

Treatment group in induction: 200 mg → 100 mg SC.
Treatment group in maintenance: Responder to golimumab induction → randomized to golimumab 50 mg maintenance.
Dose adjusted? Yes.
Adjusted treatment group: Golimumab 100 mg.

Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 19 Aug 2009 (Study Day -41)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 19 Aug 2009 (Study Day -41)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 19 Aug 2009 (Study Day -41)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 19 Aug 2009 (Study Day -41)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 01 Sep 2009 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 01 Sep 2009 (Study Day -28)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 2 (Ind), 01 Sep 2009 (Study Day -28)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 29 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 29 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg

Week 0 (Main), 29 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	50 mg
Week 4 (Main), 27 Oct 2009 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 27 Oct 2009 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 27 Oct 2009 (Study Day 29)	Admin. 2/ Inj. 6	Golimumab	50 mg
Week 8 (Main), 26 Nov 2009 (Study Day 59)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 26 Nov 2009 (Study Day 59)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 26 Nov 2009 (Study Day 59)	Admin. 3/ Inj. 9	Golimumab	50 mg
Week 12 (Main), 17 Dec 2009 (Study Day 80)	Admin. 4/ Inj. 10	Golimumab	50 mg
Week 12 (Main), 17 Dec 2009 (Study Day 80)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 17 Dec 2009 (Study Day 80)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 17 Jan 2010 (Study Day 111)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 17 Jan 2010 (Study Day 111)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 17 Jan 2010 (Study Day 111)	Admin. 5/ Inj. 15	Golimumab	50 mg
Week 20 (Main), 14 Feb 2010 (Study Day 139)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 14 Feb 2010 (Study Day 139)	Admin. 6/ Inj. 17	Golimumab	50 mg
Week 20 (Main), 14 Feb 2010 (Study Day 139)	Admin. 6/ Inj. 18	Placebo	0 mg
Week 24 (Main), 16 Mar 2010 (Study Day 169)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 24 (Main), 16 Mar 2010 (Study Day 169)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 28 (Main), 13 Apr 2010 (Study Day 197)	Admin. 2/ Inj. 3	Golimumab	100 mg
Week 28 (Main), 13 Apr 2010 (Study Day 197)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 32 (Main)—dose not done	NA	NA	NA
Week 32 (Main), 11 May 2010 (Study Day 225)	Admin. 3/ Inj. 5	Placebo	0 mg
Week 32 (Main), 11 May 2010 (Study Day 225)	Admin. 3/ Inj. 6	Golimumab	100 mg
Week 36 (Main), 01 Jun 2010 (Study Day 246)	Admin. 4/ Inj. 7	Golimumab	100 mg
Week 36 (Main), 01 Jun 2010 (Study Day 246)	Admin. 4/ Inj. 8	Placebo	0 mg
Week 40 (Main), 07 Jul 2010 (Study Day 282)	Admin. 5/ Inj. 9	Golimumab	100 mg
Week 40 (Main), 07 Jul 2010 (Study Day 282)	Admin. 5/ Inj. 10	Placebo	0 mg
Week 44 (Main), 28 Jul 2010 (Study Day 303)	Admin. 6/ Inj. 11	Golimumab	100 mg
Week 44 (Main), 28 Jul 2010 (Study Day 303)	Admin. 6/ Inj. 12	Placebo	0 mg
Week 48 (Main), 02 Sep 2010 (Study Day 339)	Admin. 7/ Inj. 13	Golimumab	100 mg
Week 48 (Main), 02 Sep 2010 (Study Day 339)	Admin. 7/ Inj. 14	Placebo	0 mg
Week 52 (Main), 04 Oct 2010 (Study Day 371)	Admin. 8/ Inj. 15	Golimumab	100 mg
Week 52 (Main), 04 Oct 2010 (Study Day 371)	Admin. 8/ Inj. 16	Placebo	0 mg
Treatment status:			
Study treatment discontinuation?	No.		
Date of last study agent administration in maintenance:	04 Oct 2010.		
Last scheduled study treatment visit in maintenance:	Week 52 (Main).		
Study status:			
Date of disposition status:	17 Oct 2010.		
Ended study participation as of Week 54?	No.		
Entered extension study?	Yes.		

被験者識別コード：7727-00007

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Fulminant ulcerative colitis)	Unlikely	16 Sep 2009 22 Sep 2009 (7 days)
Baseline demographic information: 1[redacted]-year-old (DOB: 25 Jul [redacted]) Caucasian male. Weight: 64.1 kg; height: 180 cm.			
Relevant medical history at baseline: 報告なし			
Baseline smoking status: Not reported.			
Ulcerative colitis history: Date of diagnosis: 1995. UC disease duration: 13.1 years.			

Prior/concomitant medication, route	**Start date**	**End date**
Prednisone, oral	27 Dec 2008	Ongoing
Mesalazine, oral	Prior	Ongoing

Midazolam hydrochloride, intravenous	26 Mar 2009	26 Mar 2009
Pethidine hydrochloride, intravenous	26 Mar 2009	26 Mar 2009
Midazolam, intravenous	26 Mar 2009	26 Mar 2009
Pethidine, intravenous	26 Mar 2009	26 Mar 2009
Prednisone, oral	26 Mar 2009	01 Apr 2009
Prednisone, oral	02 Apr 2009	08 Apr 2009
Ibuprofen, oral	16 Apr 2009	01 May 2009
Prednisone, oral	09 Apr 2009	15 Apr 2009
Prednisone, oral	16 Apr 2009	22 Apr 2009
Prednisone, oral	23 Apr 2009	29 Apr 2009
Prednisone, oral	27 Dec 2008	25 Mar 2009
Prednisone, oral	30 Apr 2009	06 May 2009
Prednisone, oral	07 May 2009	13 May 2009
Paracetamol, oral	14 Sep 2009	14 Sep 2009
I.V. solutions, intravenous	14 Sep 2009	14 Sep 2009
Enoxaparin, subcutaneous	18 Sep 2009	22 Sep 2009
Esomeprazole, intravenous	18 Sep 2009	21 Sep 2009
Esomeprazole, oral	23 Sep 2009	September 2009
Hydromorphone, intravenous	18 Sep 2009	18 Sep 2009
Methocarbamol, intravenous	17 Sep 2009	20 Sep 2009
Metronidazole, intravenous	17 Sep 2009	21 Sep 2009
Piperacillin w/tazobactam /01606301/, intravenous	17 Sep 2009	17 Sep 2009
Vicodin, oral	18 Sep 2009	Ongoing
Hydromorphone, intravenous	18 Sep 2009	18 Sep 2009
Morphine, intravenous	18 Sep 2009	18 Sep 2009
Morphine, intravenous	21 Sep 2009	21 Sep 2009
I.V. solutions, intravenous	16 Sep 2009	20 Sep 2009

Treatment group in induction: 200 mg → 100 mg SC.
Treatment group in maintenance: Responder to golimumab induction → randomized to golimumab 50 mg maintenance.
Dose adjusted? Yes.
Adjusted treatment group: Golimumab 100 mg.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 12 Feb 2009 (Study Day -42)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 12 Feb 2009 (Study Day -42)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 12 Feb 2009 (Study Day -42)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 12 Feb 2009 (Study Day -42)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 02 Mar 2009 (Study Day -24)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 02 Mar 2009 (Study Day -24)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 02 Mar 2009 (Study Day -24)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 26 Mar 2009 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	50 mg
Week 0 (Main), 26 Mar 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 26 Mar 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 27 Apr 2009 (Study Day 33)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 27 Apr 2009 (Study Day 33)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 27 Apr 2009 (Study Day 33)	Admin. 2/ Inj. 6	Golimumab	50 mg
Week 8 (Main), 28 May 2009 (Study Day 64)	Admin. 3/ Inj. 7	Golimumab	50 mg
Week 8 (Main), 28 May 2009 (Study Day 64)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 28 May 2009 (Study Day 64)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 18 Jun 2009 (Study Day 85)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 18 Jun 2009 (Study Day 85)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 18 Jun 2009 (Study Day 85)	Admin. 4/ Inj. 12	Golimumab	50 mg
Week 16 (Main), 16 Jul 2009 (Study Day 113)	Admin. 5/ Inj. 13	Golimumab	50 mg
Week 16 (Main), 16 Jul 2009 (Study Day 113)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 16 Jul 2009 (Study Day 113)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 13 Aug 2009 (Study Day 141)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 20 (Main), 13 Aug 2009 (Study Day 141)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 20 (Main), 13 Aug 2009 (Study Day 141)	Admin. 1/ Inj. 3	Golimumab	100 mg

Week 24 (Main)—dose not done	NA	NA	NA
Week 24 (Main)—dose not done	NA	NA	NA
Week 24 (Main)—dose not done	NA	NA	NA
Week 28 (Main)—dose not done	NA	NA	NA

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	13 Aug 2009.
Last scheduled study treatment visit in maintenance:	Week 20 (Main).
Date of study treatment discontinuation:	16 Sep 2009.

Study status:

Date of study discontinuation:	19 Oct 2009.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	Worsening UC.
Date of disposition status:	19 Oct 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7206-00003

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Serious infection	結膜炎 (Acute conjunctivitis)	Unlikely	04 Apr 2010 14 Apr 2010 (11 days)
SAE/ Serious infection	リンパ節症 (Cervical lymphadenopathy)	Unlikely	04 Apr 2010 14 Apr 2010 (11 days)
SAE/ Serious infection	外耳炎 (Retroauricular infection)	Unlikely	04 Apr 2010 14 Apr 2010 (11 days)
SAE/ Serious infection	ブドウ球菌感染 (Infection due to Staphylococcus aureus)	Unlikely	06 Apr 2010 2010

Baseline demographic information: 2[redacted]-year-old (DOB: 01 Mar [redacted]) Caucasian female.
Weight: 109 kg; height: 165 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:

Date of diagnosis:	01 Dec 2006.
UC disease duration:	2.7 years.

Prior/concomitant medication, route	**Start date**	**End date**
Prednisolone, oral	01 Jul 2009	Ongoing
Mesalazine, oral	August 2008	Ongoing
Lekovit Ca, oral	Prior	21 Sep 2009
Lekovit Ca, oral	21 Sep 2009	Ongoing
Octenisept, topical	04 Jan 2010	17 Jan 2010
Mupirocin, topical	04 Jan 2010	17 Jan 2010
Octenidine, topical	04 Jan 2010	17 Jan 2010
Linezolid, topical	04 Jan 2010	17 Jan 2010
Kanamycin, topical	31 Dec 2009	17 Jan 2010
Triclosan, topical	06 Apr 2010	14 Apr 2010
Flucloxacillin, intravenous	06 Apr 2010	10 Apr 2010
Flucloxacillin, oral	11 Apr 2010	15 Apr 2010
Gentamicin, ophthalmic	06 Apr 2010	April 2010

Treatment group in induction:	400 mg → 200 mg SC.
Treatment group in maintenance:	Responder to golimumab induction → randomized to golimumab 50 mg maintenance.
Dose adjusted?	No.

Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 21 Aug 2009 (Study Day -48)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 21 Aug 2009 (Study Day -48)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 21 Aug 2009 (Study Day -48)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 21 Aug 2009 (Study Day -48)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 04 Sep 2009 (Study Day -34)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 04 Sep 2009 (Study Day -34)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 08 Oct 2009 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	50 mg
Week 0 (Main), 08 Oct 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 08 Oct 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 09 Nov 2009 (Study Day 33)	Admin. 2/ Inj. 4	Golimumab	50 mg
Week 4 (Main), 09 Nov 2009 (Study Day 33)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 09 Nov 2009 (Study Day 33)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 07 Dec 2009 (Study Day 61)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 07 Dec 2009 (Study Day 61)	Admin. 3/ Inj. 8	Golimumab	50 mg
Week 8 (Main), 07 Dec 2009 (Study Day 61)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 06 Jan 2010 (Study Day 91)	Admin. 4/ Inj. 10	Golimumab	50 mg
Week 12 (Main), 06 Jan 2010 (Study Day 91)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 06 Jan 2010 (Study Day 91)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 03 Feb 2010 (Study Day 119)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 03 Feb 2010 (Study Day 119)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 03 Feb 2010 (Study Day 119)	Admin. 5/ Inj. 15	Golimumab	50 mg
Week 20 (Main), 01 Mar 2010 (Study Day 145)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 01 Mar 2010 (Study Day 145)	Admin. 6/ Inj. 17	Golimumab	50 mg
Week 24 (Main), 31 Mar 2010 (Study Day 175)	Admin. 7/ Inj. 18	Golimumab	50 mg
Week 24 (Main), 31 Mar 2010 (Study Day 175)	Admin. 7/ Inj. 19	Placebo	0 mg
Week 30 (Main)—dose not done	NA	NA	NA
Treatment status:			
Study treatment discontinuation?	Yes.		
Reason for treatment discontinuation:	Other.		
Other reason for treatment discontinuation:	Withdrawal consent.		
Date of last study agent administration in maintenance:	31 Mar 2010.		
Last scheduled study treatment visit in maintenance:	Week 24 (Main).		
Date of study treatment discontinuation:	07 Apr 2010.		
Study status:			
Date of study discontinuation:	07 Apr 2010.		
Reason for noncompletion:	Withdrawal of consent.		
Date of disposition status:	07 Apr 2010.		
Ended study participation as of Week 54?	Yes.		
Entered extension study?	No.		

c) ゴリムマブ 100 mg 群

被験者識別コード：6737-00003

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Serious infection	虫垂炎 (Appendicitis)	Not related	16 Oct 2008 17 Oct 2008 (2 days)
Baseline demographic information: 2[redacted]-year-old (DOB: 29 Mar [redacted]) Caucasian male. Weight: 72.2 kg; height: 178 cm.			
Relevant medical history at baseline: 報告なし			
Baseline smoking status: Not reported.			
Ulcerative colitis history:			
Date of diagnosis:	28 Mar 2002.		
UC disease duration:	6.2 years.		

Prior/concomitant medication, route	Start date	End date
Loperamide hydrochloride, oral	11 Jun 2008	Ongoing
Paracetamol, oral	01 Jan 2008	Ongoing
Oxycocet, oral	26 Jun 2008	08 Jul 2008
Loperamide, oral	Prior	Ongoing
Paracetamol, oral	Prior	Ongoing
Morphine, intravenous	16 Oct 2008	17 Oct 2008
Oxycocet, oral	17 Oct 2008	31 Oct 2008
Metronidazole, intravenous	16 Oct 2008	17 Oct 2008
Ciprofloxacin, intravenous	16 Oct 2008	16 Oct 2008
Oxycocet, oral	24 Apr 2009	25 May 2009
Naproxen, oral	11 May 2009	25 May 2009
Treatment group in induction:	1 mg/kg IV.	
Treatment group in maintenance:	Responder to golimumab induction → randomized to golimumab 100 mg maintenance.	
Dose adjusted?	No.	
Treatment received:		

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 19 Jun 2008 (Study Day -40)	NA	Golimumab	1.0 mg/kg
Week 0 (Main), 29 Jul 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 29 Jul 2008 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 29 Jul 2008 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 27 Aug 2008 (Study Day 30)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 27 Aug 2008 (Study Day 30)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 4 (Main), 27 Aug 2008 (Study Day 30)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 23 Sep 2008 (Study Day 57)	Admin. 3/ Inj. 7	Golimumab	100 mg
Week 8 (Main), 23 Sep 2008 (Study Day 57)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 23 Sep 2008 (Study Day 57)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 21 Oct 2008 (Study Day 85)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 21 Oct 2008 (Study Day 85)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 21 Oct 2008 (Study Day 85)	Admin. 4/ Inj. 12	Golimumab	100 mg
Week 16 (Main), 18 Nov 2008 (Study Day 113)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 18 Nov 2008 (Study Day 113)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 18 Nov 2008 (Study Day 113)	Admin. 5/ Inj. 15	Golimumab	100 mg
Week 20 (Main), 15 Dec 2008 (Study Day 140)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 15 Dec 2008 (Study Day 140)	Admin. 6/ Inj. 18	Golimumab	100 mg
Week 20 (Main), 15 Dec 2008 (Study Day 140)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 24 (Main), 13 Jan 2009 (Study Day 169)	Admin. 7/ Inj. 21	Golimumab	100 mg
Week 24 (Main), 13 Jan 2009 (Study Day 169)	Admin. 7/ Inj. 20	Placebo	0 mg
Week 24 (Main), 13 Jan 2009 (Study Day 169)	Admin. 7/ Inj. 19	Placebo	0 mg
Week 28 (Main), 10 Feb 2009 (Study Day 197)	Admin. 8/ Inj. 23	Placebo	0 mg
Week 28 (Main), 10 Feb 2009 (Study Day 197)	Admin. 8/ Inj. 24	Golimumab	100 mg
Week 28 (Main), 10 Feb 2009 (Study Day 197)	Admin. 8/ Inj. 22	Placebo	0 mg
Week 32 (Main), 11 Mar 2009 (Study Day 226)	Admin. 9/ Inj. 27	Golimumab	100 mg
Week 32 (Main), 11 Mar 2009 (Study Day 226)	Admin. 9/ Inj. 25	Placebo	0 mg
Week 32 (Main), 11 Mar 2009 (Study Day 226)	Admin. 9/ Inj. 26	Placebo	0 mg
Week 36 (Main), 07 Apr 2009 (Study Day 253)	Admin. 10/ Inj. 28	Placebo	0 mg
Week 36 (Main), 07 Apr 2009 (Study Day 253)	Admin. 10/ Inj. 29	Placebo	0 mg
Week 36 (Main), 07 Apr 2009 (Study Day 253)	Admin. 10/ Inj. 30	Golimumab	100 mg
Week 40 (Main), 05 May 2009 (Study Day 281)	Admin. 11/ Inj. 31	Placebo	0 mg
Week 40 (Main), 05 May 2009 (Study Day 281)	Admin. 11/ Inj. 32	Placebo	0 mg
Week 40 (Main), 05 May 2009 (Study Day 281)	Admin. 11/ Inj. 33	Golimumab	100 mg
Week 44 (Main), 03 Jun 2009 (Study Day 310)	Admin. 12/ Inj. 34	Placebo	0 mg
Week 44 (Main), 03 Jun 2009 (Study Day 310)	Admin. 12/ Inj. 36	Golimumab	100 mg
Week 44 (Main), 03 Jun 2009 (Study Day 310)	Admin. 12/ Inj. 35	Placebo	0 mg
Week 48 (Main), 30 Jun 2009 (Study Day 337)	Admin. 13/ Inj. 37	Placebo	0 mg
Week 48 (Main), 30 Jun 2009 (Study Day 337)	Admin. 13/ Inj. 38	Placebo	0 mg
Week 48 (Main), 30 Jun 2009 (Study Day 337)	Admin. 13/ Inj. 39	Golimumab	100 mg
Week 52 (Main), 28 Jul 2009 (Study Day 365)	Admin. 14/ Inj. 42	Golimumab	100 mg

Week 52 (Main), 28 Jul 2009 (Study Day 365)	Admin. 14/ Inj. 41	Placebo	0 mg
Week 52 (Main), 28 Jul 2009 (Study Day 365)	Admin. 14/ Inj. 40	Placebo	0 mg
Treatment status:			
Study treatment discontinuation?	No.		
Date of last study agent administration in maintenance:	28 Jul 2009.		
Last scheduled study treatment visit in maintenance:	Week 52 (Main).		
Study status:			
Date of disposition status:	12 Aug 2009.		
Ended study participation as of Week 54?	No.		
Entered extension study?	Yes.		

被験者識別コード：7478-00001

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Serious infection	虫垂炎 (Acute appendicitis)	Possible	24 Mar 2009 31 Mar 2009 (8 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 27 Jun [redacted]) Caucasian male.
Weight: 59.5 kg; height: 180 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 14 Dec 2007.
UC disease duration: 1.0 year.

Prior/concomitant medication, route	**Start date**	**End date**
Mesalazine, oral	22 May 2008	Ongoing
Prednisone, oral	07 Mar 2008	Ongoing
Esomeprazole magnesium, oral	02 Sep 2008	Ongoing
Caffetin /00541501/, oral	24 Dec 2008	24 Dec 2008
Esomeprazole, oral	02 Sep 2008	12 Mar 2009
Prednisone, oral	07 Apr 2008	12 Mar 2009
Ceftriaxone, intravenous	24 Mar 2009	28 Mar 2009

Treatment group in induction: 100 mg → 50 mg SC.
Treatment group in maintenance: Responder to golimumab induction → randomized to golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 11 Dec 2008 (Study Day -42)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 11 Dec 2008 (Study Day -42)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 11 Dec 2008 (Study Day -42)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 11 Dec 2008 (Study Day -42)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 25 Dec 2008 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 25 Dec 2008 (Study Day -28)	Admin. 2/ Inj. 6	Golimumab	50 mg
Week 2 (Ind), 25 Dec 2008 (Study Day -28)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 22 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 22 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 22 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 19 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 19 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 19 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 8 (Main), 19 Mar 2009 (Study Day 57)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 19 Mar 2009 (Study Day 57)	Admin. 3/ Inj. 8	Golimumab	100 mg
Week 8 (Main), 19 Mar 2009 (Study Day 57)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 21 Apr 2009 (Study Day 90)	Admin. 4/ Inj. 10	Golimumab	100 mg
Week 12 (Main), 21 Apr 2009 (Study Day 90)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 21 Apr 2009 (Study Day 90)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 14 May 2009 (Study Day 113)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 14 May 2009 (Study Day 113)	Admin. 5/ Inj. 14	Golimumab	100 mg

Week 16 (Main), 14 May 2009 (Study Day 113)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 11 Jun 2009 (Study Day 141)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 11 Jun 2009 (Study Day 141)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 20 (Main), 11 Jun 2009 (Study Day 141)	Admin. 6/ Inj. 18	Golimumab	100 mg
Week 24 (Main), 29 Jul 2009 (Study Day 189)	Admin. 7/ Inj. 19	Placebo	0 mg
Week 24 (Main), 29 Jul 2009 (Study Day 189)	Admin. 7/ Inj. 20	Placebo	0 mg
Week 24 (Main), 29 Jul 2009 (Study Day 189)	Admin. 7/ Inj. 21	Golimumab	100 mg
Week 28 (Main), 19 Aug 2009 (Study Day 210)	Admin. 8/ Inj. 22	Placebo	0 mg
Week 28 (Main), 19 Aug 2009 (Study Day 210)	Admin. 8/ Inj. 23	Golimumab	100 mg
Week 28 (Main), 19 Aug 2009 (Study Day 210)	Admin. 8/ Inj. 24	Placebo	0 mg
Week 32 (Main), 16 Sep 2009 (Study Day 238)	Admin. 9/ Inj. 25	Placebo	0 mg
Week 32 (Main), 16 Sep 2009 (Study Day 238)	Admin. 9/ Inj. 26	Placebo	0 mg
Week 32 (Main), 16 Sep 2009 (Study Day 238)	Admin. 9/ Inj. 27	Golimumab	100 mg
Week 36 (Main), 05 Oct 2009 (Study Day 257)	Admin. 10/ Inj. 28	Golimumab	100 mg
Week 36 (Main), 05 Oct 2009 (Study Day 257)	Admin. 10/ Inj. 29	Placebo	0 mg
Week 36 (Main), 05 Oct 2009 (Study Day 257)	Admin. 10/ Inj. 30	Placebo	0 mg
Week 40 (Main), 29 Oct 2009 (Study Day 281)	Admin. 11/ Inj. 31	Placebo	0 mg
Week 40 (Main), 29 Oct 2009 (Study Day 281)	Admin. 11/ Inj. 32	Placebo	0 mg
Week 40 (Main), 29 Oct 2009 (Study Day 281)	Admin. 11/ Inj. 33	Golimumab	100 mg
Week 44 (Main), 26 Nov 2009 (Study Day 309)	Admin. 12/ Inj. 34	Placebo	0 mg
Week 44 (Main), 26 Nov 2009 (Study Day 309)	Admin. 12/ Inj. 35	Golimumab	100 mg
Week 44 (Main), 26 Nov 2009 (Study Day 309)	Admin. 12/ Inj. 36	Placebo	0 mg
Week 48 (Main), 28 Dec 2009 (Study Day 341)	Admin. 13/ Inj. 37	Placebo	0 mg
Week 48 (Main), 28 Dec 2009 (Study Day 341)	Admin. 13/ Inj. 38	Golimumab	100 mg
Week 48 (Main), 28 Dec 2009 (Study Day 341)	Admin. 13/ Inj. 39	Placebo	0 mg
Week 52 (Main), 01 Feb 2010 (Study Day 376)	Admin. 14/ Inj. 40	Placebo	0 mg
Week 52 (Main), 01 Feb 2010 (Study Day 376)	Admin. 14/ Inj. 41	Placebo	0 mg
Week 52 (Main), 01 Feb 2010 (Study Day 376)	Admin. 14/ Inj. 42	Golimumab	100 mg
Treatment status:			
Study treatment discontinuation?	No.		
Date of last study agent administration in maintenance:	01 Feb 2010.		
Last scheduled study treatment visit in maintenance:	Week 52 (Main).		
Study status:			
Date of disposition status:	18 Feb 2010.		
Ended study participation as of Week 54?	No.		
Entered extension study?	Yes.		

被験者識別コード：7703-00002

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Not related	20 Jun 2008 July 2008
Baseline demographic information: 5[redacted]-year-old (DOB: 01 Jan [redacted]) Caucasian female. Weight: 54.1 kg; height: 168 cm.			
Relevant medical history at baseline: 報告なし			
Baseline smoking status: Not reported.			
Ulcerative colitis history:			
Date of diagnosis:	1977.		
UC disease duration:	30.1 years.		

Prior/concomitant medication, route	**Start date**	**End date**
Balsalazide sodium, oral	28 Sep 2005	Ongoing
Hyoscine methobromide, oral	August 2007	Ongoing
Prednisone, oral	06 Dec 2007	Ongoing
Propofol, intravenous	24 Jan 2008	24 Jan 2008
Midazolam hydrochloride, intravenous	24 Jan 2008	24 Jan 2008
Magnesium citrate, oral	23 Jan 2008	23 Jan 2008
Propofol, intravenous	20 Mar 2008	20 Mar 2008

Midazolam hydrochloride, intravenous	20 Mar 2008	20 Mar 2008
Magnesium citrate, oral	19 Mar 2008	19 Mar 2008
Balsalazide, oral	Prior	Ongoing
Hyoscine, oral	Prior	Ongoing
Metronidazole, oral	22 Apr 2008	04 May 2008
Ciprofloxacin, oral	24 Apr 2008	30 Apr 2008
Hydrocortisone, intravenous	15 May 2008	15 May 2008
Diphenhydramine, intravenous	15 May 2008	15 May 2008
Propofol, intravenous	20 Jun 2008	20 Jun 2008
Midazolam, intravenous	20 Jun 2008	20 Jun 2008
Venlafaxine, oral	20 Jun 2008	Ongoing

Treatment group in induction: 100 mg → 50 mg SC.
Treatment group in maintenance: Responder to golimumab induction → randomized to golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 07 Feb 2008 (Study Day -42)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 07 Feb 2008 (Study Day -42)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 07 Feb 2008 (Study Day -42)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 07 Feb 2008 (Study Day -42)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 21 Feb 2008 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 21 Feb 2008 (Study Day -28)	Admin. 2/ Inj. 6	Golimumab	50 mg
Week 2 (Ind), 21 Feb 2008 (Study Day -28)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 20 Mar 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 20 Mar 2008 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 20 Mar 2008 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 22 Apr 2008 (Study Day 34)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 22 Apr 2008 (Study Day 34)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 22 Apr 2008 (Study Day 34)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 8 (Main), 15 May 2008 (Study Day 57)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 15 May2008 (Study Day 57)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 15 May2008 (Study Day 57)	Admin. 3/ Inj. 9	Golimumab	100 mg
Week 12 (Main)—dose not done	NA	NA	NA

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	15 May 2008.
Last scheduled study treatment visit in maintenance:	Week 8 (Main).
Date of study treatment discontinuation:	20 Jun 2008.

Study status:

Date of study discontinuation:	20 Jun 2008.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	AE of worsening of ulcerative colitis.
Date of disposition status:	20 Jun 2008.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7207-00004

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	顔面不全麻痺 (Peripheral facial nerve paresis)	Unlikely	19 Nov 2008 April 2009

Baseline demographic information: 5[redacted]-year-old (DOB: 01 Aug [redacted]) Caucasian male. Weight: 72.9 kg; height: 170 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:
Date of diagnosis: January 2006.
UC disease duration: 2.2 years.

Prior/concomitant medication, route	Start date	End date
Mesalazine, oral	17 Mar 2008	Ongoing
Azathioprine, oral	17 Mar 2008	Ongoing
Azathioprine, oral	March 2007	16 Mar 2008
Prednisone, oral	21 Nov 2008	04 Dec 2008

Treatment group in induction: 200 mg → 100 mg SC.
Treatment group in maintenance: Responder to golimumab induction → randomized to golimumab 100 mg maintenance.
Dose adjusted? No

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 23 Apr 2008 (Study Day -42)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 23 Apr 2008 (Study Day -42)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 23 Apr 2008 (Study Day -42)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 23 Apr 2008 (Study Day -42)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 07 May 2008 (Study Day -28)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 07 May 2008 (Study Day -28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 07 May 2008 (Study Day -28)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 04 Jun 2008 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 04 Jun 2008 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 04 Jun 2008 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 02 Jul 2008 (Study Day 29)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 4 (Main), 02 Jul 2008 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 02 Jul 2008 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 30 Jul 2008 (Study Day 57)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 30 Jul 2008 (Study Day 57)	Admin. 3/ Inj. 8	Golimumab	100 mg
Week 8 (Main), 30 Jul 2008 (Study Day 57)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 27 Aug 2008 (Study Day 85)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 27 Aug 2008 (Study Day 85)	Admin. 4/ Inj. 11	Golimumab	100 mg
Week 12 (Main), 27 Aug 2008 (Study Day 85)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 24 Sep 2008 (Study Day 113)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 24 Sep 2008 (Study Day 113)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 24 Sep 2008 (Study Day 113)	Admin. 5/ Inj. 15	Golimumab	100 mg
Week 20 (Main), 23 Oct 2008 (Study Day 142)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 23 Oct 2008 (Study Day 142)	Admin. 6/ Inj. 17	Golimumab	100 mg
Week 20 (Main), 23 Oct 2008 (Study Day 142)	Admin. 6/ Inj. 18	Placebo	0 mg
Week 24 (Main), 25 Nov 2008 (Study Day 175)	Admin. 7/ Inj. 19	Golimumab	100 mg
Week 24 (Main), 25 Nov 2008 (Study Day 175)	Admin. 7/ Inj. 20	Placebo	0 mg
Week 24 (Main), 25 Nov 2008 (Study Day 175)	Admin. 7/ Inj. 21	Placebo	0 mg
Week 28 (Main)—dose not done	NA	NA	NA

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Adverse event.
Date of last study agent administration in maintenance: 25 Nov 2008.
Last scheduled study treatment visit in maintenance: Week 24 (Main).
Date of study treatment discontinuation: 16 Dec 2008.

Study status:
Date of study discontinuation: 12 Jan 2009.
Reason for noncompletion: Other.
Other reason for noncompletion/details: Due to sponsor decision (SAE).
Date of disposition status: 12 Jan 2009.
Ended study participation as of Week 54? Yes.
Entered extension study? No.

被験者識別コード：7408-00005

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Ulcerative colitis exacerbation)	Not related	23 Oct 2009 05 Nov 2009 (14 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 25 Feb [redacted]) Caucasian female.
Weight: 76.3 kg; height: 173 cm.

Relevant medical history at baseline: アフタ性口内炎

Baseline smoking status: Nonsmoker.

Ulcerative colitis history:
Date of diagnosis: 18 Dec 1995.
UC disease duration: 13.3 years.

Prior/concomitant medication, route	Start date	End date
Sulfasalazine, oral	January 2009	Ongoing
Levothyroxine sodium, oral	November 2008	Ongoing
Electrolyte solutions, intravenous	25 Mar2009	25 Mar 2009
Glucose, intravenous	25 Mar2009	25 Mar 2009
Potassium chloride, intravenous	25 Mar2009	25 Mar 2009
Thiethylperazine maleate, intravenous	25 Mar2009	25 Mar 2009
Famotidine, intravenous	25 Mar2009	25 Mar 2009
Sulfasalazine, oral	January 2009	24 Oct 2009
Metronidazole, topical	2008	23 Oct 2009
Diosmin, oral	23 Jun 2009	Ongoing
Augmentin /00756801/, oral	30 Sep 2009	07 Oct 2009
Ketoconazole, oral	30 Sep 2009	20 Oct 2009
Acetylcysteine, oral	30 Sep 2009	07 Oct 2009
Ruscoroid, rectal	30 Sep 2009	05 Oct 2009
Mesalazine, oral	23 Oct 2009	Ongoing
Folic acid, oral	23 Oct 2009	Ongoing
Spironolactone, oral	23 Oct 2009	January 2010
Mesalazine, rectal	23 Oct 2009	12 Nov 2009
Hydrocortisone, intravenous	23 Oct 2009	27 Oct 2009
Ciprofloxacin, intravenous	23 Oct 2009	05 Nov 2009
Metronidazole, intravenous	23 Oct 2009	05 Nov 2009
Pantoprazole, oral	23 Oct 2009	05 Nov 2009
Potassium, oral	23 Oct 2009	05 Nov 2009
Iron dextran, intravenous	23 Oct 2009	27 Oct 2009
Pantoprazole, oral	05 Nov 2009	Ongoing
Potassium, oral	05 Nov 2009	Ongoing
Prednisone, oral	28 Oct 2009	10 Feb 2010
Red blood cells, intravenous	27 Oct 2009	28 Oct 2009
Midazolam, intravenous	30 Oct 2009	30 Oct 2009

Treatment group in induction: 200 mg → 100 mg SC.
Treatment group in maintenance: Responder to golimumab induction → randomized to golimumab 100 mg maintenance.
Dose adjusted? Yes.
Adjusted treatment group: Golimumab 100 mg.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 20 Mar 2009 (Study Day -39	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 20 Mar 2009 (Study Day -39)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 20 Mar 2009 (Study Day -39)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 20 Mar 2009 (Study Day -39)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 03 Apr 2009 (Study Day -25)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 03 Apr 2009 (Study Day -25)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 2 (Ind), 03 Apr 2009 (Study Day -25)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 28 Apr 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 28 Apr 2009 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg

Week 0 (Main), 28 Apr 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 26 May 2009 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 26 May 2009 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 26 May 2009 (Study Day 29)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 8 (Main), 23 Jun 2009 (Study Day 57)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 23 Jun 2009 (Study Day 57)	Admin. 3/ Inj. 8	Golimumab	100 mg
Week 8 (Main), 23 Jun 2009 (Study Day 57)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 23 Jul 2009 (Study Day 87)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 23 Jul 2009 (Study Day 87)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 23 Jul 2009 (Study Day 87)	Admin. 4/ Inj. 12	Golimumab	100 mg
Week 16 (Main), 20 Aug 2009 (Study Day 115)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 20 Aug 2009 (Study Day 115)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 20 Aug 2009 (Study Day 115)	Admin. 5/ Inj. 15	Golimumab	100 mg
Week 20 (Main), 17 Sep 2009 (Study Day 143)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 20 (Main), 17 Sep 2009 (Study Day 143)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 20 (Main), 17 Sep 2009 (Study Day 143)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 24 (Main), 16 Oct 2009 (Study Day 172)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 24 (Main), 16 Oct 2009 (Study Day 172)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 24 (Main), 16 Oct 2009 (Study Day 172)	Admin. 2/ Inj. 6	Golimumab	100 mg

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	16 Oct 2009.
Last scheduled study treatment visit in maintenance:	Week 24 (Main).
Date of study treatment discontinuation:	23 Oct 2009.

Study status:

Date of disposition status:	11 Feb 2010.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7704-00002

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE/ Event of interest: Malignancy	肺腺癌 (Adenocarcinoma right upper lobe/lung)	Possible	04 Nov 2009 16 Nov 2009 (13 days)

Baseline demographic information: 6[redacted]-year-old (DOB: 24 Jan [redacted]) Caucasian female.
Weight: 85.3 kg; height: 170 cm.

Relevant medical history at baseline: 関節炎，関節痛，喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:

Date of diagnosis:	December 2005.
UC disease duration:	2.9 years.

Prior/concomitant medication, route	**Start date**	**End date**
Azathioprine, oral	15 Sep 2008	Ongoing
Calcite D, oral	04 Jun 2007	Ongoing
Colesevelam hydrochloride, oral	24 Oct 2006	Ongoing
Cyanocobalamin, subcutaneous	24 Oct 2006	Ongoing
Gabapentin, oral	14 Nov 2007	Ongoing
Paroxetine hydrochloride, oral	07 Dec 2007	Ongoing
Propacet, oral	07 Mar 2007	Ongoing
Lidocaine, topical	Prior	Ongoing
Levofloxacin, oral	22 Dec 2008	26 Dec 2008
Paracetamol, oral	18 Dec 2008	23 Dec 2008
Cortisone, other	06 Apr 2009	06 Apr 2009
Omeprazole, oral	29 Apr 2009	Ongoing
Pethidine, intravenous	17 Aug 2009	17 Aug 2009

Midazolam, intravenous	17 Aug 2009	17 Aug 2009
Influenza vaccine, intramuscular	29 Sep 2009	29 Sep 2009
Cyamopsis tetragonoloba, oral	Nov 2009	Ongoing
Docusate, oral	07 Nov 2009	Ongoing
Guaifenesin, oral	07 Nov 2009	Ongoing
Neotracin/00038301/, topical	07 Nov 2009	Ongoing
Iron, intravenous	December 2009	Ongoing
Azithromycin, oral	December 2009	Ongoing
Seretide, inhalation	November 2009	Ongoing
Methylprednisolone, oral	07 Dec 2009	03 Jan 2010
Benzonatate, oral	07 Dec 2009	03 Jan 2010
Prednisone, oral	04 Jan 2010	09 Jan 2010
Treatment group in induction:	200 mg → 100 mg SC.	
Treatment group in maintenance:	Responder to golimumab induction → randomized to golimumab 100 mg maintenance.	
Dose adjusted?	No.	

Treatment received:

Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 10 Dec 2008 (Study Day -43)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 10 Dec 2008 (Study Day -43)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 10 Dec 2008 (Study Day -43)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 10 Dec 2008 (Study Day -43)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 29 Dec 2008 (Study Day -24)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 29 Dec 2008 (Study Day -24)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 2 (Ind), 29 Dec 2008 (Study Day -24)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 22 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 22 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 22 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 20 Feb 2009 (Study Day 30)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 4 (Main), 20 Feb 2009 (Study Day 30)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 20 Feb 2009 (Study Day 30)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 23 Mar 2009 (Study Day 61)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 23 Mar 2009 (Study Day 61)	Admin. 3/ Inj. 8	Golimumab	100 mg
Week 8 (Main), 23 Mar 2009 (Study Day 61)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 17 Apr 2009 (Study Day 86)	Admin. 4/ Inj. 10	Golimumab	100 mg
Week 12 (Main), 17 Apr 2009 (Study Day 86)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 17 Apr 2009 (Study Day 86)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 15 May 2009 (Study Day 114)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 15 May 2009 (Study Day 114)	Admin. 5/ Inj. 14	Golimumab	100 mg
Week 16 (Main), 15 May 2009 (Study Day 114)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 12 Jun 2009 (Study Day 142)	Admin. 6/ Inj. 16	Golimumab	100 mg
Week 20 (Main), 12 Jun 2009 (Study Day 142)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 20 (Main), 12 Jun 2009 (Study Day 142)	Admin. 6/ Inj. 18	Placebo	0 mg
Week 24 (Main), 10 Jul 2009 (Study Day 170)	Admin. 7/ Inj. 19	Placebo	0 mg
Week 24 (Main), 10 Jul 2009 (Study Day 170)	Admin. 7/ Inj. 20	Golimumab	100 mg
Week 24 (Main), 10 Jul 2009 (Study Day 170)	Admin. 7/ Inj. 21	Placebo	0 mg
Week 28 (Main), 07 Aug 2009 (Study Day 198)	Admin. 8/ Inj. 22	Placebo	0 mg
Week 28 (Main), 07 Aug 2009 (Study Day 198)	Admin. 8/ Inj. 23	Placebo	0 mg
Week 28 (Main), 07 Aug 2009 (Study Day 198)	Admin. 8/ Inj. 24	Golimumab	100 mg
Week 32 (Main), 04 Sep 2009 (Study Day 226)	Admin. 9/ Inj. 25	Golimumab	100 mg
Week 32 (Main), 04 Sep 2009 (Study Day 226)	Admin. 9/ Inj. 26	Placebo	0 mg
Week 32 (Main), 04 Sep 2009 (Study Day 226)	Admin. 9/ Inj. 27	Placebo	0 mg
Week 36 (Main), 02 Oct 2009 (Study Day 254)	Admin. 10/ Inj. 29	Golimumab	100 mg
Week 36 (Main), 02 Oct 2009 (Study Day 254)	Admin. 10/ Inj. 28	Placebo	0 mg
Week 36 (Main), 02 Oct 2009 (Study Day 254)	Admin. 10/ Inj. 30	Placebo	0 mg

Treatment status:	
Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	02 Oct 2009.
Last scheduled study treatment visit in maintenance:	Week 36 (Main).
Date of study treatment discontinuation:	02 Nov2009.
Study status:	
Date of disposition status:	11 Jan 2010.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7796-00002

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Serious infection	虫垂炎 (Acute appendicitis)	Unlikely	13 Jul 2010 14 Jul 2010 (2 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 27 Oct [redacted]) Caucasian male.
Weight: 63.2 kg; height: 170 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped ≤ 1 year ago).

Ulcerative colitis history:
Date of diagnosis: 2007.
UC disease duration: 2.2 years.

Prior/concomitant medication, route	**Start date**	**End date**
Magnesium, oral	09 Mar 2010	09 Mar 2010
Mesalazine, oral	15 Jan 2010	15 Feb 2010
Fleet enema /00129701, rectal	10 Mar 2010	10 Mar 2010
Fleet enema /00129701, rectal	23 Apr 2010	23 Apr 2010
Tramadol, oral	06 Jan 2010	2010
Magnesium phosphate, oral	09 Mar 2010	09 Mar 2010
Mesalazine, oral	15 Jan 2010	12 Feb 2010
Vicodin, oral	14 Jul 2010	20 Jul 2010
Pip/tazo, intravenous	13 Jul 2010	14 Jul 2010
Fleet enema /00129701/, oral	04 Feb 2011	04 Feb 2011

Treatment group in induction: 200 mg → 100 mg SC.
Treatment group in maintenance: Responder to golimumab induction → randomized to golimumab 100 mg maintenance.
Dose adjusted? Yes.
Adjusted treatment group: Golimumab 100 mg.

Treatment received:

Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 10 Mar 2010 (Study Day -44)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 10 Mar 2010 (Study Day -44)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 10 Mar 2010 (Study Day -44)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 10 Mar 2010 (Study Day -44)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 19 Mar 2010 (Study Day -35)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 19 Mar 2010 (Study Day -35)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 0 (Main), 23 Apr 2010 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Main), 23 Apr 2010 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 4 (Main), 21 May 2010 (Study Day 29)	Admin. 2/ Inj. 3	Placebo	0 mg
Week 4 (Main), 21 May 2010 (Study Day 29)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 8 (Main), 21 Jun 2010 (Study Day 60)	Admin. 3/ Inj. 5	Golimumab	100 mg
Week 8 (Main), 21 Jun 2010 (Study Day 60)	Admin. 3/ Inj. 6	Placebo	0 mg
Week 12 (Main), 23 Jul 2010 (Study Day 92)	Admin. 4/ Inj. 7	Golimumab	100 mg
Week 12 (Main), 23 Jul 2010 (Study Day 92)	Admin. 4/ Inj. 8	Placebo	0 mg
Week 16 (Main), 13 Aug 2010 (Study Day 113)	Admin. 5/ Inj. 9	Placebo	0 mg
Week 16 (Main), 13 Aug 2010 (Study Day 113)	Admin. 5/ Inj. 10	Golimumab	100 mg
Week 20 (Main), 10 Sep 2010 (Study Day 141)	Admin. 6/ Inj. 11	Placebo	0 mg

Week 20 (Main), 10 Sep 2010 (Study Day 141)	Admin. 6/ Inj. 12	Golimumab	100 mg
Week 24 (Main), 15 Oct 2010 (Study Day 176)	Admin. 7/ Inj. 14	Golimumab	100 mg
Week 24 (Main), 15 Oct 2010 (Study Day 176)	Admin. 7/ Inj. 13	Placebo	0 mg
Week 28 (Main), 12 Nov 2010 (Study Day 204)	Admin. 8/ Inj. 15	Golimumab	100 mg
Week 28 (Main), 12 Nov 2010 (Study Day 204)	Admin. 8/ Inj. 16	Placebo	0 mg
Week 32 (Main), 10 Dec 2010 (Study Day 232)	Admin. 9/ Inj. 17	Placebo	0 mg
Week 32 (Main), 10 Dec 2010 (Study Day 232)	Admin. 9/ Inj. 18	Golimumab	100 mg
Week 36 (Main), 12 Jan 2011 (Study Day 265)	Admin. 10/ Inj. 20	Golimumab	100 mg
Week 36 (Main), 12 Jan 2011 (Study Day 265)	Admin. 10/ Inj. 19	Placebo	0 mg
Week 40 (Main), 28 Jan 2011 (Study Day 281)	Admin. 11/ Inj. 22	Golimumab	100 mg
Week 40 (Main), 28 Jan 2011 (Study Day 281)	Admin. 11/ Inj. 21	Placebo	0 mg
Week 44 (Main), 24 Feb 2011 (Study Day 308)	Admin. 12/ Inj. 23	Placebo	0 mg
Week 44 (Main), 24 Feb 2011 (Study Day 308)	Admin. 12/ Inj. 24	Golimumab	100 mg
Week 48 (Main), 31 Mar 2011 (Study Day 343)	Admin. 13/ Inj. 26	Golimumab	100 mg
Week 48 (Main), 31 Mar 2011 (Study Day 343)	Admin. 13/ Inj. 25	Placebo	0 mg
Unscheduled 1 (Main)—dose not done	NA	NA	NA
Unscheduled 2 (Main), 15 Apr 2011 (Study Day 358)	Admin. 1/ Inj. 2	Golimumab	100 mg
Unscheduled 2 (Main), 15 Apr 2011 (Study Day 358)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 52 (Main), 22 Apr 2011 (Study Day 365)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 52 (Main), 22 Apr 2011 (Study Day 365)	Admin. 2/ Inj. 3	Placebo	0 mg

Treatment status:

Study treatment discontinuation?	No.
Date of last study agent administration in maintenance:	22 Apr 2011.
Last scheduled study treatment visit in maintenance:	Week 52 (Main).

Study status:

Date of study discontinuation:	14 Jul 2011.
Reason for noncompletion:	Lost to follow-up.
Date of disposition status:	14 Jul 2011.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：6402-00007

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
Event of interest: Active TB	結核 (*Mycobacterium tuberculosis* infection likely)	Possible	17 Nov 2010 10 Jun 2011 (206 days)
SAE/ Permanent discontinuation of study agent due to AE	肺浸潤 (Infiltration of right medial lung lobe of unknown origin)	Unlikely	12 May 2011 Ongoing

Baseline demographic information: 4[redacted]-year-old (DOB: 03 Jul [redacted]) Caucasian male from Poland. Weight: 72.4 kg; height: 182 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:

Date of diagnosis:	05 Aug 1993.
UC disease duration:	16.7 years.

Prior/concomitant medication, route	**Start date**	**End date**
Mesalazine, oral	20 Apr 2005	Ongoing
Methylprednisolone, oral	01 Dec 2009	Ongoing
Ferrous sulfate, oral	15 Jul 2009	Ongoing
Folic acid, oral	15 Jul 2009	Ongoing
Methylprednisolone, oral	01 Dec 2009	21 Feb 2011
Iron, oral	15 Jul 2009	Ongoing
Isoniazid, oral	22 Nov 2010	Ongoing

Treatment group in induction:	400 mg → 200 mg SC.
Treatment group in maintenance:	Responder to golimumab induction → randomized to golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 07 Apr 2010 (Study Day -48)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 07 Apr 2010 (Study Day -48)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 07 Apr 2010 (Study Day -48)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 07 Apr 2010 (Study Day -48)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 23 Apr 2010 (Study Day -32)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 23 Apr 2010 (Study Day -32)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 25 May 2010 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 25 May 2010 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 4 (Main), 29 Jun 2010 (Study Day 36)	Admin. 2/ Inj. 3	Placebo	0 mg
Week 4 (Main), 29 Jun 2010 (Study Day 36)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 8 (Main), 27 Jul 2010 (Study Day 64)	Admin. 3/ Inj. 5	Golimumab	100 mg
Week 8 (Main), 27 Jul 2010 (Study Day 64)	Admin. 3/ Inj. 6	Placebo	0 mg
Week 12 (Main), 24 Aug 2010 (Study Day 92)	Admin. 4/ Inj. 7	Placebo	0 mg
Week 12 (Main), 24 Aug 2010 (Study Day 92)	Admin. 4/ Inj. 8	Golimumab	100 mg
Week 16 (Main), 21 Sep 2010 (Study Day 120)	Admin. 5/ Inj. 9	Golimumab	100 mg
Week 16 (Main), 21 Sep 2010 (Study Day 120)	Admin. 5/ Inj. 10	Placebo	0 mg
Week 20 (Main), 22 Oct 2010 (Study Day 151)	Admin. 6/ Inj. 11	Placebo	0 mg
Week 20 (Main), 22 Oct 2010 (Study Day 151)	Admin. 6/ Inj. 12	Golimumab	100 mg
Week 24 (Main)—dose not done	NA	NA	NA
Week 28 (Main), 16 Dec 2010 (Study Day 206)	Admin. 7/ Inj. 13	Placebo	0 mg
Week 28 (Main), 16 Dec 2010 (Study Day 206)	Admin. 7/ Inj. 14	Golimumab	100 mg
Week 30 (Main)—dose not done	NA	NA	NA
Week 32 (Main), 04 Jan 2011 (Study Day 225)	Admin. 8/ Inj. 15	Golimumab	100 mg
Week 32 (Main), 04 Jan 2011 (Study Day 225)	Admin. 8/ Inj. 16	Placebo	0 mg
Week 36 (Main), 25 Jan 2011 (Study Day 246)	Admin. 9/ Inj. 17	Golimumab	100 mg
Week 36 (Main), 25 Jan 2011 (Study Day 246)	Admin. 9/ Inj. 18	Placebo	0 mg
Week 40 (Main), 22 Feb 2011 (Study Day 274)	Admin. 10/ Inj. 19	Golimumab	100 mg
Week 40 (Main), 22 Feb 2011 (Study Day 274)	Admin. 10/ Inj. 20	Placebo	0 mg
Week 44 (Main), 22 Mar 2011 (Study Day 302)	Admin. 11/ Inj. 21	Placebo	0 mg
Week 44 (Main), 22 Mar 2011 (Study Day 302)	Admin. 11/ Inj. 22	Golimumab	100 mg
Week 48 (Main), 20 Apr 2011 (Study Day 331)	Admin. 12/ Inj. 23	Golimumab	100 mg
Week 48 (Main), 20 Apr 2011 (Study Day 331)	Admin. 12/ Inj. 24	Placebo	0 mg
Week 52 (Main), 18 May 2011 (Study Day 359)	Admin. 13/ Inj. 25	Placebo	0 mg
Week 52 (Main), 18 May 2011 (Study Day 359)	Admin. 13/ Inj. 26	Golimumab	100 mg

Treatment status:	
Study treatment discontinuation?	No.
Date of last study agent administration in maintenance:	18 May 2011.
Last scheduled study treatment visit in maintenance:	Week 52 (Main).
Study status:	
Date of disposition status:	01 Jun 2011.
Ended study participation as of Week 54?	No.
Entered extension study?	Yes.

被験者識別コード：6407-00032

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE/ Event of interest: Heart failure	心不全 (Heart failure with preserved systolic function)	Unlikely	04 Mar 2011 08 Mar 2011 (5 days)
Died/ SAE/ Event of interest: Heart failure	心不全 (Heart failure)	Unlikely	23 Apr 2011 08 May 2011 (16 days)

Baseline demographic information: 6[redacted]-year-old (DOB: 30 Nov [redacted]) Caucasian male.
Weight: 63.5 kg; height: 164 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:
Date of diagnosis: 10 Jan 2001.
UC disease duration: 9.3 years.

Prior/concomitant medication, route	Start date	End date
Methylprednisolone, oral	December 2009	Ongoing
Mesalazine, oral	December 2009	Ongoing
Omeprazole, oral	February 2010	Ongoing
Ticlopidine, oral	2000	Ongoing
Amoxicillin, oral	25 Jan 2011	02 Feb 2011
Enoxaparin, subcutaneous	04 Mar 2011	Ongoing
Ramipril, oral	04 Mar 2011	Ongoing
Furosemide, oral	04 Mar 2011	Ongoing
Potassium, oral	04 Mar 2011	Ongoing

Treatment group in induction: 400 mg → 200 mg SC.
Treatment group in maintenance: Responder to golimumab induction → randomized to golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 27 Apr 2010 (Study Day -42)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 27 Apr 2010 (Study Day -42)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 27 Apr 2010 (Study Day -42)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 27 Apr 2010 (Study Day -42)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 11 May 2010 (Study Day -28)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 11 May 2010 (Study Day -28)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 08 Jun 2010 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Main), 08 Jun 2010 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 4 (Main), 06 Jul 2010 (Study Day 29)	Admin. 2/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 06 Jul 2010 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 8 (Main), 03 Aug 2010 (Study Day 57)	Admin. 3/ Inj. 5	Golimumab	100 mg
Week 8 (Main), 03 Aug 2010 (Study Day 57)	Admin. 3/ Inj. 6	Placebo	0 mg
Week 12 (Main), 31 Aug 2010 (Study Day 85)	Admin. 4/ Inj. 7	Placebo	0 mg
Week 12 (Main), 31 Aug 2010 (Study Day 85)	Admin. 4/ Inj. 8	Golimumab	100 mg
Week 16 (Main), 28 Sep 2010 (Study Day 113)	Admin. 5/ Inj. 9	Placebo	0 mg
Week 16 (Main), 28 Sep 2010 (Study Day 113)	Admin. 5/ Inj. 10	Golimumab	100 mg
Week 20 (Main), 26 Oct 2010 (Study Day 141)	Admin. 6/ Inj. 11	Placebo	0 mg
Week 20 (Main), 26 Oct 2010 (Study Day 141)	Admin. 6/ Inj. 12	Golimumab	100 mg
Week 24 (Main), 23 Nov 2010 (Study Day 169)	Admin. 7/ Inj. 13	Golimumab	100 mg
Week 24 (Main), 23 Nov 2010 (Study Day 169)	Admin. 7/ Inj. 14	Placebo	0 mg
Week 28 (Main), 27 Dec 2010 (Study Day 203)	Admin. 8/ Inj. 15	Golimumab	100 mg
Week 28 (Main), 27 Dec 2010 (Study Day 203)	Admin. 8/ Inj. 16	Placebo	0 mg
Week 32 (Main), 18 Jan 2011 (Study Day 225)	Admin. 9/ Inj. 17	Golimumab	100 mg
Week 32 (Main), 18 Jan 2011 (Study Day 225)	Admin. 9/ Inj. 18	Placebo	0 mg
Week 36 (Main), 15 Feb 2011 (Study Day 253)	Admin. 10/ Inj. 19	Golimumab	100 mg
Week 36 (Main), 15 Feb 2011 (Study Day 253)	Admin. 10/ Inj. 20	Placebo	0 mg

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Adverse event.
Date of last study agent administration in maintenance: 15 Feb 2011.
Last scheduled study treatment visit in maintenance: Week 36 (Main).
Date of study treatment discontinuation: 17 Mar 2011.

Study status:	
Date of study discontinuation:	17 Mar 2011.
Reason for noncompletion:	Withdrawal of consent.
Date of disposition status:	17 Mar 2011.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7007-00004

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Unlikely	February 2010 17 Mar 2010

Baseline demographic information: 4[redacted]-year-old (DOB: 21 Oct [redacted]) Caucasian female.
Weight: 89 kg; height: 178 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:
Date of diagnosis: 04 Feb 2003.
UC disease duration: 6.4 years.

Prior/concomitant medication, route	**Start date**	**End date**
Flucloxacillin, oral	18 Jun 2009	26 Jun 2009
Flucloxacillin, oral	05 Jul 2009	09 Jul 2009
Isotretinoin, oral	26 Jun 2009	Ongoing
Isotretinoin, oral	26 Jun 2009	01 Dec 2009
Paracetamol, oral	11 Mar 2010	12 Mar 2010
Cefalexin, oral	14 Mar 2010	22 Mar 2010
Loratadine, oral	12 Mar 2010	12 Mar 2010
Ergocalciferol, oral	12 Mar 2010	Ongoing
Enoxaparin, subcutaneous	12 Mar 2010	17 Mar 2010
Prednisolone, oral	14 Mar 2010	18 Mar 2010
Infliximab, intravenous	12 Mar 2010	12 Mar 2010
Fleet enema /00129701, rectal	16 Mar 2010	16 Mar 2010
Fentanyl, intravenous	16 Mar 2010	16 Mar 2010
Midazolam, intravenous	16 Mar 2010	16 Mar 2010
Propofol, intravenous	16 Mar 2010	16 Mar 2010
Hydrocortisone, intravenous	11 Mar 2010	14 Mar 2010
Azathioprine, oral	17 Mar 2010	08 Jun 2010
Prednisolone, oral	19 Mar 2010	23 Mar 2010
Azathioprine, oral	09 Jun 2010	Ongoing
Prednisolone, oral	24 Mar 2010	28 Mar 2010
Prednisolone, oral	29 Mar 2010	02 Apr 2010
Prednisolone, oral	03 Apr 2010	07 Apr 2010
Prednisolone, oral	08 Apr 2010	12 Apr 2010
Prednisolone, oral	17 Apr 2010	21 Apr 2010
Prednisolone, oral	08 Jun 2010	12 Jun 2010
Prednisolone, oral	13 Jun 2010	17 Jun 2010
Prednisolone, oral	18 Jun 2010	22 Jun 2010
Prednisolone, oral	23 Jun 2010	27 Jun 2010
Prednisolone, oral	28 Jun 2010	Ongoing
Infliximab, intravenous	01 Apr 2010	01 Apr 2010
Infliximab, intravenous	30 Apr 2010	30 Apr 2010
Infliximab, intravenous	28 Jun 2010	28 Jun 2010

Treatment group in induction:	400 mg → 200 mg SC.
Treatment group in maintenance:	Responder to golimumab induction → randomized to golimumab 100 mg maintenance.
Dose adjusted?	Yes.
Adjusted treatment group:	Golimumab 100 mg.

Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 08 Jul 2009 (Study Day -42)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 08 Jul 2009 (Study Day -42)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 08 Jul 2009 (Study Day -42)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 08 Jul 2009 (Study Day -42)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 21 Jul 2009 (Study Day -29)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 21 Jul 2009 (Study Day -29)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 2 (Ind), 21 Jul 2009 (Study Day -29)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 19 Aug 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 19 Aug 2009 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Main), 19 Aug 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 15 Sep 2009 (Study Day 28)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 15 Sep 2009 (Study Day 28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 15 Sep2009 (Study Day 28)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 8 (Main), 13 Oct 2009 (Study Day 56)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 13 Oct 2009 (Study Day 56)	Admin. 3/ Inj. 8	Golimumab	100 mg
Week 8 (Main), 13 Oct 2009 (Study Day 56)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 10 Nov 2009 (Study Day 84)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 10 Nov 2009 (Study Day 84)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 10 Nov 2009 (Study Day 84)	Admin. 4/ Inj. 12	Golimumab	100 mg
Week 16 (Main), 08 Dec 2009 (Study Day 112)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 08 Dec 2009 (Study Day 112)	Admin. 5/ Inj. 14	Golimumab	100 mg
Week 16 (Main), 08 Dec 2009 (Study Day 112)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 05 Jan 2010 (Study Day 140)	Admin. 6/ Inj. 16	Golimumab	100 mg
Week 20 (Main), 05 Jan 2010 (Study Day 140)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 20 (Main), 05 Jan 2010 (Study Day 140)	Admin. 6/ Inj. 18	Placebo	0 mg
Week 24 (Main), 02 Feb 2010 (Study Day 168)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 24 (Main), 02 Feb 2010 (Study Day 168)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 24 (Main), 02 Feb 2010 (Study Day 168)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 28 (Main), 02 Mar 2010 (Study Day 196)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 28 (Main), 02 Mar 2010 (Study Day 196)	Admin. 2/ Inj. 5	Golimumab	100 mg
Treatment status:			
Study treatment discontinuation?	Yes.		
Reason for treatment discontinuation:	Adverse event.		
Date of last study agent administration in maintenance:	02 Mar 2010.		
Last scheduled study treatment visit in maintenance:	Week 28 (Main).		
Date of study treatment discontinuation:	16 Mar 2010.		
Study status:			
Date of disposition status:	28 Jun 2010.		
Ended study participation as of Week 54?	Yes.		
Entered extension study?	No.		

被験者識別コード：7008-00016

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Unlikely	15 Oct 2010 21 Oct 2010 (7 days)
Baseline demographic information: 6[redacted]-year-old (DOB: 11 Jan [redacted]) Caucasian female. Weight: 72.1 kg; height: 157 cm.			
Relevant medical history at baseline: 関節炎，関節痛，自己免疫性肝炎，喫煙（過去）			
Baseline smoking status: Prior smoker (stopped > 1 year ago).			
Ulcerative colitis history: Date of diagnosis: 1973. UC disease duration: 35.8 years.			

Prior/concomitant medication, route	Start date	End date
Mercaptopurine, oral	2004	Ongoing
Esomeprazole magnesium, oral	2005	Ongoing
Meloxicam, oral	15 Sep 2009	Ongoing
Metformin, oral	07 Oct 2009	Ongoing
Nicotine, transdermal	October 2009	Ongoing
Loperamide hydrochloride, oral	2000	Ongoing
Prednisone, oral	20 Sep 2009	Ongoing
Isoniazid, oral	04 Nov 2009	Ongoing
Pyridoxine, oral	04 Nov 2009	Ongoing
Midazolam, intravenous	27 Oct 2009	27 Oct 2009
Fentanyl, intravenous	27 Oct 2009	27 Oct 2009
Midazolam, intravenous	15 Dec 2009	15 Dec 2009
Fentanyl, intravenous	15 Dec 2009	15 Dec 2009
Esomeprazole, oral	2005	Ongoing
Meloxicam, oral	15 Sep 2009	03 Nov 2009
Metformin, oral	07 Oct 2009	10 Jan 2010
Nicotine, transdermal	October 2005	October 2008
Loperamide, oral	2000	Ongoing
Ferric hydroxide polymaltose complex, intravenous	01 Mar 2010	01 Mar 2010
Lidocaine, subcutaneous	01 Mar 2010	01 Mar 2010
Influenza vaccine, subcutaneous	08 Apr 2010	08 Apr 2010
Terbinafine, topical	08 Apr 2010	01 Oct 2010
Midazolam, intravenous	14 Jul 2010	14 Jul 2010
Fentanyl, intravenous	14 Jul 2010	14 Jul 2010
Movicol /01749801/, oral	18 Aug 2010	14 Oct 2010
Docusate, oral	14 Aug 2010	Ongoing
Midazolam, intravenous	20 Aug 2010	20 Aug 2010
Fentanyl, intravenous	20 Aug 2010	20 Aug 2010
Lekovit Ca, oral	03 Oct 2010	Ongoing
Oxycodone, oral	04 Oct 2010	04 Oct 2010
Oxycodone, oral	03 Oct 2010	04 Oct 2010
Chloramphenicol, od (right eye)	30 Sep 2010	30 Oct 2010
Tobramycin, od (right eye)	30 Sep 2010	30 Oct 2010
Panadeine co, oral	03 Oct 2010	04 Oct 2010
Paracetamol, oral	03 Oct 2010	03 Oct 2010
Heparin, subcutaneous	15 Oct 2010	21 Oct 2010
Hydrocortisone, intravenous	15 Oct 2010	19 Oct 2010
Spironolactone, oral	16 Oct 2010	20 Oct 2010
Paracetamol, oral	20 Oct 2010	20 Oct 2010
Temazepam, oral	20 Oct 2010	20 Oct 2010
Metformin, oral	30 Dec 2010	08 Feb 2011
Calcium carbonate, oral	18 Oct 2010	Ongoing
Midazolam, intravenous	15 Oct 2010	15 Oct 2010
Propofol, intravenous	15 Oct 2010	15 Oct 2010
Prednefrin /00330801, topical	15 Oct 2010	30 Oct 2010
Propofol, intravenous	18 Jan 2011	18 Jan 2011
Propofol, intravenous	17 Dec 2010	17 Dec 2010
Midazolam, intravenous	17 Dec 2010	17 Dec 2010
Fentanyl, intravenous	17 Dec 2010	17 Dec 2010
Metformin, oral	09 Feb 2011	Ongoing
Gliclazide, oral	09 Feb 2011	Ongoing
Treatment group in induction:	400 mg → 200 mg SC.	
Treatment group in maintenance:	Responder to golimumab induction → randomized to golimumab 100 mg maintenance.	
Dose adjusted?	Yes.	
Adjusted treatment group:	Golimumab 100 mg.	

Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 04 Nov 2009 (Study Day -42)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 04 Nov 2009 (Study Day -42)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 04 Nov 2009 (Study Day -42)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 04 Nov 2009 (Study Day -42)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 18 Nov 2009 (Study Day -28)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 18 Nov 2009 (Study Day -28)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 16 Dec 2009 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 16 Dec 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 16 Dec 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 13 Jan 2010 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 13 Jan 2010 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 13 Jan 2010 (Study Day 29)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 8 (Main), 10 Feb 2010 (Study Day 57)	Admin. 3/ Inj. 7	Golimumab	100 mg
Week 8 (Main), 10 Feb 2010 (Study Day 57)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 10 Feb 2010 (Study Day 57)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main)—dose not done	NA	NA	NA
Week 12 (Main), 10 Mar 2010 (Study Day 85)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 10 Mar 2010 (Study Day 85)	Admin. 4/ Inj. 11	Golimumab	100 mg
Week 16 (Main), 07 Apr 2010 (Study Day 113)	Admin. 5/ Inj. 12	Placebo	0 mg
Week 16 (Main), 07 Apr 2010 (Study Day 113)	Admin. 5/ Inj. 13	Golimumab	100 mg
Week 20 (Main), 05 May 2010 (Study Day 141)	Admin. 6/ Inj. 14	Placebo	0 mg
Week 20 (Main), 05 May 2010 (Study Day 141)	Admin. 6/ Inj. 15	Golimumab	100 mg
Week 24 (Main), 26 May 2010 (Study Day 162)	Admin. 7/ Inj. 16	Golimumab	100 mg
Week 24 (Main), 26 May 2010 (Study Day 162)	Admin. 7/ Inj. 17	Placebo	0 mg
Week 28 (Main), 23 Jun 2010 (Study Day 190)	Admin. 8/ Inj. 18	Golimumab	100 mg
Week 28 (Main), 23 Jun 2010 (Study Day 190)	Admin. 8/ Inj. 19	Placebo	0 mg
Week 32 (Main), 21 Jul 2010 (Study Day 218)	Admin. 9/ Inj. 20	Placebo	0 mg
Week 32 (Main), 21 Jul 2010 (Study Day 218)	Admin. 9/ Inj. 21	Golimumab	100 mg
Week 36 (Main)—dose not done	NA	NA	NA
Unscheduled 1 (Main), 20 Aug 2010 (Study Day 248)	Admin. 1/ Inj. 1	Golimumab	100 mg
Unscheduled 1 (Main), 20 Aug 2010 (Study Day 248)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 40 (Main), 15 Sep 2010 (Study Day 274)	Admin. 2/ Inj. 3	Golimumab	100 mg
Week 40 (Main), 15 Sep 2010 (Study Day 274)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 44 (Main), 13 Oct 2010 (Study Day 302)	Admin. 3/ Inj. 5	Placebo	0 mg
Week 44 (Main), 13 Oct 2010 (Study Day 302)	Admin. 3/ Inj. 6	Golimumab	100 mg
Treatment status:			
Study treatment discontinuation?	Yes.		
Reason for treatment discontinuation:	Adverse event.		
Date of last study agent administration in maintenance:	13 Oct 2010.		
Last scheduled study treatment visit in maintenance:	Week 44 (Main).		
Date of study treatment discontinuation:	15 Oct 2010.		
Study status:			
Date of disposition status:	02 Feb 2011.		
Ended study participation as of Week 54?	No.		
Entered extension study?	No.		

被験者識別コード：7026-00030

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE/ Serious infection	心膜炎 (Pericarditis)	Possible	07 Feb 2011 31 May 2011 (114 days)
Baseline demographic information: 2[redacted]-year-old (DOB: 11 Jul [redacted]) Caucasian male. Weight: 66 kg; height: 174 cm.			
Relevant medical history at baseline: 関節痛，喫煙（過去）			
Baseline smoking status: Prior smoker.			

Ulcerative colitis history: Date of diagnosis: July 2009. UC disease duration: 0.9 years.		
Prior/concomitant medication, route	**Start date**	**End date**
Azathioprine, oral	15 Apr 2010	Ongoing
Prednisolone, oral	15 May 2010	Ongoing
Pantoprazole sodium, oral	20 Apr 2010	Ongoing
Lekovit CA, oral	09 Apr 2010	Ongoing
Bactrim, oral	22 Jun 2010	Ongoing
Azathioprine, oral	15 Apr 2010	20 Aug 2010
Prednisolone, oral	15 May 2010	21 Jul 2010
Pantoprazole, oral	20 Apr 2010	03 Aug 2010
Lekovit CA, oral	09 Apr 2010	18 Aug 2010
Bactrim, oral	22 Jun 2010	18 Aug 2010
Prednisolone, oral	22 Jul 2010	28 Jul 2010
Prednisolone, oral	29 Jul 2010	04 Aug 2010
Prednisolone, oral	05 Aug 2010	11 Aug 2010
Prednisolone, oral	12 Aug 2010	18 Aug 2010
Acetylsalicylic acid, oral	27 Dec 2010	30 Dec 2010
Neocitran /00430301/, oral	30 Dec 2010	30 Dec 2010
Augmentin /00756801/, oral	10 Feb 2011	11 Feb 2011
Dalteparin, subcutaneous	11 Feb 2011	22 Feb 2011
Metamizole, oral	11 Feb 2011	24 Feb 2011
Furosemide, intravenous	17 Feb 2011	17 Feb 2011
Furosemide, oral	18 Feb 2011	25 Feb 2011
Cefpirome, intravenous	11 Feb 2011	21 Feb 2011
Nebivolol, oral	11 Feb 2011	21 Feb 2011
Pantoprazole, oral	11 Feb 2011	22 Feb 2011
Ibuprofen, oral	03 Mar 2011	08 Mar 2011
Metamizole, oral	25 Feb 2011	04 Mar 2011
Metronidazole, oral	02 Mar 2011	16 Mar 2011
Prednisolone, intravenous	21 Mar 2011	21 Mar 2011
Levofloxacin, oral	22 Mar 2011	23 Mar 2011
Azathioprine, oral	22 Mar 2011	Ongoing
Furosemide, oral	26 Feb 2011	06 Mar 2011
Prednisolone, oral	22 Mar 2011	25 Mar 2011
Prednisolone, oral	25 Mar 2011	01 Apr 2011
Prednisolone, oral	02 Apr 2011	20 Apr 2011
Prednisolone, oral	21 Apr 2011	04 May 2011
Prednisolone, oral	05 May 2011	14 May 2011
Prednisolone, oral	15 May 2011	24 May 2011
Prednisolone, oral	25 May 2011	Ongoing
Treatment group in induction:	400 mg → 200 mg SC.	
Treatment group in maintenance:	Responder to golimumab induction → randomized to golimumab 100 mg maintenance.	
Dose adjusted?	Yes.	
Adjusted treatment group:	Golimumab 100 mg.	

Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 08 Jun 2010 (Study Day -42)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 08 Jun 2010 (Study Day -42)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 08 Jun 2010 (Study Day -42)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 08 Jun 2010 (Study Day -42)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 22 Jun 2010 (Study Day -28)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 22 Jun 2010 (Study Day -28)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 20 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 20 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 4 (Main), 17 Aug 2010 (Study Day 29)	Admin. 2/ Inj. 3	Placebo	0 mg
Week 4 (Main), 17 Aug 2010 (Study Day 29)	Admin. 2/ Inj. 4	Golimumab	100 mg

Week 8 (Main), 16 Sep 2010 (Study Day 59)	Admin. 3/ Inj. 5	Golimumab	100 mg
Week 8 (Main), 16 Sep 2010 (Study Day 59)	Admin. 3/ Inj. 6	Placebo	0 mg
Week 12 (Main), 12 Oct 2010 (Study Day 85)	Admin. 4/ Inj. 7	Placebo	0 mg
Week 12 (Main), 12 Oct 2010 (Study Day 85)	Admin. 4/ Inj. 8	Golimumab	100 mg
Unscheduled 1 (Main)—dose not done	NA	NA	NA
Unscheduled 1 (Main)—dose not done	NA	NA	NA
Week 16 (Main), 10 Nov 2010 (Study Day 114)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 16 (Main), 10 Nov 2010 (Study Day 114)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 20 (Main), 07 Dec 2010 (Study Day 141)	Admin. 2/ Inj. 3	Golimumab	100 mg
Week 20 (Main), 07 Dec 2010 (Study Day 141)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 24 (Main), 04 Jan 2011 (Study Day 169)	Admin. 3/ Inj. 5	Golimumab	100 mg
Week 24 (Main), 04 Jan 2011 (Study Day 169)	Admin. 3/ Inj. 6	Placebo	0 mg
Week 28 (Main), 01 Feb 2011 (Study Day 197)	Admin. 4/ Inj. 7	Golimumab	100 mg
Week 28 (Main), 01 Feb 2011 (Study Day 197)	Admin. 4/ Inj. 8	Placebo	0 mg

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	01 Feb 2011.
Last scheduled study treatment visit in maintenance:	Week 28 (Main).
Date of study treatment discontinuation:	25 Mar 2011.

Study status:

Date of disposition status:	31 May 2011.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7126-00011

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Flare of UC)	Not related	04 Mar 2010 09 Mar 2010 (6 days)

Baseline demographic information: 6[redacted]-year-old (DOB: 02 Sep [redacted]) Caucasian female.
Weight: 71.6 kg; height: 172 cm.

Relevant medical history at baseline: 結節性紅斑，喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:
Date of diagnosis: 1975.
UC disease duration: 33.6 years.

Prior/concomitant medication, route	**Start date**	**End date**
Prednisone, oral	24 Jul 2009	20 Nov 2009
Vitamineral, oral	Prior	Ongoing
Escitalopram, oral	Prior	Ongoing
Zolpidem, oral	21 Jun 2009	28 Sep 2009
Fusidic acid, ophthalmic	02 Oct 2009	07 Oct 2009
Phenoxymethylpenicillin, oral	21 Dec 2009	27 Dec 2009
Xylometazoline, nasogastric	28 Dec 2009	04 Jan 2010
Paracetamol, oral	16 Jan 2010	30 Jan 2010
Codeine, oral	16 Jan 2010	30 Jan 2010
Infliximab, intravenous	04 Mar 2010	05 Mar 2010
Ciprofloxacin, intravenous	07 Mar 2010	08 Mar 2010
Ciprofloxacin, intravenous	09 Mar 2010	10 Mar 2010
Metronidazole, intravenous	09 Mar 2010	10 Mar 2010
Metronidazole, intravenous	07 Mar 2010	08 Mar 2010

Treatment group in induction:	400 mg → 200 mg SC.
Treatment group in maintenance:	Responder to golimumab induction → randomized to golimumab 100 mg maintenance.
Dose adjusted?	Yes.
Adjusted treatment group:	Golimumab 100 mg.

Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 11 Aug 2009 (Study Day -44)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 11 Aug 2009 (Study Day -44)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 11 Aug 2009 (Study Day -44)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 11 Aug 2009 (Study Day -44)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 24 Aug 2009 (Study Day -31)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 24 Aug 2009 (Study Day -31)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 24 Aug 2009 (Study Day -31)	Admin. 2/ Inj. 7	Golimumab	100 mg
Week 0 (Main), 24 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 24 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Main), 24 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 22 Oct 2009 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 22 Oct 2009 (Study Day 29)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 4 (Main), 22 Oct 2009 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 8 (Main), 26 Nov 2009 (Study Day 64)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 26 Nov 2009 (Study Day 64)	Admin. 3/ Inj. 8	Golimumab	100 mg
Week 8 (Main), 26 Nov 2009 (Study Day 64)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 28 Dec 2009 (Study Day 96)	Admin. 4/ Inj. 10	Golimumab	100 mg
Week 12 (Main), 28 Dec 2009 (Study Day 96)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 28 Dec 2009 (Study Day 96)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 18 Jan 2010 (Study Day 117)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 18 Jan 2010 (Study Day 117)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 18 Jan 2010 (Study Day 117)	Admin. 5/ Inj. 15	Golimumab	100 mg
Week 20 (Main), 11 Feb 2010 (Study Day 141)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 11 Feb 2010 (Study Day 141)	Admin. 6/ Inj. 17	Golimumab	100 mg
Week 20 (Main), 11 Feb 2010 (Study Day 141)	Admin. 6/ Inj. 18	Placebo	0 mg
Unscheduled 1 (Main), 26 Feb 2010 (Study Day 156)	Admin. 1/ Inj. 1	Placebo	0 mg
Unscheduled 1 (Main), 26 Feb 2010 (Study Day 156)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 24 (Main)—dose not done	NA	NA	NA
Treatment status:			
Study treatment discontinuation?	Yes.		
Reason for treatment discontinuation:	Adverse event.		
Date of last study agent administration in maintenance:	26 Feb 2010.		
Last scheduled study treatment visit in maintenance:	Week 20 (Main).		
Date of study treatment discontinuation:	04 Mar 2010.		
Study status:			
Date of disposition status:	18 Jun 2010.		
Ended study participation as of Week 54?	Yes.		
Entered extension study?	No.		

被験者識別コード：7716-00010

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Not related	11 Oct 2009 16 Oct 2009 (6 days)
Baseline demographic information: 3[redacted]-year-old (DOB: 26 Jun [redacted]) Black female. Weight: 92.1 kg; height: 160 cm.			
Relevant medical history at baseline: 喫煙（過去）			
Baseline smoking status: Prior smoker (stopped > 1 year ago).			
Ulcerative colitis history:			
Date of diagnosis: 1996.			
UC disease duration: 11.9 years.			
Prior/concomitant medication, route	**Start date**	**End date**	
Mesalazine, oral	2004	Ongoing	
Mesalazine, oral	Prior	Ongoing	
Dicycloverine, oral	18 Mar 2009	Ongoing	

Medinite, oral	30 Apr 2009	30 Apr 2009
Cetirizine, oral	01 May 2009	01 May 2009
Vicodin, oral	20 Jun 2009	04 Jul 2009
Sertraline, oral	16 Jun 2009	Ongoing
Quetiapine, oral	15 Oct 2009	Ongoing
Omeprazole, oral	15 Oct 2009	29 Oct 2009
Oxycocet, oral	15 Oct 2009	Ongoing
Iron, oral	15 Oct 2009	Ongoing
Pantoprazole, intravenous	11 Oct 2009	15 Oct 2009
Hydromorphone, intravenous	11 Oct 2009	11 Oct 2009
Promethazine, intravenous	11 Oct 2009	11 Oct 2009
Levofloxacin, intravenous	11 Oct 2009	15 Oct 2009
Metronidazole, oral	11 Oct 2009	15 Oct 2009
Fentanyl, intravenous	13 Oct 2009	13 Oct 2009
Midazolam, intravenous	13 Oct 2009	13 Oct 2009
I.V. solutions, intravenous	11 Oct 2009	15 Oct 2009
Methylprednisolone, intravenous	11 Oct 2009	15 Oct 2009
Red blood cells, intravenous	13 Oct 2009	13 Oct 2009
Metronidazole, intravenous	11 Oct 2009	11 Oct 2009
Prednisone, oral	13 Oct 2009	Ongoing
Treatment group in induction:	400 mg → 200 mg SC.	
Treatment group in maintenance:	Responder to golimumab induction → randomized to golimumab 100 mg maintenance.	
Dose adjusted?	No.	

Treatment received:

Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 25 Nov 2008 (Study Day -45)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 25 Nov 2008 (Study Day -45)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 25 Nov 2008 (Study Day -45)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 25 Nov 2008 (Study Day -45)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 09 Dec 2008 (Study Day -31)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 09 Dec 2008 (Study Day -31)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 09 Dec 2008 (Study Day -31)	Admin. 2/ Inj. 7	Golimumab	100 mg
Week 0 (Main), 09 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 09 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 09 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 06 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 06 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 4 (Main), 06 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 06 Mar 2009 (Study Day 57)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 06 Mar 2009 (Study Day 57)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 06 Mar 2009 (Study Day 57)	Admin. 3/ Inj. 9	Golimumab	100 mg
Week 12 (Main), 03 Apr 2009 (Study Day 85)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 03 Apr 2009 (Study Day 85)	Admin. 4/ Inj. 11	Golimumab	100 mg
Week 12 (Main), 03 Apr 2009 (Study Day 85)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 01 May 2009 (Study Day 113)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 01 May 2009 (Study Day 113)	Admin. 5/ Inj. 14	Golimumab	100 mg
Week 16 (Main), 01 May 2009 (Study Day 113)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 29 May 2009 (Study Day 141)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 29 May 2009 (Study Day 141)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 20 (Main), 29 May 2009 (Study Day 141)	Admin. 6/ Inj. 18	Golimumab	100 mg
Week 24 (Main), 25 Jun 2009 (Study Day 168)	Admin. 7/ Inj. 19	Placebo	0 mg
Week 24 (Main), 25 Jun 2009 (Study Day 168)	Admin. 7/ Inj. 20	Placebo	0 mg
Week 24 (Main), 25 Jun 2009 (Study Day 168)	Admin. 7/ Inj. 21	Golimumab	100 mg
Week 28 (Main), 24 Jul 2009 (Study Day 197)	Admin. 8/ Inj. 22	Placebo	0 mg
Week 28 (Main), 24 Jul 2009 (Study Day 197)	Admin. 8/ Inj. 23	Placebo	0 mg
Week 28 (Main), 24 Jul 2009 (Study Day 197)	Admin. 8/ Inj. 24	Golimumab	100 mg
Week 32 (Main), 20 Aug 2009 (Study Day 224)	Admin. 9/ Inj. 25	Placebo	0 mg
Week 32 (Main), 20 Aug 2009 (Study Day 224)	Admin. 9/ Inj. 26	Placebo	0 mg

Week 32 (Main), 20 Aug 2009 (Study Day 224)	Admin. 9/ Inj. 27	Golimumab	100 mg
Treatment status:			
Study treatment discontinuation?	Yes.		
Reason for treatment discontinuation:	Adverse event.		
Date of last study agent administration in maintenance:	20 Aug 2009.		
Last scheduled study treatment visit in maintenance:	Week 32 (Main).		
Date of study treatment discontinuation:	26 Oct 2009.		
Study status:			
Date of study discontinuation:	26 Oct 2009.		
Reason for noncompletion:	Other.		
Other reason for noncompletion/details:	Loss of therapeutic results.		
Date of disposition status:	26 Oct 2009.		
Ended study participation as of Week 54?	Yes.		
Entered extension study?	No.		

被験者識別コード：7752-00002

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	妊娠 (Pregnancy)	Not related	18 Jun 2009 29 Jan 2010 (226 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 29 Dec [redacted]) Caucasian female. Weight: 62.5 kg; height: 158 cm.

Relevant medical history at baseline: 関節痛，結節性紅斑，喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:
Date of diagnosis: 01 Aug 2006.
UC disease duration: 1.8 years.

Prior/concomitant medication, route	**Start date**	**End date**
Azathioprine, oral	12 Feb 2008	Ongoing
Prednisone, oral	04 Dec 2007	Ongoing
General nutrients, oral	03 May 2008	Ongoing
Naproxen sodium, oral	14 May 2008	Ongoing
Paracetamol, oral	14 May 2008	Ongoing
Vicodin, oral	13 May 2008	17 May 2008
Azathioprine, oral	12 Feb 2008	22 Jun 2009
Prednisone, oral	04 Dec 2007	22 Apr 2009
Naproxen, oral	14 May 2008	09 Sep 2008
Paracetamol, oral	14 May 2008	09 Sep 2008
Ibuprofen, oral	28 Dec 2007	18 Jun 2009
Vicodin, oral	19 Nov 2008	17 Jun 2009
Dicycloverine, oral	19 Nov 2008	20 Nov 2008
Andrographis paniculata, oral	04 Feb 2009	16 Feb 2009
Unspecified herbal, oral	02 Feb 2009	27 Feb 2009
Fentanyl, intravenous	16 Feb 2009	16 Feb 2009
Oxycocet, oral	16 Feb 2009	17 Feb 2009
Sodium chloride, intravenous	16 Feb 2009	16 Feb 2009
Methylprednisolone, intravenous	16 Feb 2009	16 Feb 2009
Unspecified herbal, oral	20 Apr 2009	08 May 2009
Andrographis paniculata, oral	20 Apr 2009	08 May 2009
Azithromycin, oral	25 Apr 2009	29 Apr 2009
Ofloxacin, otic	25 Apr 2009	01 May 2009
Dexamethasone, intramuscular	25 Apr 2009	25 Apr 2009
Silver colloidal, topical	08 Jun 2009	08 Jul 2009
Multivitamins with minerals/90003801/, oral	27 Jun 2009	08 Jul 2009
Chlorophyll, oral	27 Jun 2009	08 Jul 2009
Chloramphenicol, oral	27 Jun 2009	08 Jul 2009
Mesalazine, oral	22 Jun 2009	27 Jun 2009
Citalopram, oral	02 Jul 2009	08 Jul 2009

Paracetamol, oral	19 Jun 2009	Ongoing
Prednisone, oral	21 Jul 2009	Ongoing
Mesalazine, oral	21 Jul 2009	Ongoing
Clindamycin, oral	05 Oct 2009	16 Oct 2009
Antidiarrhoeal microorganisms, oral	08 Oct 2009	Ongoing

Treatment group in induction: 400 mg → 200 mg SC.
Treatment group in maintenance: Responder to golimumab induction → randomized to golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 04 Jun 2008 (Study Day -44)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 04 Jun 2008 (Study Day -44)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 04 Jun 2008 (Study Day -44)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 04 Jun 2008 (Study Day -44)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 18 Jun 2008 (Study Day -30)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 18 Jun 2008 (Study Day -30)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 2 (Ind), 18 Jun 2008 (Study Day -30)	Admin. 2/ Inj. 7	Golimumab	100 mg
Week 0 (Main), 18 Jul 2008 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 18 Jul 2008 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 18 Jul 2008 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 13 Aug 2008 (Study Day 27)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 4 (Main), 13 Aug 2008 (Study Day 27)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 13 Aug 2008 (Study Day 27)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 10 Sep 2008 (Study Day 55)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 10 Sep 2008 (Study Day 55)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 10 Sep 2008 (Study Day 55)	Admin. 3/ Inj. 9	Golimumab	100 mg
Week 12 (Main), 09 Oct 2008 (Study Day 84)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 09 Oct 2008 (Study Day 84)	Admin. 4/ Inj. 11	Golimumab	100 mg
Week 12 (Main), 09 Oct 2008 (Study Day 84)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 06 Nov 2008 (Study Day 112)	Admin. 5/ Inj. 13	Golimumab	100 mg
Week 16 (Main), 06 Nov 2008 (Study Day 112)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 06 Nov 2008 (Study Day 112)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 03 Dec 2008 (Study Day 139)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 03 Dec 2008 (Study Day 139)	Admin. 6/ Inj. 17	Golimumab	100 mg
Week 20 (Main), 03 Dec 2008 (Study Day 139)	Admin. 6/ Inj. 18	Placebo	0 mg
Week 24 (Main), 02 Jan 2009 (Study Day 169)	Admin. 7/ Inj. 19	Placebo	0 mg
Week 24 (Main), 02 Jan 2009 (Study Day 169)	Admin. 7/ Inj. 20	Golimumab	100 mg
Week 24 (Main), 02 Jan 2009 (Study Day 169)	Admin. 7/ Inj. 21	Placebo	0 mg
Week 28 (Main), 28 Jan 2009 (Study Day 195)	Admin. 8/ Inj. 22	Placebo	0 mg
Week 28 (Main), 28 Jan 2009 (Study Day 195)	Admin. 8/ Inj. 23	Golimumab	100 mg
Week 28 (Main), 28 Jan 2009 (Study Day 195)	Admin. 8/ Inj. 24	Placebo	0 mg
Week 32 (Main), 25 Feb 2009 (Study Day 223)	Admin. 9/ Inj. 25	Placebo	0 mg
Week 32 (Main), 25 Feb 2009 (Study Day 223)	Admin. 9/ Inj. 26	Golimumab	100 mg
Week 32 (Main), 25 Feb 2009 (Study Day 223)	Admin. 9/ Inj. 27	Placebo	0 mg
Week 36 (Main), 24 Mar 2009 (Study Day 250)	Admin. 10/ Inj. 28	Placebo	0 mg
Week 36 (Main), 24 Mar 2009 (Study Day 250)	Admin. 10/ Inj. 29	Golimumab	100 mg
Week 36 (Main), 24 Mar 2009 (Study Day 250)	Admin. 10/ Inj. 30	Placebo	0 mg
Week 40 (Main), 22 Apr 2009 (Study Day 279)	Admin. 11/ Inj. 31	Golimumab	100 mg
Week 40 (Main), 22 Apr 2009 (Study Day 279)	Admin. 11/ Inj. 32	Placebo	0 mg
Week 40 (Main), 22 Apr 2009 (Study Day 279)	Admin. 11/ Inj. 33	Placebo	0 mg
Week 44 (Main), 15 May 2009 (Study Day 302)	Admin. 12/ Inj. 34	Golimumab	100 mg
Week 44 (Main), 15 May 2009 (Study Day 302)	Admin. 12/ Inj. 35	Placebo	0 mg
Week 44 (Main), 15 May 2009 (Study Day 302)	Admin. 12/ Inj. 36	Placebo	0 mg
Week 48 (Main), 15 Jun 2009 (Study Day 333)	Admin. 13/ Inj. 37	Golimumab	100 mg
Week 48 (Main), 15 Jun 2009 (Study Day 333)	Admin. 13/ Inj. 38	Placebo	0 mg
Week 48 (Main), 15 Jun 2009 (Study Day 333)	Admin. 13/ Inj. 39	Placebo	0 mg

Treatment status:	
Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	15 Jun 2009.
Last scheduled study treatment visit in maintenance:	Week 48 (Main).
Date of study treatment discontinuation:	18 Jun 2009.
Study status:	
Date of disposition status:	09 Oct 2009.
Ended study participation as of Week 54?	No.
Entered extension study?	No.

被験者識別コード：7806-00002

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Serious infection	感染性小腸結腸炎 (Acute bacterial colitis)	Not related	24 Aug 2010 31 Aug 2010 (8 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 12 Nov [redacted]) Asian female.
Weight: 44.1 kg; height: 157 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 12 Sep 2007.
UC disease duration: 1.8 years.

Prior/concomitant medication, route	**Start date**	**End date**
Sulfasalazine, oral	12 Oct 2007	Ongoing
Mercaptopurine, oral	26 Dec 2008	Ongoing
Prednisolone, oral	15 May 2009	07 Jun 2009
Lansoprazole, oral	12 Oct 2007	Ongoing
Prednisolone, oral	08 Jun 2009	Ongoing
Isoniazid, oral	10 Jun 2009	Ongoing
Lidocaine hydrochloride, topical	26 Jun 2009	26 Jun 2009
Saccharated iron oxide, intravenous	17 Jul 2009	17 Jul 2009
Saccharated iron oxide, intravenous	03 Aug 2009	03 Aug 2009
Glycerol, rectal	17 Aug 2009	17 Aug 2009
Lidocaine hydrochloride, topical	17 Aug 2009	17 Aug 2009
Sulfasalazine, oral	12 Oct 2007	Ongoing
Mercaptopurine, oral	30 Apr 2008	24 Aug 2010
Prednisolone, oral	27 Oct 2007	27 Sep 2009
Dextromethorphan, oral	26 Aug 2009	01 Sep 2009
Domiphen, oral	26 Aug 2009	01 Sep 2009
Cefcapene, oral	02 Sep 2009	09 Sep 2009
Ambroxol, oral	02 Sep 2009	09 Sep 2009
Clarithromycin, oral	09 Sep 2009	16 Sep 2009
Montelukast, oral	09 Sep 2009	16 Sep 2009
Carbocisteine, oral	02 Sep 2009	09 Sep 2009
Loratadine, oral	09 Sep 2009	16 Sep 2009
Ketotifen, intranasal	09 Sep 2009	16 Sep 2009
Lansoprazole, oral	12 Oct 2007	27 Sep 2009
Isoniazid, oral	10 Jun 2009	03 Jan 2010
Magnesium citrate, oral	14 Mar 2010	14 Mar 2010
Fosfocol fides, oral	15 Mar 2010	15 Mar 2010
Ringer-acetat, intravenous	23 Aug 2010	24 Aug 2010
Thiamine, intravenous	23 Aug 2010	23 Aug 2010
Fosfomycin, oral	23 Aug 2010	29 Aug 2010
Streptococcus faecalis, oral	23 Aug 2010	29 Aug 2010
Ringer-lactate, intravenous	24 Aug 2010	29 Aug 2010
Fosfomycin, intravenous	24 Aug 2010	30 Aug 2010
Sodium chloride, intravenous	24 Aug 2010	30 Aug 2010

Thiamine, intravenous	25 Aug 2010	30 Aug 2010
Solita-t3, intravenous	25 Aug 2010	30 Aug 2010
Azulene, topical	03 Sep 2010	17 Sep 2010
Lactomin, oral	06 Sep 2010	Ongoing

Treatment group in induction:	400 mg → 200 mg SC.
Treatment group in maintenance:	Responder to golimumab induction. → randomized to golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 03 Jul 2009 (Study Day -45)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 03 Jul 2009 (Study Day -45)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 03 Jul 2009 (Study Day -45)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 03 Jul 2009 (Study Day -45)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 17 Jul 2009 (Study Day -31)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 17 Jul 2009 (Study Day -31)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 2 (Ind), 17 Jul 2009 (Study Day -31)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 17 Aug 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 17 Aug 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 17 Aug 2009 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 14 Sep 2009 (Study Day 29)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 4 (Main), 14 Sep 2009 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 14 Sep 2009 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 09 Oct 2009 (Study Day 54)	Admin. 3/ Inj. 7	Golimumab	100 mg
Week 8 (Main), 09 Oct 2009 (Study Day 54)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 09 Oct 2009 (Study Day 54)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 09 Nov 2009 (Study Day 85)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 09 Nov 2009 (Study Day 85)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 09 Nov 2009 (Study Day 85)	Admin. 4/ Inj. 12	Golimumab	100 mg
Week 16 (Main), 07 Dec 2009 (Study Day 113)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 07 Dec 2009 (Study Day 113)	Admin. 5/ Inj. 14	Golimumab	100 mg
Week 16 (Main), 07 Dec 2009 (Study Day 113)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 04 Jan 2010 (Study Day 141)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 04 Jan 2010 (Study Day 141)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 20 (Main), 04 Jan 2010 (Study Day 141)	Admin. 6/ Inj. 18	Golimumab	100 mg
Week 24 (Main), 01 Feb 2010 (Study Day 169)	Admin. 7/ Inj. 19	Golimumab	100 mg
Week 24 (Main), 01 Feb 2010 (Study Day 169)	Admin. 7/ Inj. 20	Placebo	0 mg
Week 24 (Main), 01 Feb 2010 (Study Day 169)	Admin. 7/ Inj. 21	Placebo	0 mg
Week 28 (Main), 01 Mar 2010 (Study Day 197)	Admin. 8/ Inj. 22	Golimumab	100 mg
Week 28 (Main), 01 Mar 2010 (Study Day 197)	Admin. 8/ Inj. 23	Placebo	0 mg
Week 32 (Main), 30 Mar 2010 (Study Day 226)	Admin. 9/ Inj. 24	Golimumab	100 mg
Week 32 (Main), 30 Mar 2010 (Study Day 226)	Admin. 9/ Inj. 25	Placebo	0 mg
Week 36 (Main), 27 Apr 2010 (Study Day 254)	Admin. 10/ Inj. 26	Placebo	0 mg
Week 36 (Main), 27 Apr 2010 (Study Day 254)	Admin. 10/ Inj. 27	Golimumab	100 mg
Week 40 (Main), 25 May 2010 (Study Day 282)	Admin. 11/ Inj. 28	Golimumab	100 mg
Week 40 (Main), 25 May 2010 (Study Day 282)	Admin. 11/ Inj. 29	Placebo	0 mg
Week 44 (Main), 22 Jun 2010 (Study Day 310)	Admin. 12/ Inj. 30	Placebo	0 mg
Week 44 (Main), 22 Jun 2010 (Study Day 310)	Admin. 12/ Inj. 31	Golimumab	100 mg
Week 48 (Main), 20 Jul 2010 (Study Day 338)	Admin. 13/ Inj. 32	Placebo	0 mg
Week 48 (Main), 20 Jul 2010 (Study Day 338)	Admin. 13/ Inj. 33	Golimumab	100 mg
Week 52 (Main), 20 Aug 2010 (Study Day 369)	Admin. 14/ Inj. 34	Placebo	0 mg
Week 52 (Main), 20 Aug 2010 (Study Day 369)	Admin. 14/ Inj. 35	Golimumab	100 mg

Treatment status:

Study treatment discontinuation?	No.
Date of last study agent administration in maintenance:	20 Aug 2010.
Last scheduled study treatment visit in maintenance:	Week 52 (Main).

Study status:	
Date of disposition status:	06 Sep 2010.
Ended study participation as of Week 54?	No.
Entered extension study?	Yes.

2) ランダム割付けされなかった被験者

a) プラセボ寛解導入 responder

被験者識別コード：7752-00012

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Ulcerative colitis exacerbation)	Unlikely	14 Dec 2010 20 Dec 2010 (7 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 14 Oct [redacted]) Caucasian female.
Weight: 71.7 kg; height: 170 cm.

Relevant medical history at baseline: 関節痛，喫煙（過去）

Baseline smoking status: Prior smoker (stopped <= 1 year ago).

Ulcerative colitis history:
Date of diagnosis: 19 Mar 2009.
UC disease duration: 1.4 years.

Prior/concomitant medication, route	**Start date**	**End date**
Rabeprazole sodium, oral	24 Feb 2009	Ongoing
Loperamide hydrochloride, oral	27 Jul 2009	Ongoing
Azathioprine, oral	13 Apr 2009	Ongoing
Mesalazine, oral	02 Jul 2009	Ongoing
Nuvaring, intravaginal	04 Nov 2009	Ongoing
Prednisone, oral	22 Oct 2009	Ongoing
Citalopram, oral	08 Apr 2010	Ongoing
Multivitamin /00831701/, oral	30 Jun 2010	Ongoing
Vitamin B12 nos, oral	30 Jun 2010	Ongoing
Paracetamol, oral	14 Jul 2004	Ongoing
Naproxen sodium, oral	14 Jul 2004	Ongoing
Folic acid, oral	18 Jul 2007	Ongoing
Ferrous sulfate, oral	29 Jul 2010	Ongoing
Nitrofurantoin, oral	27 Jul 2010	03 Aug 2010
Laxatives, oral	28 Jul 2010	28 Jul 2010
Bisacodyl, oral	28 Jul 2010	28 Jul 2010
Propofol, intravenous	29 Jul 2010	29 Jul 2010
Midazolam hydrochloride, intravenous	29 Jul 2010	29 Jul 2010
Red blood cells, intravenous	03 Aug 2010	03 Aug 2010
Ciprofloxacin, oral	09 Aug 2010	16 Aug 2010
Fleet enema /00129701/, rectal	14 Sep 2010	14 Sep 2010
Rabeprazole, oral	24 Feb 2009	16 Dec 2010
Loperamide, oral	27 Jul 2009	07 Oct 2010
Nuvaring, intravaginal	04 Nov 2009	13 Jan 2011
Prednisone, oral	22 Oct 2009	15 Dec 2010
Citalopram, oral	08 Apr 2010	07 Dec 2010
Multivitamin/00831701/, oral	30 Jun 2010	14 Oct 2010
Naproxen, oral	14 Jul 2004	Ongoing
Folic acid, oral	18 Jul 2007	14 Oct 2010
Iron, oral	29 Jul 2010	Ongoing
Lomotil, oral	07 Oct 2010	Ongoing
Ketorolac, intramuscular	23 Oct 2010	23 Oct 2010
Ketorolac, oral	23 Oct 2010	26 Oct 2010
Propofol, intravenous	09 Dec 2010	09 Dec 2010
Midazolam, intravenous	09 Dec 2010	09 Dec 2010

Fleet enema /00129701/, rectal	09 Dec 2010	09 Dec 2010
Esomeprazole, oral	17 Dec 2010	Ongoing
Nystatin, oral	16 Dec 2010	21 Dec 2010
Promethazine, intravenous	16 Dec 2010	17 Dec 2010
Prednisone, oral	19 Dec 2010	Ongoing
Methylprednisolone, intravenous	16 Dec 2010	19 Dec 2010
Pethidine, intravenous	16 Dec 2010	17 Dec 2010
Dextrose and sodium chloride injection, intravenous	17 Dec 2010	19 Dec 2010
Solutions affecting the electrolyte balance, intravenous	16 Dec 2010	17 Dec 2010
Zolpidem, oral	17 Dec 2010	18 Dec 2010
Infliximab, intravenous	04 Apr 2011	Ongoing

Treatment group in induction: Placebo SC.
Treatment group in maintenance: Responder to placebo induction → received placebo maintenance.
Dose adjusted? Yes.
Adjusted treatment group: Golimumab 100 mg.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 02 Aug 2010 (Study Day -43)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 02 Aug 2010 (Study Day -43)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 02 Aug 2010 (Study Day -43)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 02 Aug 2010 (Study Day -43)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 17 Aug 2010 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 17 Aug 2010 (Study Day -28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 0 (Main), 14 Sep 2010 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 14 Sep 2010 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 4 (Main), 12 Oct 2010 (Study Day 29)	Admin. 2/ Inj. 3	Placebo	0 mg
Week 4 (Main), 12 Oct 2010 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 8 (Main), 10 Nov 2010 (Study Day 58)	Admin. 3/ Inj. 5	Placebo	0 mg
Week 8 (Main), 10 Nov 2010 (Study Day 58)	Admin. 3/ Inj. 6	Placebo	0 mg
Week 12 (Main), 09 Dec 2010 (Study Day 87)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 12 (Main), 09 Dec 2010 (Study Day 87)	Admin. 1/ Inj. 2	Golimumab	100 mg

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Adverse event.
Date of last study agent administration in maintenance: 09 Dec 2010.
Last scheduled study treatment visit in maintenance: Week 12 (Main).
Date of study treatment discontinuation: 20 Dec 2010.

Study status:
Date of disposition status: 21 Apr 2011.
Ended study participation as of Week 54? Yes.
Entered extension study? No.

被験者識別コード：7755-00003

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Serious infection	気管支炎 (Acute bronchitis)	Possible	05 Sep 2010 11 Sep 2010 (7 days)

Baseline demographic information: 4[redacted]-year-old (DOB: 07 Jan [redacted]) Caucasian female.
Weight: 90 kg; height: 155 cm.

Relevant medical history at baseline: 関節痛，アフタ性口内炎

Baseline smoking status: Nonsmoker.

Ulcerative colitis history:
Date of diagnosis: 01 Jan 1981.
UC disease duration: 29.1 years.

Prior/concomitant medication, route	Start date	End date
Vitamin B12 nos, oral	01 Feb 2009	Ongoing
Ferrous sulfate, oral	01 Sep 2008	Ongoing

Vitamin D nos, oral	01 Oct 2009	Ongoing
Montelukast sodium, oral	01 Feb 2010	Ongoing
Azelastine hydrochloride, inhalation	01 Apr 2009	Ongoing
Seretide, inhalation	01 Apr 2009	Ongoing
Lansoprazole, oral	01 Oct 2009	Ongoing
Ultracet, oral	18 Jan 2010	Ongoing
Moviprep, subcutaneous	17 Feb 2010	17 Feb 2010
Midazolam hydrochloride, intravenous	18 Feb 2010	18 Feb 2010
Pethidine hydrochloride, intravenous	18 Feb 2010	18 Feb 2010
Prednisone, oral	11 Jan 2010	Ongoing
Mesalazine, oral	18 Jan 2010	Ongoing
Bisacodyl, oral	05 Apr 2010	05 Apr 2010
Bisacodyl, rectal	06 Apr 2010	06 Apr 2010
Alprazolam, oral	06 Apr 2010	06 Apr 2010
Iron, oral	01 Sep 2008	05 Sep 2010
Montelukast, oral	01 Feb 2010	Ongoing
Azelastine, inhalation	01 Apr 2009	20 May 2009
Seretide, inhalation	01 Apr 2009	30 Apr 2011
Lansoprazole, oral	01 Oct 2009	25 Aug 2011
Prednisone, oral	11 Jan 2010	31 May 2010
Magnesium citrate, oral	11 Aug 2010	11 Aug 2010
Bisacodyl, oral	11 Aug 2010	11 Aug 2010
Levofloxacin, oral	06 Sep 2010	Ongoing
Guaifenesin, oral	06 Sep 2010	11 Sep 2010
Combivent, inhalation	06 Sep 2010	11 Sep 2010
Acetylsalicylic acid, oral	07 Sep 2010	07 Sep 2010
Iron, oral	06 Sep 2010	Ongoing
Pantoprazole, oral	06 Sep 2010	07 Sep 2010
Sertraline, oral	07 Sep 2010	13 Aug 2011
Azithromycin, oral	14 Oct 2010	14 Oct 2010
Azithromycin, oral	15 Oct 2010	18 Oct 2010
Guaifenesin, oral	14 Oct 2010	18 Oct 2010
Loratadine, oral	04 Nov 2010	14 Dec 2010
Azithromycin, oral	14 Dec 2010	19 Dec 2010
Fexofenadine, oral	14 Dec 2010	30 Dec 2010
Budesonide, intranasal	14 Dec 2010	11 Jan 2011
Alprazolam, oral	18 Apr 2011	18 Apr 2011
Magnesium citrate, oral	17 Apr 2011	17 Apr 2011
Bisacodyl, oral	17 Apr 2011	17 Apr 2011

Treatment group in induction:	Placebo SC.
Treatment group in maintenance:	Responder to placebo induction → received placebo maintenance.
Dose adjusted?	Yes.
Adjusted treatment group:	Golimumab 100 mg.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 23 Feb 2010 (Study Day -42)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 23 Feb 2010 (Study Day -42)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 23 Feb 2010 (Study Day -42)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 23 Feb 2010 (Study Day -42)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 09 Mar 2010 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 09 Mar 2010 (Study Day -28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 0 (Main), 06 Apr 2010 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 06 Apr 2010 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 4 (Main), 04 May 2010 (Study Day 29)	Admin. 2/ Inj. 3	Placebo	0 mg
Week 4 (Main), 04 May 2010 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 8 (Main), 01 Jun 2010 (Study Day 57)	Admin. 3/ Inj. 5	Placebo	0 mg
Week 8 (Main), 01 Jun 2010 (Study Day 57)	Admin. 3/ Inj. 6	Placebo	0 mg
Week 12 (Main), 29 Jun 2010 (Study Day 85)	Admin. 4/ Inj. 7	Placebo	0 mg

Week 12 (Main), 29 Jun 2010 (Study Day 85)	Admin. 4/ Inj. 8	Placebo	0 mg
Week 16 (Main), 27 Jul 2010 (Study Day 113)	Admin. 5/ Inj. 9	Placebo	0 mg
Week 16 (Main), 27 Jul 2010 (Study Day 113)	Admin. 5/ Inj. 10	Placebo	0 mg
Unscheduled 1 (Main), 12 Aug 2010 (Study Day 129)	Admin. 1/ Inj. 1	Golimumab	100 mg
Unscheduled 1 (Main), 12 Aug 2010 (Study Day 129)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 20 (Main), 24 Aug 2010 (Study Day 141)	Admin. 2/ Inj. 3	Golimumab	100 mg
Week 20 (Main), 24 Aug 2010 (Study Day 141)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 24 (Main), 21 Sep 2010 (Study Day 169)	Admin. 3/ Inj. 5	Golimumab	100 mg
Week 24 (Main), 21 Sep 2010 (Study Day 169)	Admin. 3/ Inj. 6	Placebo	0 mg
Week 28 (Main), 19 Oct 2010 (Study Day 197)	Admin. 4/ Inj. 7	Golimumab	100 mg
Week 28 (Main), 19 Oct 2010 (Study Day 197)	Admin. 4/ Inj. 8	Placebo	0 mg
Week 32 (Main), 23 Nov 2010 (Study Day 232)	Admin. 5/ Inj. 9	Golimumab	100 mg
Week 32 (Main), 23 Nov 2010 (Study Day 232)	Admin. 5/ Inj. 10	Placebo	0 mg
Week 36 (Main), 14 Dec 2010 (Study Day 253)	Admin. 6/ Inj. 11	Placebo	0 mg
Week 36 (Main), 14 Dec 2010 (Study Day 253)	Admin. 6/ Inj. 12	Golimumab	100 mg
Week 40 (Main), 12 Jan 2011 (Study Day 282)	Admin. 7/ Inj. 13	Golimumab	100 mg
Week 40 (Main), 12 Jan 2011 (Study Day 282)	Admin. 7/ Inj. 14	Placebo	0 mg
Week 44 (Main), 09 Feb 2011 (Study Day 310)	Admin. 8/ Inj. 15	Placebo	0 mg
Week 44 (Main), 09 Feb 2011 (Study Day 310)	Admin. 8/ Inj. 16	Golimumab	100 mg
Week 48 (Main), 09 Mar 2011 (Study Day 338)	Admin. 9/ Inj. 17	Golimumab	100 mg
Week 48 (Main), 09 Mar 2011 (Study Day 338)	Admin. 9/ Inj. 18	Placebo	0 mg
Week 52 (Main), 06 Apr 2011 (Study Day 366)	Admin. 10/ Inj. 19	Placebo	0 mg
Week 52 (Main), 06 Apr 2011 (Study Day 366)	Admin. 10/ Inj. 20	Golimumab	100 mg
Treatment status:			
Study treatment discontinuation?	No.		
Date of last study agent administration in maintenance:	06 Apr 2011.		
Last scheduled study treatment visit in maintenance:	Week 52 (Main).		
Study status:			
Date of disposition status:	18 Apr 2011.		
Ended study participation as of Week 54?	No.		
Entered extension study?	Yes.		

被験者識別コード：7816-00002

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Unlikely	28 Jun 2010 21 Aug 2010 (55 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 10 Aug [redacted]) Asian female. Weight: 52 kg; height: 161 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped ≤1 year ago).

Ulcerative colitis history:
Date of diagnosis: 23 Jul 2008.
UC disease duration: 1.1 years.

Prior/concomitant medication, route	**Start date**	**End date**
Prednisolone, oral	11 Aug 2009	Ongoing
Mesalazine, oral	31 Jul 2009	Ongoing
Alfacalcidol, oral	01 Aug 2009	Ongoing
Risedronate sodium, oral	01 Aug 2009	Ongoing
Famotidine, oral	23 Jul 2009	Ongoing
Prednisolone, oral	11 Aug 2009	27 Jun 2010
Mesalazine, oral	Prior	Ongoing
Alfacalcidol, oral	01 Aug 2009	Ongoing
Risedronic acid, oral	01 Aug 2009	Ongoing
Azulene, oral	19 Mar 2010	Ongoing
Lactobacillus bifidus, lyophilized, oral	19 Mar 2010	Ongoing
Aczym, oral	19 Mar 2010	Ongoing

Prednisolone, intravenous	28 Jun 2010	27 Jul 2010
Ringer-acetate, intravenous	28 Jun 2010	05 Aug 2010
Glycine max, intravenous	28 Jun 2010	27 Jul 2010
Solutions for parenteral nutrition, intravenous	29 Jun 2010	09 Aug 2010
Paracetamol, oral	29 Jun 2010	09 Aug 2010
Iopamidol, intravenous	29 Jun 2010	29 Jun 2010
Lidocaine, topical	30 Jun 2010	17 Aug 2010
Nafamostat, intravenous	30 Jun 2010	17 Aug 2010
Shouseiryuutou, oral	05 Jul 2010	15 Jul 2010
Ohpeg, oral	07 Jul 2010	07 Jul 2010
Dimeticone, oral	07 Jul 2010	07 Jul 2010
Metoclopramide, oral	07 Jul 2010	07 Jul 2010
Elental, oral	09 Jul 2010	09 Jul 2010
Glucose, intravenous	10 Jul 2010	21 Aug 2010
Saccharated iron oxide, intravenous	10 Jul 2010	21 Aug 2010
Teprenone, oral	09 Jul 2010	Ongoing
Prednisolone, rectal	16 Jul 2010	17 Aug 2010
Pronase, oral	13 Jul 2010	13 Jul 2010
Sodium bicarbonate, oral	13 Jul 2010	13 Jul 2010
Dimeticone, oral	13 Jul 2010	13 Jul 2010
Lidocaine, oral	13 Jul 2010	13 Jul 2010
Diazepam, intravenous	13 Jul 2010	13 Jul 2010
Zolpidem, oral	16 Jul 2010	25 Jul 2010
Prednisolone, oral	28 Jul 2010	Ongoing
Iron, oral	22 Aug 2010	18 Sep 2010

Treatment group in induction: Placebo SC.
Treatment group in maintenance: Responder to placebo induction → received placebo maintenance.
Dose adjusted? Yes.
Adjusted treatment group: Golimumab 100 mg.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 12 Sep 2009 (Study Day -42)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 12 Sep 2009 (Study Day -42)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 12 Sep 2009 (Study Day -42)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 12 Sep 2009 (Study Day -42)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 26 Sep 2009 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 26 Sep 2009 (Study Day -28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 0 (Main), 24 Oct 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 24 Oct 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 24 Oct 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 14 Nov 2009 (Study Day 22)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 14 Nov 2009 (Study Day 22)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 14 Nov 2009 (Study Day 22)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 19 Dec 2009 (Study Day 57)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 19 Dec 2009 (Study Day 57)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 19 Dec 2009 (Study Day 57)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 20 Jan 2010 (Study Day 89)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 20 Jan 2010 (Study Day 89)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 20 Jan 2010 (Study Day 89)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 17 Feb 2010 (Study Day 117)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 17 Feb 2010 (Study Day 117)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 17 Feb 2010 (Study Day 117)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 11 Mar 2010 (Study Day 139)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 11 Mar 2010 (Study Day 139)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 24 (Main), 10 Apr 2010 (Study Day 169)	Admin. 7/ Inj. 18	Placebo	0 mg
Week 24 (Main), 10 Apr 2010 (Study Day 169)	Admin. 7/ Inj. 19	Placebo	0 mg
Week 28 (Main), 08 May 2010 (Study Day 197)	Admin. 8/ Inj. 20	Placebo	0 mg
Week 28 (Main), 08 May 2010 (Study Day 197)	Admin. 8/ Inj. 21	Placebo	0 mg

Week 32 (Main), 07 Jun 2010 (Study Day 227)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 32 (Main), 07 Jun 2010 (Study Day 227)	Admin. 1/ Inj. 2	Golimumab	100 mg
Unscheduled 1 (Main)—dose not done	NA	NA	NA
Treatment status:			
Study treatment discontinuation?	Yes.		
Reason for treatment discontinuation:	Adverse event.		
Date of last study agent administration in maintenance:	07 Jun 2010.		
Last scheduled study treatment visit in maintenance:	Week 32 (Main).		
Date of study treatment discontinuation:	28 Jun 2010.		
Study status:			
Date of disposition status:	02 Oct 2010.		
Ended study participation as of Week 54?	Yes.		
Entered extension study?	No.		

b) プラセボ寛解導入 non-responder

被験者識別コード：6257-00008

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Acute exacerbation of ulcerative colitis)	Unlikely	23 Aug 2008 28 Aug 2008 (6 days)

Baseline demographic information: 5[redacted]-year-old (DOB: 04 Sep [redacted]) Asian female. Weight: 50 kg; height: 162 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 28 Dec 2006.
UC disease duration: 1.3 years.

Prior/concomitant medication, route	**Start date**	**End date**
Mesalazine, oral	28 Dec 2006	Ongoing
Prednisolone, oral	10 Mar 2008	22 May 2008
Atenolol, oral	14 Mar 2001	Ongoing
Insulin human, subcutaneous	17 Mar 2008	Ongoing
Rifampicin, oral	04 Apr 2008	Ongoing
Prednisolone, oral	27 May 2008	Ongoing
Rifinah, oral	04 Apr 2008	Ongoing
Hyoscine, oral	24 Aug 2008	24 Aug 2008

Treatment group in induction: Placebo IV.
Treatment group in maintenance: Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 08 Apr 2008 (Study Day -48)	NA	Placebo	0 mg/kg
Week 0 (Main), 26 May 2008 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 26 May 2008 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 26 May 2008 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 25 Jun 2008 (Study Day 31)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 25 Jun 2008 (Study Day 31)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 25 Jun 2008 (Study Day 31)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 8 (Main), 23 Jul 2008 (Study Day 59)	Admin. 3/ Inj. 7	Golimumab	100 mg
Week 8 (Main), 23 Jul 2008 (Study Day 59)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 23 Jul 2008 (Study Day 59)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 21 Aug 2008 (Study Day 88)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 21 Aug 2008 (Study Day 88)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 21 Aug 2008 (Study Day 88)	Admin. 4/ Inj. 12	Golimumab	100 mg

Treatment status:	
Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	21 Aug 2008.
Last scheduled study treatment visit in maintenance:	Week 12 (Main).
Date of study treatment discontinuation:	09 Sep 2008.
Study status:	
Date of study discontinuation:	09 Sep 2008.
Reason for noncompletion:	Withdrawal of consent.
Date of disposition status:	09 Sep 2008.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：6112-00014

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
Event of interest: GI abscess/ stricture/ colectomy	肛門膿瘍 (Perianal abscess)	Unlikely	17 Jan 2010 18 Jan 2010 (2 days)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Unlikely	12 Jan 2010 18 Jan 2010 (7 days)
SAE	小腸閉塞 (Small bowel obstruction)	Unlikely	22 Feb 2010 26 Feb 2010 (5 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 20 May [redacted]) Caucasian male.
Weight: 74.6 kg; height: 187 cm.

Relevant medical history at baseline: アフタ性口内炎

Baseline smoking status: Nonsmoker.

Ulcerative colitis history:
Date of diagnosis: 24 Jan 2006.
UC disease duration: 3.6 years.

Prior/concomitant medication, route	**Start date**	**End date**
Prednisone, oral	Prior	Ongoing
Magnesium citrate, oral	10 Aug 2009	10 Aug 2009
Fleet enema /00129701/, rectal	11 Aug 2009	11 Aug 2009
Calcium carbonate, oral	05 May 2006	Ongoing
Vitamin D nos, oral	05 May 2006	Ongoing
Magnesium citrate, oral	29 Sep 2009	29 Sep 2009
Fleet enema /00129701/, rectal	30 Sep 2009	30 Sep 2009
Paracetamol, oral	17 Oct 2009	22 Oct 2009
Benylin antitusivo /01376601/, oral	17 Oct 2009	22 Oct 2009
Influenza vaccine, intramuscular	01 Nov 2009	01 Nov 2009

Treatment group in induction: Placebo SC.
Treatment group in maintenance: Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 18 Aug 2009 (Study Day -43)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 18 Aug 2009 (Study Day -43)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 18 Aug 2009 (Study Day -43)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 18 Aug 2009 (Study Day -43)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 01 Sep 2009 (Study Day -29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 01 Sep 2009 (Study Day -29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 0 (Main), 30 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 30 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 30 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 27 Oct 2009 (Study Day 28)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 27 Oct 2009 (Study Day 28)	Admin. 2/ Inj. 5	Placebo	0 mg

Week 4 (Main), 27 Oct 2009 (Study Day 28)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 8 (Main), 18 Nov 2009 (Study Day 50)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 18 Nov 2009 (Study Day 50)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 18 Nov 2009 (Study Day 50)	Admin. 3/ Inj. 9	Golimumab	100 mg
Week 12 (Main), 15 Dec 2009 (Study Day 77)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 15 Dec 2009 (Study Day 77)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 15 Dec 2009 (Study Day 77)	Admin. 4/ Inj. 12	Golimumab	100 mg

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	15 Dec 2009.
Last scheduled study treatment visit in maintenance:	Week 12 (Main).
Date of study treatment discontinuation:	12 Jan 2010.

Study status:

Date of disposition status:	15 Apr 2010.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：6207-00002

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE/ Serious infection	肺炎 (Pneumonia)	Possible	27 Sep 2010 06 Oct 2010 (10 days)

Baseline demographic information: 1[redacted]-year-old (DOB: 01 Oct [redacted]) Caucasian male.
Weight: 92.7 kg; height: 193 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:

Date of diagnosis:	09 Mar 2009.
UC disease duration:	1.1 years.

Prior/concomitant medication, route	**Start date**	**End date**
Mesalazine, oral	July 2009	12 Jan 2010
Prednisolone, oral	12 Feb 2010	Ongoing
Loperamide hydrochloride, oral	01 Mar 2010	Ongoing
Lekovit ca, oral	02 Feb 2010	Ongoing
Prednisolone, oral	12 Feb 2010	21 Sep 2010
Pip/tazo, intravenous	27 Sep 2010	06 Oct 2010
Clarithromycin, intravenous	27 Sep 2010	06 Oct 2010
Levofloxacin, oral	13 Sep 2010	16 Sep 2010

Treatment group in induction:	Placebo SC.
Treatment group in maintenance:	Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:

Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 31 Mar 2010 (Study Day -42)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 31 Mar 2010 (Study Day -42)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 31 Mar 2010 (Study Day -42)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 31 Mar 2010 (Study Day -42)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 14 Apr 2010 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 14 Apr 2010 (Study Day -28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 0 (Main), 12 May 2010 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 12 May 2010 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 4 (Main), 09 Jun 2010 (Study Day 29)	Admin. 2/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 09 Jun 2010 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 8 (Main), 07 Jul 2010 (Study Day 57)	Admin. 3/ Inj. 5	Golimumab	100 mg
Week 8 (Main), 07 Jul 2010 (Study Day 57)	Admin. 3/ Inj. 6	Placebo	0 mg
Week 12 (Main), 04 Aug 2010 (Study Day 85)	Admin. 4/ Inj. 7	Placebo	0 mg

Week 12 (Main), 04 Aug 2010 (Study Day 85)	Admin. 4/ Inj. 8	Golimumab	100 mg
Week 16 (Main)—dose not done	NA	NA	NA
Week 16 (Main), 01 Sep 2010 (Study Day 113)	Admin. 5/ Inj. 9	Golimumab	100 mg
Week 16 (Main), 01 Sep 2010 (Study Day 113)	Admin. 5/ Inj. 10	Placebo	0 mg

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	01 Sep 2010.
Last scheduled study treatment visit in maintenance:	Week 16 (Main).
Date of study treatment discontinuation:	04 Oct 2010.

Study status:

Date of study discontinuation:	12 Nov 2010.
Reason for noncompletion:	Lost to follow-up.
Date of disposition status:	12 Nov 2010.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：6354-00003

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	細菌性敗血症 (Bacteremia/ sepsis)	Possible	22 Nov 2010 Ongoing

Baseline demographic information: 5[redacted]-year-old (DOB: 07 Jan [redacted]) Caucasian male.
Weight: 69.3 kg; height: 171 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:

Date of diagnosis:	March 2008.
UC disease duration:	1.6 years.

Prior/concomitant medication, route	**Start date**	**End date**
Ramipril, oral	Prior	Ongoing
Ibuprofen, oral	27 Oct 2009	Ongoing
Mesalazine, oral	09 Jun 2009	November 2009
Paracetamol, oral	29 Nov 2009	Ongoing
Ramipril, oral	2001	February 2011
Ibuprofen, oral	27 Oct 2009	December 2010
General nutrients, oral	01 Jan 2010	29 Jul 2010
Paracetamol, oral	01 Apr 2010	Ongoing
Iron, oral	26 Jul 2010	August 2010
Metoclopramide, rectal	22 Nov 2010	28 Nov 2010
Nadroparin, subcutaneous	22 Nov 2010	28 Nov 2010
Ramipril, oral	22 Nov 2010	28 Nov 2010
Methadone, subcutaneous	22 Nov 2010	24 Nov 2010
Paracetamol, oral	22 Nov 2010	28 Nov 2010
Flucloxacillin, oral	24 Nov 2010	28 Nov 2010

Treatment group in induction:	Placebo SC.
Treatment group in maintenance:	Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:

Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 10 Nov 2009 (Study Day -49)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 10 Nov 2009 (Study Day -49)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 10 Nov 2009 (Study Day -49)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 10 Nov 2009 (Study Day -49)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 24 Nov 2009 (Study Day -35)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 24 Nov 2009 (Study Day -35)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 0 (Main), 29 Dec 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg

Week 0 (Main), 29 Dec 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 29 Dec 2009 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 25 Jan 2010 (Study Day 28)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 25 Jan 2010 (Study Day 28)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 4 (Main), 25 Jan 2010 (Study Day 28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 22 Feb 2010 (Study Day 56)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 22 Feb 2010 (Study Day 56)	Admin. 3/ Inj. 8	Golimumab	100 mg
Week 8 (Main), 22 Feb 2010 (Study Day 56)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 22 Mar 2010 (Study Day 84)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 22 Mar 2010 (Study Day 84)	Admin. 4/ Inj. 11	Golimumab	100 mg
Week 16 (Main), 19 Apr 2010 (Study Day 112)	Admin. 5/ Inj. 12	Golimumab	100 mg
Week 16 (Main), 19 Apr 2010 (Study Day 112)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 20 (Main), 17 May 2010 (Study Day 140)	Admin. 6/ Inj. 14	Placebo	0 mg
Week 20 (Main), 17 May 2010 (Study Day 140)	Admin. 6/ Inj. 15	Golimumab	100 mg
Week 24 (Main), 14 Jun 2010 (Study Day 168)	Admin. 7/ Inj. 16	Placebo	0 mg
Week 24 (Main), 14 Jun 2010 (Study Day 168)	Admin. 7/ Inj. 17	Golimumab	100 mg
Week 28 (Main), 12 Jul 2010 (Study Day 196)	Admin. 8/ Inj. 18	Golimumab	100 mg
Week 28 (Main), 12 Jul 2010 (Study Day 196)	Admin. 8/ Inj. 19	Placebo	0 mg
Week 32 (Main), 09 Aug 2010 (Study Day 224)	Admin. 9/ Inj. 20	Golimumab	100 mg
Week 32 (Main), 09 Aug 2010 (Study Day 224)	Admin. 9/ Inj. 21	Placebo	0 mg
Week 36 (Main), 06 Sep 2010 (Study Day 252)	Admin. 10/ Inj. 22	Golimumab	100 mg
Week 36 (Main), 06 Sep 2010 (Study Day 252)	Admin. 10/ Inj. 23	Placebo	0 mg
Week 40 (Main), 27 Sep 2010 (Study Day 273)	Admin. 11/ Inj. 24	Golimumab	100 mg
Week 40 (Main), 27 Sep 2010 (Study Day 273)	Admin. 11/ Inj. 25	Placebo	0 mg
Week 44 (Main)—dose not done	NA	NA	NA
Week 44 (Main), 29 Oct 2010 (Study Day 305)	Admin. 12/ Inj. 26	Placebo	0 mg
Week 44 (Main), 29 Oct 2010 (Study Day 305)	Admin. 12/ Inj. 27	Golimumab	100 mg
Unscheduled 3 (Main)—dose not done	NA	NA	NA
Unscheduled 1 (Main)—dose not done	NA	NA	NA

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	29 Oct 2010.
Last scheduled study treatment visit in maintenance:	Week 44 (Main).
Date of study treatment discontinuation:	23 Nov 2010.

Study status:

Date of study discontinuation:	24 Nov 2010.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	Adverse events: Abdominal pain and fever.
Date of disposition status:	24 Nov 2010.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：6747-00009

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	妊娠 (Pregnancy)	Not related	08 Apr 2010 14 Jan 2011 (282 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 12 Jun [redacted]) Caucasian female.
Weight: 64.4 kg; height: 157 cm.

Relevant medical history at baseline: 喫煙（現在）

Baseline smoking status: Current smoker.

Ulcerative colitis history:

Date of diagnosis:	19 Feb 2009.
UC disease duration:	0.5 years.

Prior/concomitant medication, route	Start date	End date
Prednisone, oral	24 Jun 2009	02 Oct 2009
Mesalazine, oral	24 Jun 2009	Ongoing
Pethidine hydrochloride, intravenous	07 Aug 2009	07 Aug 2009
Midazolam hydrochloride, intravenous	07 Aug 2009	07 Aug 2009
Conlunett, oral	06 Jan 2009	Ongoing
Fentanyl, intravenous	25 Sep 2009	25 Sep 2009
Midazolam hydrochloride, intravenous	25 Sep 2009	25 Sep 2009
Prednisone, oral	24 Jun 2009	10 Oct 2009
Fentanyl, intravenous	23 Apr 2010	23 Apr 2010
Midazolam, intravenous	23 Apr 2010	23 Apr 2010
Augmentin /00756801/, oral	13 May 2010	22 May 2010
Paracetamol, oral	01 Jul 2010	Ongoing
Psyllium hydrophilic mucilloid, oral	01 Jul 2010	Ongoing
Omeprazole, oral	13 Aug 2010	Ongoing
Prenatal vitamins /01549301/, oral	19 Oct 2010	14 Jan 2011
Iron, oral	19 Oct 2010	14 Jan 2011
Anesthetics, spinal	14 Jan 2011	14 Jan 2011
Morphine, intravenous	14 Jan 2011	16 Jan 2011
Ibuprofen, oral	16 Jan 2011	Ongoing
Vicodin, oral	16 Jan 2011	Ongoing

Treatment group in induction:	Placebo SC.
Treatment group in maintenance:	Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 12 Aug 2009 (Study Day -44)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 12 Aug 2009 (Study Day -44)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 12 Aug 2009 (Study Day -44)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 12 Aug 2009 (Study Day -44)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 28 Aug 2009 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 28 Aug 2009 (Study Day -28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 28 Aug 2009 (Study Day -28)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 25 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 25 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Main), 25 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 23 Oct 2009 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 23 Oct 2009 (Study Day 29)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 4 (Main), 23 Oct 2009 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 20 Nov 2009 (Study Day 57)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 20 Nov 2009 (Study Day 57)	Admin. 3/ Inj. 8	Golimumab	100 mg
Week 8 (Main), 20 Nov 2009 (Study Day 57)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 17 Dec 2009 (Study Day 84)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 17 Dec 2009 (Study Day 84)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 17 Dec 2009 (Study Day 84)	Admin. 4/ Inj. 12	Golimumab	100 mg
Week 16 (Main), 21 Jan 2010 (Study Day 119)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 21 Jan 2010 (Study Day 119)	Admin. 5/ Inj. 14	Golimumab	100 mg
Week 16 (Main), 21 Jan 2010 (Study Day 119)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 25 Feb 2010 (Study Day 154)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 25 Feb 2010 (Study Day 154)	Admin. 6/ Inj. 17	Golimumab	100 mg
Week 24 (Main), 11 Mar 2010 (Study Day 168)	Admin. 7/ Inj. 18	Golimumab	100 mg
Week 24 (Main), 11 Mar 2010 (Study Day 168)	Admin. 7/ Inj. 19	Placebo	0 mg
Week 28 (Main), 12 Apr 2010 (Study Day 200)	Admin. 8/ Inj. 20	Placebo	0 mg
Week 28 (Main), 12 Apr 2010 (Study Day 200)	Admin. 8/ Inj. 21	Golimumab	100 mg
Week 32 (Main), 14 May 2010 (Study Day 232)	Admin. 9/ Inj. 22	Placebo	0 mg
Week 32 (Main), 14 May 2010 (Study Day 232)	Admin. 9/ Inj. 23	Golimumab	100 mg
Week 36 (Main), 04 Jun 2010 (Study Day 253)	Admin. 10/ Inj. 24	Placebo	0 mg
Week 36 (Main), 04 Jun 2010 (Study Day 253)	Admin. 10/ Inj. 25	Golimumab	100 mg

Week 40 (Main), 08 Jul 2010 (Study Day 287)	Admin. 11/ Inj. 26	Placebo	0 mg
Week 40 (Main), 08 Jul 2010 (Study Day 287)	Admin. 11/ Inj. 27	Golimumab	100 mg
Week 44 (Main), 06 Aug 2010 (Study Day 316)	Admin. 12/ Inj. 28	Golimumab	100 mg
Week 44 (Main), 06 Aug 2010 (Study Day 316)	Admin. 12/ Inj. 29	Placebo	0 mg
Week 48 (Main), 27 Aug 2010 (Study Day 337)	Admin. 13/ Inj. 30	Golimumab	100 mg
Week 48 (Main), 27 Aug 2010 (Study Day 337)	Admin. 13/ Inj. 31	Placebo	0 mg
Week 52 (Main), 05 Oct 2010 (Study Day 376)	Admin. 14/ Inj. 32	Golimumab	100 mg
Week 52 (Main), 05 Oct 2010 (Study Day 376)	Admin. 14/ Inj. 33	Placebo	0 mg

Treatment status:

Study treatment discontinuation?	No.
Date of last study agent administration in maintenance:	05 Oct 2010.
Last scheduled study treatment visit in maintenance:	Week 52 (Main).

Study status:

Date of study discontinuation:	19 Oct 2010.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	Pregnancy adverse event.
Date of disposition status:	19 Oct 2010.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7001-00003

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Minor progression of disease)	Not related	16 Apr 2009 20 Apr 2009 (5 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 19 Oct [redacted]) Caucasian female.
Weight: 63.7 kg; height: 162 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:

Date of diagnosis:	1998
UC disease duration:	10.0 years.

Prior/concomitant medication, route	**Start date**	**End date**
Prednisolone, oral	15 Nov 2008	Ongoing
Sulfasalazine, oral	June 2006	Ongoing
Calcium carbonate, oral	22 Oct 2008	Ongoing
Potassium chloride, oral	29 Oct 2008	Ongoing
Colecalciferol, oral	Prior	Ongoing
Prednisolone, oral	15 Nov 2008	15 Apr 2009
Sulfasalazine, oral	June 2006	15 Apr 2009
Calcium carbonate, oral	22 Oct 2008	15 Apr 2009
Potassium, oral	29 Oct 2008	15 Apr 2009
Colecalciferol, oral	Prior	15 Apr 2009
Prednisolone, oral	19 Apr 2009	09 Jun 2009
Hydrocortisone, intravenous	16 Apr 2009	18 Apr 2009
Fleet enema /00129701, rectal	16 Apr 2009	16 Apr 2009
Morphine, intravenous	16 Apr 2009	16 Apr 2009
Enoxaparin, subcutaneous	16 Apr 2009	20 Apr 2009
Paracetamol, oral	16 Apr 2009	20 Apr 2009
Oxycodone, oral	18 Apr 2009	20 Apr 2009

Treatment group in induction:	Placebo SC.
Treatment group in maintenance:	Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 15 Dec 2008 (Study Day -38)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 15 Dec 2008 (Study Day -38)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 15 Dec 2008 (Study Day -38)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 0 (Ind), 15 Dec 2008 (Study Day -38)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 2 (Ind), 29 Dec 2008 (Study Day -24)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 29 Dec 2008 (Study Day -24)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 29 Dec 2008 (Study Day -24)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 22 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 22 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Main), 22 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 19 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 19 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 4 (Main), 19 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 19 Mar 2009 (Study Day 57)	Admin. 3/ Inj. 7	Golimumab	100 mg
Week 8 (Main), 19 Mar 2009 (Study Day 57)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 19 Mar 2009 (Study Day 57)	Admin. 3/ Inj. 9	Placebo	0 mg

Treatment status:	
Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	19 Mar 2009.
Last scheduled study treatment visit in maintenance:	Week 8 (Main).
Date of study treatment discontinuation:	20 Apr 2009
Study status:	
Date of disposition status:	23 Jun 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7002-00009

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Serious infection	ウイルス性下気道感染 (Viral chest infection)	Possible	12 May 2010 14 May 2010 (3 days)
SAE	潰瘍性大腸炎 (Worsening of UC)	Not related	07 Jun 2010 08 Jun 2010 (2 days)

Baseline demographic information: 4[redacted]-year-old (DOB: 07 Sep [redacted]) Caucasian male.
Weight: 107 kg; height: 180 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:
Date of diagnosis: 01 Mar 2009.
UC disease duration: 0.9 years.

Prior/concomitant medication, route	**Start date**	**End date**
Balsalazide sodium, oral	April 2009	Ongoing
Prednisolone, oral	November 2008	Ongoing
Metformin hydrochloride, oral	March 2008	Ongoing
Methotrexate, subcutaneous	May 2009	Ongoing
Ascorbic acid, oral	May 2009	Ongoing
Calcium carbonate, oral	November 2009	Ongoing
Folic acid, oral	May 2009	Ongoing
Salbutamol, inhalation	1972	Ongoing
Seretide, inhalation	2006	Ongoing
Insulin glargine, subcutaneous	October 2009	Ongoing
Sulfacetamide sodium, ophthalmic	December 2009	26 Jan 2010
Balsalazide, oral	April 2009	Ongoing
Metformin, oral	March 2008	Ongoing
Metoclopramide, intravenous	12 May 2010	12 May 2010

Ceftriaxone, intravenous	12 May 2010	12 May 2010
Hydrocortisone, intravenous	12 May 2010	12 May 2010
Sodium chloride, intravenous	12 May 2010	12 May 2010
Fentanyl, intravenous	08 Jun 2010	11 Jun 2010
Morphine, intravenous	09 Jun 2010	09 Jun 2010
Ondansetron, intravenous	08 Jun 2010	12 Jun 2010
Temazepam, oral	10 Jun 2010	11 Jun 2010
Prochlorperazine, intravenous	12 Jun 2010	12 Jun 2010
Paracetamol, intravenous	08 Jun 2010	14 Jun 2010
Colonlytely /01271501/, rectal	07 Jun 2010	07 Jun 2010
Bisacodyl, oral	07 Jun 2010	07 Jun 2010
Enoxaparin, subcutaneous	08 Jun 2010	16 Jun 2010
Ascorbic acid, oral	07 Jun 2010	17 Jun 2010
Tramadol, oral	08 Jun 2010	17 Jun 2010
Esomeprazole, oral	07 Jun 2010	13 Jun 2010
Hydrocortisone, intravenous	07 Jun 2010	11 Jun 2010
Oxycodone, oral	09 Jun 2010	14 Jun 2010
Oxycodone, oral	10 Jun 2010	12 Jun 2010
Promethazine, oral	15 Jun 2010	16 Jun 2010
Oxycodone, oral	11 Jun 2010	17 Jun 2010
Esomeprazole, oral	14 Jun 2010	Ongoing
Celecoxib, oral	15 Jun 2010	Ongoing
Glucose, intravenous	07 Jun 2010	07 Jun 2010
Sodium chloride, intravenous	08 Jun 2010	13 Jun 2010
Flebobag ring lact, intravenous	08 Jun 2010	13 Jun 2010

Treatment group in induction:	Placebo SC.
Treatment group in maintenance:	Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 27 Jan 2010 (Study Day -42)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 27 Jan 2010 (Study Day -42)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 27 Jan 2010 (Study Day -42)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 27 Jan 2010 (Study Day -42)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 10 Feb 2010 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 10 Feb 2010 (Study Day -28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 0 (Main), 10 Mar 2010 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 10 Mar 2010 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 4 (Main), 08 Apr 2010 (Study Day 30)	Admin. 2/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 08 Apr 2010 (Study Day 30)	Admin. 2/ Inj. 4	Placebo	0 mg
Unscheduled 1 (Main)—dose not done	NA	NA	NA
Unscheduled 1 (Main)—dose not done	NA	NA	NA

Treatment status:	
Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Unsatisfactory therapeutic effect.
Date of last study agent administration in maintenance:	08 Apr 2010.
Last scheduled study treatment visit in maintenance:	Week 4 (Main).
Date of study treatment discontinuation:	19 May 2010.
Study status:	
Date of disposition status:	25 Aug 2010.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7008-00007

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Serious infection	乳房膿瘍 (Breast abscess—right breast)	Possible	15 Jun2009 26 Aug 2009 (73 days)
SAE/ Serious infection	皮下組織膿瘍 (Superficial subcutaneous abscess on back of neck)	Possible	28 Feb 2010 10 May 2010 (72 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 10 Jun [redacted]) Caucasian female.
Weight: 86 kg; height: 170 cm.

Relevant medical history at baseline: 関節痛，アフタ性口内炎

Baseline smoking status: Nonsmoker.

Ulcerative colitis history:
Date of diagnosis: 2003.
UC disease duration: 5.3 years.

Prior/concomitant medication, route	Start date	End date
Insulin glargine, subcutaneous	June 2007	Ongoing
Insulin aspart, subcutaneous	June 2007	Ongoing
Sertraline hydrochloride, oral	December 2008	Ongoing
Cefalexin monohydrate, oral	18 Apr 2009	25 Apr 2009
Isoniazid, oral	29 Apr 2009	Ongoing
Pyridoxine, oral	29 Apr 2009	Ongoing
Midazolam, intravenous	29 Apr 2009	29 Apr 2009
Fentanyl, intravenous	29 Apr 2009	29 Apr 2009
Midazolam, intravenous	10 Jun 2009	10 Jun 2009
Fentanyl, intravenous	10 Jun 2009	10 Jun 2009
Cefalexin monohydrate, oral	10 Jun 2009	Ongoing
Isoniazid, oral	29 Apr2009	29 Jan 2010
Pyridoxine, oral	29 Apr 2009	29 Jan 2010
Cefalexin, oral	10 Jun 2009	15 Jun 2009
Penicillin nos, intravenous	15 Jun 2009	17 Jun 2009
Flucloxacillin, intravenous	15 Jun 2009	17 Jun 2009
Heparin, subcutaneous	15 Jun 2009	17 Jun 2009
Sertraline, oral	December 2008	Ongoing
Paracetamol, oral	15 Jun 2009	17 Jun 2009
Flucloxacillin, intravenous	17 Jun 2009	01 Jul 2009
Penicillin nos, intravenous	17 Jun 2009	24 Jun 2009
Dicloxacillin, oral	01 Jul 2009	11 Jul 2009
Xylocaine-epinephrine, subcutaneous	15 Jun 2009	15 Jun 2009
Calcium with vitamin D /01233101/, oral	19 Aug 2009	08 Sep 2010
Paracetamol, oral	14 Dec 2009	16 Dec 2009
Midazolam, intravenous	08 Jan 2010	08 Jan 2010
Fentanyl, intravenous	08 Jan 2010	08 Jan 2010
Mometasone, topical	03 Feb 2010	24 Jun 2010
Ciprofloxacin, oral	06 Mar 2010	14 Mar 2010
Lincomycin, intravenous	01 Mar 2010	09 Mar 2010
Oxycodone, oral	02 Mar 2010	09 Mar 2010
Metoclopramide, intravenous	02 Mar 2010	02 Mar 2010
Clindamycin, oral	09 Mar 2010	18 Mar 2010
Mebendazole, oral	12 Apr 2010	12 Apr 2010
Fentanyl, intravenous	25 Jun 2010	25 Jun 2010
Midazolam, intravenous	25 Jun 2010	25 Jun 2010
Propofol, intravenous	25 Jun 2010	25 Jun 2010
Chloramphenicol, topical	13 Jun 2010	16 Jun 2010
Dermaveen /01380301, topical	25 Jun 2010	28 Jul 2010

Treatment group in induction:	Placebo SC.
Treatment group in maintenance:	Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 29 Apr 2009 (Study Day -65)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 29 Apr 2009 (Study Day -65)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 29 Apr 2009 (Study Day -65)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 29 Apr 2009 (Study Day -65)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 13 May 2009 (Study Day -51)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 13 May 2009 (Study Day -51)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 13 May 2009 (Study Day -51)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 03 Jul 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 03 Jul 2009 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Main), 03 Jul 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 8 (Main), 29 Jul 2009 (Study Day 27)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 8 (Main), 29 Jul 2009 (Study Day 27)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 8 (Main), 29 Jul 2009 (Study Day 27)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 12 (Main), 26 Aug 2009 (Study Day 55)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 12 (Main), 26 Aug 2009 (Study Day 55)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 12 (Main), 26 Aug 2009 (Study Day 55)	Admin. 3/ Inj. 9	Golimumab	100 mg
Week 16 (Main), 30 Sep 2009 (Study Day 90)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 16 (Main), 30 Sep 2009 (Study Day 90)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 16 (Main), 30 Sep 2009 (Study Day 90)	Admin. 4/ Inj. 12	Golimumab	100 mg
Week 20 (Main), 28 Oct 2009 (Study Day 118)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 20 (Main), 28 Oct 2009 (Study Day 118)	Admin. 5/ Inj. 14	Golimumab	100 mg
Week 20 (Main), 28 Oct 2009 (Study Day 118)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 24 (Main), 25 Nov 2009 (Study Day 146)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 24 (Main), 25 Nov 2009 (Study Day 146)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 24 (Main), 25 Nov 2009 (Study Day 146)	Admin. 6/ Inj. 18	Golimumab	100 mg
Week 28 (Main), 22 Dec 2009 (Study Day 173)	Admin. 7/ Inj. 19	Placebo	0 mg
Week 28 (Main), 22 Dec 2009 (Study Day 173)	Admin. 7/ Inj. 20	Golimumab	100 mg
Week 28 (Main), 22 Dec 2009 (Study Day 173)	Admin. 7/ Inj. 21	Placebo	0 mg
Week 32 (Main), 27 Jan 2010 (Study Day 209)	Admin. 8/ Inj. 22	Placebo	0 mg
Week 32 (Main), 27 Jan 2010 (Study Day 209)	Admin. 8/ Inj. 23	Golimumab	100 mg
Week 32 (Main), 27 Jan 2010 (Study Day 209)	Admin. 8/ Inj. 24	Placebo	0 mg
Week 36 (Main), 17 Feb 2010 (Study Day 230)	Admin. 9/ Inj. 25	Placebo	0 mg
Week 36 (Main), 17 Feb 2010 (Study Day 230)	Admin. 9/ Inj. 26	Golimumab	100 mg
Week 36 (Main), 17 Feb 2010 (Study Day 230)	Admin. 9/ Inj. 27	Placebo	0 mg
Week 40 (Main)—dose not done	NA	NA	NA
Week 44 (Main), 14 Apr 2010 (Study Day 286)	Admin. 10/ Inj. 28	Placebo	0 mg
Week 44 (Main), 14 Apr 2010 (Study Day 286)	Admin. 10/ Inj. 29	Golimumab	100 mg
Week 48 (Main), 12 May 2010 (Study Day 314)	Admin. 11/ Inj. 30	Placebo	0 mg
Week 48 (Main), 12 May 2010 (Study Day 314)	Admin. 11/ Inj. 31	Golimumab	100 mg
Week 52 (Main), 09 Jun 2010 (Study Day 342)	Admin. 12/ Inj. 32	Golimumab	100 mg
Week 52 (Main), 09 Jun 2010 (Study Day 342)	Admin. 12/ Inj. 33	Placebo	0 mg

Treatment status:	
Study treatment discontinuation?	No.
Date of last study agent administration in maintenance:	09 Jun 2010.
Last scheduled study treatment visit in maintenance:	Week 52 (Main).
Study status:	
Date of disposition status:	25 Jun 2010.
Ended study participation as of Week 54?	No.
Entered extension study?	Yes.

被験者識別コード：7008-00025

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Exacerbation of ulcerative colitis)	Unlikely	26 Sep 2010 30 Sep 2010 (5 days)

Baseline demographic information: 1[redacted]-year-old (DOB: 22 May [redacted]) Caucasian female.
Weight: 70 kg; height: 169 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: April 2009.
UC disease duration: 1.2 years.

Prior/concomitant medication, route	Start date	End date
Prednisone, oral	June 2010	Ongoing
Mesalazine, oral	Prior	17 Aug 2010
Fentanyl, intravenous	23 Jul 2010	23 Jul 2010
Propofol, intravenous	23 Jul 2010	23 Jul 2010
Ferric hydroxide polymaltose complex, intravenous	25 Aug 2010	25 Aug 2010
Fentanyl, intravenous	03 Sep 2010	03 Sep 2010
Propofol, intravenous	03 Sep 2010	03 Sep 2010
Prednisone, oral	June 2010	25 Sep 2010
Metronidazole, oral	26 Sep 2010	30 Sep 2010
Ciprofloxacin, oral	26 Sep 2010	30 Sep 2010
Potassium, oral	28 Sep 2010	05 Oct 2010
Prednisone, oral	28 Sep 2010	Ongoing
Hydrocortisone, intravenous	26 Sep 2010	27 Sep 2010
Infliximab, intravenous	28 Sep 2010	25 Oct 2010

Treatment group in induction: Placebo SC.
Treatment group in maintenance: Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 23 Jul 2010 (Study Day -42)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 23 Jul 2010 (Study Day -42)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 23 Jul 2010 (Study Day -42)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 23 Jul 2010 (Study Day -42)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 10 Aug 2010 (Study Day -24)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 10 Aug 2010 (Study Day -24)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 0 (Main), 03 Sep 2010 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 03 Sep 2010 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 30 (Main)—dose not done	NA	NA	NA

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Adverse event.
Date of last study agent administration in maintenance: 03 Sep 2010.
Last scheduled study treatment visit in maintenance: Week 0 (Main).
Date of study treatment discontinuation: 27 Sep 2010.

Study status:
Date of disposition status: 15 Dec 2010.
Ended study participation as of Week 54? Yes.
Entered extension study? No.

被験者識別コード：7085-00002

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	大動脈瘤破裂 (Rupture of aneurysm of the abdominal aorta)	Not related	18 Dec 2010 18 Jan 2011 (32 days)

Baseline demographic information: 6[redacted]-year-old (DOB: 19 Aug [redacted]) Caucasian male.
Weight: 92 kg; height: 173 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker.

Ulcerative colitis history:
Date of diagnosis: 2005.
UC disease duration: 4.6 years.

Prior/concomitant medication, route	Start date	End date
Prednisone, oral	15 May 2010	Ongoing
Bisoprolol fumarate, oral	Prior	Ongoing
Ramipril, oral	Prior	Ongoing
Fenofibrate, oral	Prior	Ongoing
Acetylsalicylic acid, oral	Prior	Ongoing
Fortrans /01064301/, oral	01 Aug 2010	02 Aug 2010
Fortrans /01064301/, oral	14 Sep 2010	15 Sep 2010
Prednisone, oral	15 May 2010	18 Dec 2010
Bisoprolol, oral	Prior	Ongoing
Pentoxifylline, oral	18 Jan 2011	Ongoing
Ciprofloxacin, oral	18 Jan2011	28 Jan 2011
Bromhexine, oral	18 Jan 2011	28 Jan 2011
Esomeprazole, oral	18 Jan 2011	18 Feb 2011
Dalteparin, subcutaneous	18 Jan 2011	18 Feb 2011
Pancreatin, oral	27 Jan 2011	28 Feb 2011
Mesalazine, oral	27 Jan 2011	Ongoing

Treatment group in induction: Placebo SC.
Treatment group in maintenance: Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 04 Aug 2010 (Study Day -48)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 04 Aug 2010 (Study Day -48)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 04 Aug 2010 (Study Day -48)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 04 Aug 2010 (Study Day -48)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 17 Aug 2010 (Study Day -35)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 17 Aug 2010 (Study Day -35)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 0 (Main), 21 Sep 2010 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 21 Sep 2010 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 4 (Main), 19 Oct 2010 (Study Day 29)	Admin. 2/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 19 Oct 2010 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 8 (Main), 16 Nov 2010 (Study Day 57)	Admin. 3/ Inj. 5	Golimumab	100 mg
Week 8 (Main), 16 Nov 2010 (Study Day 57)	Admin. 3/ Inj. 6	Placebo	0 mg
Week 12 (Main), 16 Dec 2010 (Study Day 87)	Admin. 4/ Inj. 7	Placebo	0 mg
Week 12 (Main), 16 Dec 2010 (Study Day 87)	Admin. 4/ Inj. 8	Golimumab	100 mg

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Adverse event.
Date of last study agent administration in maintenance: 16 Dec 2010.
Last scheduled study treatment visit in maintenance: Week 12 (Main).
Date of study treatment discontinuation: 19 Dec 2010.

Study status:	
Date of study discontinuation:	19 Dec 2010.
Reason for noncompletion:	Other.
Other reason for non completion/details:	SAE-patient is currently attending rehabilitation programme after operation for rupture of aneurysm of abdominal aorta; approximately one month in ICU on parenteral nutrition.
Date of disposition status:	19 Dec 2010.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7207-00009

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Ulcerative colitis flare)	Unlikely	20 Mar 2009 26 Mar 2009 (7 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 01 Apr [redacted]) Caucasian male.
Weight: 104 kg; height: 186 cm.

Relevant medical history at baseline: 関節痛

Baseline smoking status: Nonsmoker.

Ulcerative colitis history:
Date of diagnosis: March 2003.
UC disease duration: 5.5 years.

Prior/concomitant medication, route	**Start date**	**End date**
Pantoprazole sodium, oral	2007	Ongoing
Calcium D3 /01483701/, oral	2007	Ongoing
Ferrous glycine sulfate, oral	29 Sep 2008	Ongoing
Prednisolone, oral	19 Sep 2008	Ongoing
Pantoprazole, oral	2007	Ongoing
Calcium carbonate, oral	2007	Ongoing
Iron, oral	29 Sep 2008	Ongoing
Prednisolone, oral	19 Sep 2008	12 Mar 2009
Moxifloxacin, oral	19 Jan 2009	29 Jan 2009
Prednisolone, intravenous	20 Mar 2009	26 Mar 2009
Prednisolone, oral	27 Mar 2009	Ongoing
Infliximab, intravenous	13 May 2009	Ongoing

Treatment group in induction: Placebo SC.
Treatment group in maintenance: Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 09 Oct 2008 (Study Day -41)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 09 Oct 2008 (Study Day -41)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 09 Oct 2008 (Study Day -41)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 09 Oct 2008 (Study Day -41)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 23 Oct 2008 (Study Day -27)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 23 Oct 2008 (Study Day -27)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 23 Oct 2008 (Study Day -27)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 19 Nov 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 19 Nov 2008 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 19 Nov 2008 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 18 Dec 2008 (Study Day 30)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 4 (Main), 18 Dec 2008 (Study Day 30)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 18 Dec 2008 (Study Day 30)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 15 Jan 2009 (Study Day 58)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 15 Jan 2009 (Study Day 58)	Admin. 3/ Inj. 8	Golimumab	100 mg

Week 8 (Main), 15 Jan 2009 (Study Day 58)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 11 Feb 2009 (Study Day 85)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 11 Feb 2009 (Study Day 85)	Admin. 4/ Inj. 11	Golimumab	100 mg
Week 12 (Main), 11 Feb 2009 (Study Day 85)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 10 Mar 2009 (Study Day 112)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 10 Mar 2009 (Study Day 112)	Admin. 5/ Inj. 14	Golimumab	100 mg
Week 16 (Main), 10 Mar 2009 (Study Day 112)	Admin. 5/ Inj. 15	Placebo	0 mg
Unscheduled 1 (Main)—dose not done	NA	NA	NA

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	10 Mar 2009.
Last scheduled study treatment visit in maintenance:	Week 16 (Main).
Date of study treatment discontinuation:	20 Mar 2009.

Study status:

Date of disposition status:	24 Jun 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7235-00001

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Serious infection/ Event of interest: GI abscess/ stricture/ colectomy	肛門膿瘍 (Perianal abscess)	Unlikely	13 Oct 2009 15 Oct 2009 (3 days)
Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of UC)	Not related	16 Dec 2009 29 Dec 2009 (14 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 31 May [redacted]) Caucasian female.
Weight: 50.6 kg; height: 176 cm.

Relevant medical history at baseline: 膿瘍の切開及びドレナージ，肛門周囲瘻手術，肛門周囲膿瘍，関節痛，壊疽性膿皮症，痔瘻

Baseline smoking status: Nonsmoker.

Ulcerative colitis history:

Date of diagnosis:	16 Apr 2004.
UC disease duration:	5.2 years.

Prior/concomitant medication, route	**Start date**	**End date**
Budesonide, oral	03 Apr 2009	Ongoing
Mesalazine, oral	15 Apr 2004	Ongoing
Diclofenac, oral	02 Aug 2009	18 Aug 2009
Tobramycin, ophthalmic	30 Jul 2009	03 Aug 2009
Meloxicam, oral	18 Aug 2009	20 Aug 2009
Isosource, oral	15 Aug 2009	Ongoing
Moxifloxacin, oral	25 Aug 2009	29 Aug 2009
Augmentin /00756801/, oral	29 Aug 2009	04 Sep 2009
Paracetamol, oral	22 Aug 2009	04 Sep 2009
Diclofenac, oral	22 Aug 2009	04 Sep 2009
Ferro-folsan /00023601/, oral	29 Aug 2009	Ongoing
Influenza vaccine, intramuscular	09 Sep 2009	09 Sep 2009
Dalteparin, subcutaneous	13 Oct 2009	25 Oct 2009
Diclofenac, oral	13 Oct 2009	15 Oct 2009
Zolpidem, oral	13 Oct 2009	13 Oct 2009
Midazolam, oral	14 Oct 2009	14 Oct 2009

Treatment group in induction:	Placebo SC.
Treatment group in maintenance:	Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 13 Jul 2009 (Study Day -37)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 13 Jul 2009 (Study Day -37)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 13 Jul 2009 (Study Day -37)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 13 Jul 2009 (Study Day -37)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 27 Jul 2009 (Study Day -23)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 27 Jul 2009 (Study Day -23)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 27 Jul 2009 (Study Day -23)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 19 Aug 2009 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 19 Aug 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 19 Aug 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Unscheduled 1 (Main)—dose not done	NA	NA	NA
Week 4 (Main), 14 Sep 2009 (Study Day 27)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 4 (Main), 14 Sep 2009 (Study Day 27)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 14 Sep 2009 (Study Day 27)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 12 Oct 2009 (Study Day 55)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 12 Oct 2009 (Study Day 55)	Admin. 3/ Inj. 8	Golimumab	100 mg
Week 8 (Main), 12 Oct 2009 (Study Day 55)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 03 Nov 2009 (Study Day 77)	Admin. 4/ Inj. 10	Golimumab	100 mg
Week 12 (Main), 03 Nov 2009 (Study Day 77)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 03 Nov 2009 (Study Day 77)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 25 Nov 2009 (Study Day 99)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 25 Nov 2009 (Study Day 99)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 25 Nov 2009 (Study Day 99)	Admin. 5/ Inj. 15	Golimumab	100 mg
Unscheduled 2 (Main)—dose not done	NA	NA	NA

Treatment status:	
Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	25 Nov 2009.
Last scheduled study treatment visit in maintenance:	Week 16 (Main).
Date of study treatment discontinuation:	17 Dec 2009.

Study status:	
Date of study discontinuation:	17 Dec 2009.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	As per investigator due to worsening of UC subject was terminated from the study.
Date of disposition status:	17 Dec 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7376-00001

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	膵炎 (Pancreatitis)	Unlikely	09 Dec 2008 24 Dec 2008 (16 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 19 Jun [redacted]) Caucasian female.
Weight: 78 kg; height: 160 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:

Date of diagnosis:	19 Jun 2007.
UC disease duration:	1.2 years.

Prior/concomitant medication, route	**Start date**	**End date**
Mesalazine, oral	June 2007	Ongoing
Salbutamol, inhalation	Prior	Ongoing
Fluticasone propionate, inhalation	Prior	Ongoing

Fluoxetine, oral	Prior	Ongoing
Pyridoxine hydrochloride, oral	Prior	Ongoing
Iron preparations, oral	29 Aug 2008	29 Aug 2008
Hydrocortisone, topical	29 Aug 2008	Ongoing
Paracetamol, oral	12 Sep 2008	12 Sep 2008
Gee's linctus, oral	27 Sep 2008	03 Oct 2008
Cetirizine hydrochloride, oral	28 Sep 2008	29 Sep 2008
Paracetamol, oral	29 Sep 2008	06 Oct 2008
Ferric hydroxide polymaltose complex, intravenous	03 Oct 2008	03 Oct 2008
Mesalazine, oral	Prior	17 Dec 2008
Paracetamol, oral	09 Nov 2008	Ongoing
Hydrocortisone, topical	29 Aug 2008	Ongoing
Electrolyte /00909901/, oral	01 Dec 2008	01 Dec 2008
Azathioprine, oral	28 Dec 2008	Ongoing
Ciclosporin, oral	22 Dec 2008	Ongoing
Bactrim, oral	28 Dec 2008	Ongoing
Omeprazole, oral	17 Dec 2008	24 Dec 2008
Codeine, oral	16 Dec 2008	18 Dec 2008
Metoclopramide, oral	15 Dec 2008	23 Dec 2008
Paracetamol, oral	15 Dec 2008	23 Dec 2008

Treatment group in induction: Placebo SC.
Treatment group in maintenance: Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 02 Sep 2008 (Study Day -42)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 02 Sep 2008 (Study Day -42)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 02 Sep 2008 (Study Day -42)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 02 Sep 2008 (Study Day -42)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 16 Sep 2008 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 16 Sep 2008 (Study Day -28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 16 Sep 2008 (Study Day -28)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 14 Oct 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 14 Oct 2008 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Main), 14 Oct 2008 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 11 Nov 2008 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 11 Nov 2008 (Study Day 29)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 4 (Main), 11 Nov 2008 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 04 Dec 2008 (Study Day 52)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 04 Dec 2008 (Study Day 52)	Admin. 3/ Inj. 8	Golimumab	100 mg
Week 8 (Main), 04 Dec 2008 (Study Day 52)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main)—dose not done	NA	NA	NA

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	04 Dec 2008.
Last scheduled study treatment visit in maintenance:	Week 8 (Main).
Date of study treatment discontinuation:	06 Jan 2009.

Study status:

Date of study discontinuation:	06 Jan 2009.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	Medical decision being hospitalized for pancreatitis.
Date of disposition status:	06 Jan 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7377-00001

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of UC requiring hospital admission)	Unlikely	22 Apr 2008 02 Sep 2008 (134 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 21 Feb [redacted]) Caucasian female.
Weight: 92.2 kg; height: 159 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 05 Jul 2007.
UC disease duration: 0.4 years.

Prior/concomitant medication, route	Start date	End date
Prednisone, oral	23 Aug 2007	Ongoing
Zopiclone, oral	Prior	Ongoing
Citalopram, oral	Prior	Ongoing
Prednisone, oral	04 Feb 2008	18 Feb 2008
Prednisone, oral	18 Feb 2008	18 Mar 2008
Prednisone, oral	18 Mar 2008	01 Apr 2008
Azathioprine, oral	22 Apr 2008	03 Jun 2008
Methylprednisolone, oral	22 Apr 2008	17 Sep 2008

Treatment group in induction: Placebo SC.
Treatment group in maintenance: Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 20 Nov 2007 (Study Day -48)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 20 Nov 2007 (Study Day -48)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 20 Nov 2007 (Study Day -48)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 20 Nov 2007 (Study Day -48)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 03 Dec 2007 (Study Day -35)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 03 Dec 2007 (Study Day -35)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 03 Dec 2007 (Study Day -35)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 07 Jan 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 07 Jan 2008 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Main), 07 Jan 2008 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 04 Feb 2008 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 04 Feb 2008 (Study Day 29)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 4 (Main), 04 Feb 2008 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 03 Mar 2008 (Study Day 57)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 03 Mar 2008 (Study Day 57)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 03 Mar 2008 (Study Day 57)	Admin. 3/ Inj. 9	Golimumab	100 mg
Week 12 (Main), 31 Mar 2008 (Study Day 85)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 31 Mar 2008 (Study Day 85)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 31 Mar 2008 (Study Day 85)	Admin. 4/ Inj. 12	Golimumab	100 mg

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Unsatisfactory therapeutic effect.
Date of last study agent administration in maintenance: 31 Mar 2008.
Last scheduled study treatment visit in maintenance: Week 12 (Main).
Date of study treatment discontinuation: 22 Apr 2008.

Study status:
Date of disposition status: 05 Aug 2008.
Ended study participation as of Week 54? Yes.
Entered extension study? No.

被験者識別コード：7402-00002

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Serious infection	腸炎 (Acute enterocolitis)	Unlikely	24 Apr 2010 06 May 2010 (13 days)

Baseline demographic information: 5[redacted]-year-old (DOB: 30 Aug [redacted]) Caucasian female.
Weight: 56 kg; height: 164 cm.

Relevant medical history at baseline: 喫煙（現在）

Baseline smoking status: Current smoker.

Ulcerative colitis history:
Date of diagnosis: November 1990.
UC disease duration: 18.4 years.

Prior/concomitant medication, route	Start date	End date
Azathioprine, oral	December 2005	Ongoing
Sulfasalazine, oral	November 1990	Ongoing
Folic acid, oral	November 1990	Ongoing
Pantoprazole, oral	June 2008	Ongoing
Levothyroxine sodium, oral	1999	Ongoing
Isoniazid, oral	10 Apr 2009	Ongoing
Levothyroxine, oral	1999	Ongoing
Isoniazid, oral	10 Apr 2009	07 Feb 2011
Rifaximin, oral	27 Apr 2010	04 May 2010
Rifaximin, oral	05 May 2010	06 May 2010
Ciprofloxacin, intravenous	27 Apr 2010	04 May 2010
Metronidazole, intravenous	27 Apr 2010	04 May 2010
Perikabiven, intravenous	27 Apr 2010	28 Apr 2010
Estazolam, oral	01 May 2010	05 May 2010

Treatment group in induction: Placebo SC.
Treatment group in maintenance: Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 14 Apr 2009 (Study Day -42)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 14 Apr 2009 (Study Day -42)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 14 Apr 2009 (Study Day -42)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 14 Apr 2009 (Study Day -42)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 29 Apr 2009 (Study Day -27)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 29 Apr 2009 (Study Day -27)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 29 Apr 2009 (Study Day -27)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 26 May 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 26 May 2009 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Main), 26 May 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 17 Jun 2009 (Study Day 23)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 17 Jun 2009 (Study Day 23)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 4 (Main), 17 Jun 2009 (Study Day 23)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 21 Jul 2009 (Study Day 57)	Admin. 3/ Inj. 7	Golimumab	100 mg
Week 8 (Main), 21 Jul 2009 (Study Day 57)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 21 Jul 2009 (Study Day 57)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 18 Aug 2009 (Study Day 85)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 18 Aug 2009 (Study Day 85)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 18 Aug 2009 (Study Day 85)	Admin. 4/ Inj. 12	Golimumab	100 mg
Week 16 (Main), 15 Sep 2009 (Study Day 113)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 15 Sep 2009 (Study Day 113)	Admin. 5/ Inj. 14	Golimumab	100 mg
Week 16 (Main), 15 Sep 2009 (Study Day 113)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 13 Oct 2009 (Study Day 141)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 13 Oct 2009 (Study Day 141)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 20 (Main), 13 Oct 2009 (Study Day 141)	Admin. 6/ Inj. 18	Golimumab	100 mg
Week 24 (Main), 04 Nov 2009 (Study Day 163)	Admin. 7/ Inj. 19	Placebo	0 mg

Week 24 (Main), 04 Nov 2009 (Study Day 163)	Admin. 7/ Inj. 20	Placebo	0 mg
Week 24 (Main), 04 Nov 2009 (Study Day 163)	Admin. 7/ Inj. 21	Golimumab	100 mg
Week 28 (Main), 08 Dec 2009 (Study Day 197)	Admin. 8/ Inj. 22	Placebo	0 mg
Week 28 (Main), 08 Dec 2009 (Study Day 197)	Admin. 8/ Inj. 23	Placebo	0 mg
Week 28 (Main), 08 Dec 2009 (Study Day 197)	Admin. 8/ Inj. 24	Golimumab	100 mg
Week 32 (Main), 05 Jan 2010 (Study Day 225)	Admin. 9/ Inj. 25	Placebo	0 mg
Week 32 (Main), 05 Jan 2010 (Study Day 225)	Admin. 9/ Inj. 26	Golimumab	100 mg
Week 32 (Main), 05 Jan 2010 (Study Day 225)	Admin. 9/ Inj. 27	Placebo	0 mg
Week 36 (Main), 02 Feb 2010 (Study Day 253)	Admin. 10/ Inj. 28	Placebo	0 mg
Week 36 (Main), 02 Feb 2010 (Study Day 253)	Admin. 10/ Inj. 29	Placebo	0 mg
Week 36 (Main), 02 Feb 2010 (Study Day 253)	Admin. 10/ Inj. 30	Golimumab	100 mg
Week 40 (Main), 02 Mar 2010 (Study Day 281)	Admin. 11/ Inj. 31	Placebo	0 mg
Week 40 (Main), 02 Mar 2010 (Study Day 281)	Admin. 11/ Inj. 32	Golimumab	100 mg
Week 44 (Main), 31 Mar 2010 (Study Day 310)	Admin. 12/ Inj. 33	Placebo	0 mg
Week 44 (Main), 31 Mar 2010 (Study Day 310)	Admin. 12/ Inj. 34	Golimumab	100 mg
Week 48 (Main), 06 May 2010 (Study Day 346)	Admin. 13/ Inj. 35	Placebo	0 mg
Week 48 (Main), 06 May 2010 (Study Day 346)	Admin. 13/ Inj. 36	Golimumab	100 mg
Week 52 (Main), 27 May 2010 (Study Day 367)	Admin. 14/ Inj. 37	Golimumab	100 mg
Week 52 (Main), 27 May 2010 (Study Day 367)	Admin. 14/ Inj. 38	Placebo	0 mg
Treatment status:			
Study treatment discontinuation?	No.		
Date of last study agent administration in maintenance:	27 May 2010.		
Last scheduled study treatment visit in maintenance:	Week 52 (Main).		
Study status:			
Date of disposition status:	09 Jun 2010.		
Ended study participation as of Week 54?	No.		
Entered extension study?	Yes.		

被験者識別コード：7722-00004

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Exacerbation of ulcerative colitis)	Not related	31 Jan 2008 07 Feb 2008 (8 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 30 Apr [redacted]) Caucasian male.
Weight: 61.8 kg; height: 177 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:
Date of diagnosis: 27 Feb 2007.
UC disease duration: 0.6 years.

Prior/concomitant medication, route	**Start date**	**End date**
Midazolam hydrochloride, intravenous	04 Oct 2007	04 Oct 2007
Fentanyl, intravenous	04 Oct 2007	04 Oct 2007
Fleet enema /00129701/, rectal	04 Oct 2007	04 Oct 2007
Loperamide, oral	02 Nov 2007	04 Nov 2007
Midazolam hydrochloride, intravenous	26 Nov 2007	26 Nov 2007
Fentanyl, intravenous	26 Nov 2007	26 Nov 2007
Fleet enema /00129701/, rectal	26 Nov 2007	26 Nov 2007
Solutions for parenteral nutrition, intravenous	01 Feb 2008	07 Feb 2008
Insulin, intravenous	01 Feb 2008	04 Feb 2008
Ibuprofen, oral	01 Feb 2008	Ongoing
Iron, intravenous	01 Feb 2008	Ongoing
Methylprednisolone, intravenous	31 Jan 2008	Ongoing
Morphine, intravenous	01 Feb 2008	Ongoing
Diphenhydramine, oral	01 Feb 2008	Ongoing
Ondansetron, oral	01 Feb 2008	Ongoing
Zolpidem, oral	01 Feb 2008	Ongoing

Oxycocet, oral	01 Feb 2008	Ongoing
Azathioprine, oral	01 Feb 2008	Ongoing
Red blood cells, intravenous	01 Feb 2008	Ongoing
Omeprazole, oral	01 Feb 2008	Ongoing

Treatment group in induction: Placebo SC.
Treatment group in maintenance: Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 11 Oct 2007 (Study Day -46)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 11 Oct 2007 (Study Day -46)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 11 Oct 2007 (Study Day -46)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 11 Oct 2007 (Study Day -46)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 25 Oct 2007 (Study Day -32)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 25 Oct 2007 (Study Day -32)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 25 Oct 2007 (Study Day -32)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 26 Nov 2007 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 26 Nov 2007 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 26 Nov 2007 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 20 Dec 2007 (Study Day 25)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 4 (Main), 20 Dec 2007 (Study Day 25)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 20 Dec 2007 (Study Day 25)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 16 Jan 2008 (Study Day 52)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 16 Jan 2008 (Study Day 52)	Admin. 3/ Inj. 8	Golimumab	100 mg
Week 8 (Main), 16 Jan 2008 (Study Day 52)	Admin. 3/ Inj. 9	Placebo	0 mg

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Adverse event.
Date of last study agent administration in maintenance: 16 Jan 2008.
Last scheduled study treatment visit in maintenance: Week 8 (Main).
Date of study treatment discontinuation: 01 Feb 2008.

Study status:
Date of study discontinuation: 06 Mar 2008.
Reason for noncompletion: Other.
Other reason for noncompletion/details: Subject did not show for 16 week follow up visit.
Date of disposition status: 06 Mar 2008.
Ended study participation as of Week 54? Yes.
Entered extension study? No.

被験者識別コード：7775-00001

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE/ Event of interest: Malignancy	甲状腺癌 (Hurthle cell carcinoma)	Possible	23 Mar 2010 13 Oct 2010 (205 days)

Baseline demographic information: 5[redacted]-year-old (DOB: 19 Sep [redacted]) Black female. Weight: 102 kg; height: 172 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:
Date of diagnosis: 01 Jan 1999.
UC disease duration: 11.1 years.

Prior/concomitant medication, route	Start date	End date
Mesalazine, oral	15 Dec 2009	Ongoing
Hydrochlorothiazide, oral	01 Jun 2007	Ongoing
Amlodipine besilate, oral	01 Jun 2007	Ongoing
Minocycline, oral	19 Mar 2010	Ongoing

Mupirocin, topical	19 Mar 2010	Ongoing
Mesalazine, oral	15 Dec 2009	08 Apr 2010
Hydrochlorothiazide, oral	01 Jun 2007	08 Apr 2010
Amlodipine, oral	01 Jun 2007	08 Apr 2010
Minocycline, oral	19 Mar 2010	08 Apr 2010
Mupirocin, topical	19 Mar 2010	08 Apr 2010
Mesalazine, oral	15 Apr 2010	Ongoing
Hydrochlorothiazide, oral	15 Apr 2010	Ongoing
Amlodipine, oral	15 Apr 2010	Ongoing
Minocycline, oral	15 Apr 2010	Ongoing
Mupirocin, topical	15 Apr 2010	Ongoing
Naproxen, oral	05 Jul 2010	Ongoing

Treatment group in induction: Placebo SC.
Treatment group in maintenance: Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 11 Feb 2010 (Study Day -40)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 11 Feb 2010 (Study Day -40)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 11 Feb 2010 (Study Day -40)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 0 (Ind), 11 Feb 2010 (Study Day -40)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 2 (Ind), 25 Feb 2010 (Study Day -26)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 25 Feb 2010 (Study Day -26)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 0 (Main), 23 Mar 2010 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 23 Mar 2010 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 4 (Main)—dose not done	NA	NA	NA
Week 4 (Main), 16 Apr 2010 (Study Day 25)	Admin. 2/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 16 Apr 2010 (Study Day 25)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 8 (Main), 17 May 2010 (Study Day 56)	Admin. 3/ Inj. 5	Golimumab	100 mg
Week 8 (Main), 17 May 2010 (Study Day 56)	Admin. 3/ Inj. 6	Placebo	0 mg
Week 12 (Main), 21 Jun 2010 (Study Day 91)	Admin. 4/ Inj. 7	Golimumab	100 mg
Week 12 (Main), 21 Jun 2010 (Study Day 91)	Admin. 4/ Inj. 8	Placebo	0 mg
Week 16 (Main), 19 Jul 2010 (Study Day 119)	Admin. 5/ Inj. 9	Placebo	0 mg
Week 16 (Main), 19 Jul 2010 (Study Day 119)	Admin. 5/ Inj. 10	Golimumab	100 mg

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	19 Jul 2010.
Last scheduled study treatment visit in maintenance:	Week 16 (Main).
Date of study treatment discontinuation:	29 Jul 2010.

Study status:

Date of study discontinuation:	10 Mar 2011.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	SAE.
Date of disposition status:	10 Mar 2011.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7809-00002

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Not related	05 Jan 2010 Ongoing

Baseline demographic information: 5[redacted]-year-old (DOB: 07 Mar [redacted]) Asian male. Weight: 67.3 kg; height: 168 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).			
Ulcerative colitis history: Date of diagnosis: March 2005. UC disease duration: 4.2 years.			
Prior/concomitant medication, route	**Start date**	**End date**	
Azathioprine, oral	14 May 2008	Ongoing	
Mesalazine, oral	25 Jan 2007	Ongoing	
Sulfasalazine, oral	14 Jun 2008	Ongoing	
Clostridium butyricum, oral	15 Sep 2007	Ongoing	
Antibiotics-resistant lactic acid bacteriae, oral	06 Jul 2007	Ongoing	
Albumin tannate, oral	23 Oct 2007	Ongoing	
Ramosetron hydrochloride, oral	07 Mar 2009	Ongoing	
Cetirizine hydrochloride, oral	14 Jun 2008	Ongoing	
Rabeprazole sodium, oral	06 Jul 2007	Ongoing	
Clotiazepam, oral	20 Nov 2008	Ongoing	
Hyoscine butylbromide, intramuscular	25 May 2009	25 May 2009	
Lidocaine, topical	25 May 2009	25 May 2009	
Hyoscine butylbromide, intramuscular	17 Jul 2009	17 Jul 2009	
Lidocaine, topical	17 Jul 2009	17 Jul 2009	
Azathioprine, oral	13 Oct 2007	22 Jan 2010	
Sulfasalazine, oral	14 Jun 2008	05 Jan 2010	
Ramosetron, oral	07 Mar 2009	Ongoing	
Cetirizine, oral	14 Jun 2008	14 Aug 2009	
Rabeprazole, oral	06 Jul 2007	Ongoing	
Hyoscine, subcutaneous	17 Jul 2000	17 Jul 2009	
Paracetamol, oral	19 Aug 2009	19 Aug 2009	
Rebamipide, oral	19 Aug 2009	19 Aug 2009	
Paracetamol, oral	15 Oct 2009	31 Oct 2009	
Rebamipide, oral	15 Oct 2009	31 Oct 2009	
Gualenic acid, topical	15 Oct 2009	31 Oct 2009	
Influenza vaccine, subcutaneous	16 Nov 2009	16 Nov 2009	
Influenza vaccine, subcutaneous	12 Dec 2009	12 Dec 2009	
Loperamide, oral	07 Dec 2009	Ongoing	
Vancomycin, oral	05 Jan 2010	11 Jan 2010	
Sorbitol lactated ringer's, intravenous	05 Jan 2010	15 Jan 2010	
Ganciclovir, intravenous	06 Jan 2010	15 Jan 2010	
Cideferron, intravenous	11 Jan 2010	15 Jan 2010	
Vancomycin, oral	20 Feb 2010	25 Feb 2010	
Azathioprine, oral	20 Feb 2010	Ongoing	
Unspecified herbal, oral	20 Mar 2010	Ongoing	
Celecoxib, oral	17 Apr 2010	Ongoing	
Treatment group in induction:	Placebo SC.		
Treatment group in maintenance:	Nonresponder to placebo induction → received golimumab 100 mg maintenance.		
Dose adjusted?	No.		
Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 06 Jun 2009 (Study Day -41)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 06 Jun 2009 (Study Day -41)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 06 Jun 2009 (Study Day -41)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 06 Jun 2009 (Study Day -41)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 19 Jun 2009 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 19 Jun 2009 (Study Day -28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 19 Jun 2009 (Study Day -28)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 17 Jul 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 17 Jul 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 17 Jul 2009 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 15 Aug 2009 (Study Day 30)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 15 Aug 2009 (Study Day 30)	Admin. 2/ Inj. 5	Placebo	0 mg

Week 4 (Main), 15 Aug 2009 (Study Day 30)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 8 (Main), 14 Sep 2009 (Study Day 60)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 14 Sep 2009 (Study Day 60)	Admin. 3/ Inj. 8	Golimumab	100 mg
Week 8 (Main), 14 Sep 2009 (Study Day 60)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 03 Oct 2009 (Study Day 79)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 03 Oct 2009 (Study Day 79)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 03 Oct 2009 (Study Day 79)	Admin. 4/ Inj. 12	Golimumab	100 mg
Week 16 (Main), 31 Oct 2009 (Study Day 107)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 31 Oct 2009 (Study Day 107)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 31 Oct 2009 (Study Day 107)	Admin. 5/ Inj. 15	Golimumab	100 mg
Week 20 (Main), 28 Nov 2009 (Study Day 135)	Admin. 6/ Inj. 16	Golimumab	100 mg
Week 20 (Main), 28 Nov 2009 (Study Day 135)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 20 (Main), 28 Nov 2009 (Study Day 135)	Admin. 6/ Inj. 18	Placebo	0 mg
Week 24 (Main), 26 Dec 2009 (Study Day 163)	Admin. 7/ Inj. 19	Golimumab	100 mg
Week 24 (Main), 26 Dec 2009 (Study Day 163)	Admin. 7/ Inj. 20	Placebo	0 mg
Week 24 (Main), 26 Dec 2009 (Study Day 163)	Admin. 7/ Inj. 21	Placebo	0 mg
Unscheduled 1 (Main)—dose not done	NA	NA	NA
Treatment status:			
Study treatment discontinuation?	Yes.		
Reason for treatment discontinuation:	Adverse event.		
Date of last study agent administration in maintenance:	26 Dec 2009.		
Last scheduled study treatment visit in maintenance:	Week 24 (Main).		
Date of study treatment discontinuation:	05 Jan 2010.		
Study status:			
Date of disposition status:	17 Apr 2010.		
Ended study participation as of Week 54?	Yes.		
Entered extension study?	No.		

被験者識別コード：7812-00002

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE/ Event of interest: Malignancy	直腸癌 (Adenocarcinoma of rectum)	Not related	30 Nov 2009 18 Jan 2010 (50 days)
Baseline demographic information: 6[redacted]-year-old (DOB: 11 Dec [redacted]) Asian female. Weight: 43.2 kg; height: 143 cm.			
Relevant medical history at baseline: 関節痛			
Baseline smoking status: Nonsmoker.			
Ulcerative colitis history: Date of diagnosis: August 1970. UC disease duration: 39.1 years.			

Prior/concomitant medication, route	**Start date**	**End date**
Mesalazine, oral	Prior	Ongoing
Azathioprine, oral	Prior	Ongoing
Famotidine, oral	07 Aug 2007	Ongoing
Risedronate sodium, oral	07 Oct 2008	Ongoing
Ferrous sodium citrate, oral	20 Aug 2009	Ongoing
Lidocaine hydrochloride, topical	05 Oct 2009	05 Oct 2009
Colyte /00751601, oral	05 Oct 2009	05 Oct 2009
Colyte /00751601, oral	16 Oct 2009	16 Oct 2009
Saccharated iron oxide, intravaginal	09 Nov 2009	09 Nov 2009
Lidocaine hydrochloride, topical	16 Nov 2009	16 Nov 2009
Influenza virus vaccine polyvalent, subcutaneous	09 Nov 2009	09 Nov 2009
Glucose injection, intravenous	09 Nov 2009	09 Nov 2009
Glucose injection, intravenous	16 Nov 2009	16 Nov 2009
Saccharated iron oxide, intravenous	16 Nov 2009	16 Nov 2009
Mesalazine, oral	Prior	24 Dec 2009
Azathioprine, oral	Prior	24 Dec 2009

Famotidine, oral	07 Aug 2007	24 Dec 2009
Risedronic acid, oral	07 Oct 2008	24 Dec 2009
Iron, oral	20 Aug 2009	24 Dec 2009
Lidocaine, topical	26 Nov 2009	26 Nov 2009
Colyte /00751601, oral	10 Dec 2009	10 Dec 2009
Lidocaine, topical	10 Dec 2009	10 Dec 2009
Sodium picosulfate, oral	13 Dec 2009	13 Dec 2009
Magnesium citrate, oral	13 Dec 2009	13 Dec 2009
Barium, other	14 Dec 2009	14 Dec 2009
Hyoscine, intramuscular	14 Dec 2009	14 Dec 2009
Propofol, intravenous	25 Dec 2009	25 Dec 2009
Ropivacaine, intravenous	25 Dec 2009	25 Dec 2009
Droperidol, intravenous	25 Dec 2009	25 Dec 2009
Atropine, intravenous	25 Dec 2009	25 Dec 2009
Landiolol, intravenous	25 Dec 2009	25 Dec 2009
Heparin, intravenous	25 Dec 2009	25 Dec 2009
Ephedrine, intravenous	25 Dec 2009	25 Dec 2009
Rocuronium, intravenous	25 Dec 2009	25 Dec 2009
Neostigmine, intravenous	25 Dec 2009	25 Dec 2009
Ibuprofen, intravenous	25 Dec 2009	25 Dec 2009
Physio, intravenous	25 Dec 2009	25 Dec 2009
Sodium bicarbonate, intravenous	25 Dec 2009	25 Dec 2009
Lidocaine, topical	17 Dec 2009	17 Dec 2009
Dimeticone, oral	17 Dec 2009	17 Dec 2009
Iohexol, topical	16 Dec 2009	16 Dec 2009
Cefmetazole, intravenous	25 Dec 2009	29 Dec 2009
Lactec /00490001, intravenous	25 Dec 2009	26 Dec 2009
Lactec /00490001/, intravenous	09 Jan 2010	10 Jan 2010
Solita-t no.2, intravenous	24 Dec 2009	12 Jan 2010
Glucose injection, intravenous	26 Dec 2009	30 Dec 2009
Saccharated iron oxide, intravenous	26 Dec 2009	30 Dec 2009
Amino acids, intravenous	28 Dec 2009	12 Jan 2010
Panthenol, intravenous	02 Jan 2010	12 Jan 2010
Metoclopramide, intravenous	30 Dec 2009	30 Dec 2009
Metoclopramide, intravenous	07 Jan 2010	07 Jan 2010
Pentazocine, intravenous	28 Dec 2009	28 Dec 2009
Loxoprofen, oral	30 Dec 2009	18 Jan 2010
Rebamipide, oral	30 Dec 2009	18 Jan 2010
Unspecified herbal, oral	02 Jan 2010	Ongoing
Risedronic acid, oral	21 Jan 2010	Ongoing
Levofloxacin, oral	23 Dec 2009	24 Dec 2009
Rebamipide, oral	23 Dec 2009	24 Dec 2009
Povidone-iodine, intrabuccal	21 Dec 2009	24 Dec 2009
Methylrosanilinium, topical	21 Dec 2009	24 Dec 2009
Zolpidem, oral	24 Dec 2009	24 Dec 2009
Sodium picosulfate, oral	24 Dec 2009	24 Dec 2009
Magnesium citrate, oral	24 Dec 2009	24 Dec 2009

Treatment group in induction:	Placebo SC.
Treatment group in maintenance:	Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 08 Oct 2009 (Study Day -39)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 08 Oct 2009 (Study Day -39)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 08 Oct 2009 (Study Day -39)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 08 Oct 2009 (Study Day -39)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 22 Oct 2009 (Study Day -25)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 22 Oct 2009 (Study Day -25)	Admin. 2/ Inj. 6	Placebo	0 mg

Week 0 (Main), 16 Nov 2009 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 16 Nov 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 16 Nov 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Unscheduled 1 (Main)—dose not done	NA	NA	NA
Treatment status:			
Study treatment discontinuation?	Yes.		
Reason for treatment discontinuation:	Adverse event.		
Date of last study agent administration in maintenance:	16 Nov 2009.		
Last scheduled study treatment visit in maintenance:	Week 0 (Main).		
Date of study treatment discontinuation:	01 Dec 2009.		
Study status:			
Date of disposition status:	01 Mar 2010.		
Ended study participation as of Week 54?	Yes.		
Entered extension study?	No.		

被験者識別コード：7813-00001

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Exacerbation of UC)	Not related	09 Jul 2009 24 Jul 2009 (16 days)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Exacerbation of UC)	Not related	24 Jul 2009 22 Aug 2009 (30 days)

Baseline demographic information: 4[redacted]-year-old (DOB: 12 Mar [redacted]) Asian male. Weight: 55.8 kg; height: 174 cm.

Relevant medical history at baseline: 関節痛，関節炎， 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:
Date of diagnosis: 09 Mar 2007.
UC disease duration: 2.2 years.

Prior/concomitant medication, route	**Start date**	**End date**
Mesalazine, oral	26 Feb 2009	Ongoing
Prednisolone, oral	26 Mar 2009	Ongoing
Rabeprazole, oral	19 Jun 2008	Ongoing
Sairei-to, oral	06 Dec 2007	Ongoing
Bio three /01068501, oral	31 Jul 2008	Ongoing
Alendronate sodium, oral	08 Apr 2009	Ongoing
Brotizolam, oral	11 Dec 2008	Ongoing
Trazodone, oral	08 Apr 2009	Ongoing
Atropine, intravenous	22 Apr 2009	22 Apr 2009
Atropin-neostigmin “sad”, intravenous	22 Apr 2009	22 Apr 2009
Rocuronium, intravenous	22 Apr 2009	22 Apr 2009
Methylephedrine, intravenous	22 Apr 2009	22 Apr 2009
Flurbiprofen, intravenous	22 Apr 2009	22 Apr 2009
Eufusol, intravenous	22 Apr 2009	24 Apr 2009
Lactec/00490001, intravenous	22 Apr 2009	22 Apr 2009
Lidocaine, topical	22 Apr 2009	22 Apr 2009
Heparin, intravenous	22 Apr 2009	22 Apr 2009
Hydrocortisone, intravenous	22 Apr 2009	22 Apr 2009
Propofol, intravenous	22 Apr 2009	22 Apr 2009
Sodium chloride, intravenous	22 Apr 2009	22 Apr 2009
Cefazolin sodium, intravenous	22 Apr 2009	24 Apr 2009
Remifentanil, intravenous	22 Apr 2009	22 Apr 2009
Morphine, intravenous	22 Apr 2009	22 Apr 2009
Metoclopramide, intravenous	22 Apr 2009	22 Apr 2009
Pentazocine, intravenous	22 Apr 2009	23 Apr 2009
Hydroxyzine, intravenous	22 Apr 2009	23 Apr 2009
Felbinac, topical	24 Apr 2009	24 Apr 2009
Loxoprofen, oral	23 Apr 2009	04 May 2009

Rebamipide, oral	23 Apr 2009	04 May 2009
Omeprazole, oral	24 Apr 2009	28 Apr 2009
Laxatives, oral	20 May 2009	20 May 2009
Lidocaine, topical	20 May 2009	20 May 2009
Dimeticone, oral	20 May 2009	20 May 2009
Hyoscine, intravenous	20 May 2009	20 May 2009
Sodium picosulfate, oral	19 May 2009	19 May 2009
Betamethasone, topical	09 Apr 2009	Ongoing
Heparinoid, topical	09 Apr 2009	04 Jun 2009
Serrapeptase, oral	11 May 2009	13 May 2009
Cefaclor, oral	11 May 2009	13 May 2009
Solutions for parenteral nutrition, intravenous	18 May 2009	19 May 2009
Soldem 3a, intravenous	18 May 2009	19 May 2009
Lidocaine, epidural	22 Apr 2009	22 Apr 2009
Xylocaine-epinephrine, intravenous	22 Apr 2009	22 Apr 2009
Pentazocine, intravenous	25 Apr 2009	25 Apr 2009
Hydroxyzine, intravenous	25 Apr 2009	25 Apr 2009
Olea europaea oil, topical	20 May 2009	20 May 2009
Ferrous citrate, oral	23 May 2009	Ongoing
Urea, topical	04 Jun 2009	Ongoing
Lidocaine, topical	02 Jul 2009	02 Jul 2009
Dimeticone, oral	02 Jul 2009	02 Jul 2009
Hyoscine, intravenous	02 Jul 2009	02 Jul 2009
Glycerol, rectal	02 Jul 2009	02 Jul 2009
Olea europaea oil, topical	02 Jul 2009	02 Jul 2009
Mesalazine, oral	20 Dec 2007	24 Oct 2009
Prednisolone, oral	08 May 2007	24 Jul 2009
Rabeprazole, oral	19 Jun 2009	Ongoing
Sairei-to, oral	06 Dec 2007	17 Sep 2009
Bactrim, oral	31 Jul 2008	Ongoing
Alendronic acid, oral	08 Apr 2009	Ongoing
Iron, oral	23 May 2009	31 Jul 2009
Brotizolam, oral	11 Dec 2008	Ongoing
Trazodone, oral	08 Apr 2009	Ongoing
Tacrolimus, oral	16 Jul 2009	24 Sep 2009
Urea, topical	04 Jun 2009	Ongoing
Betamethasone, topical	09 Apr 2009	27 Jul 2009
Olea europaea, topical	16 Jul 2009	16 Jul 2009
Sulfamethoxazole, oral	24 Jul 2009	18 Sep 2009
Trimethoprim, oral	24 Jul 2009	18 Sep 2009
Mercaptopurine, oral	06 Aug 2009	Ongoing
Cyanocobalamin, ophthalmic	30 Jul 2009	31 Aug 2009
Diphenhydramine, topical	30 Jul 2009	22 Aug 2009
Betamethasone, topical	20 Aug 2009	Ongoing
Soldem 3A, intravenous	24 Jul 2009	24 Jul 2009
Solutions for parenteral nutrition, intravenous	24 Jul 2009	29 Jul 2009
Magnesium sulfate, intravenous	27 Jul 2009	02 Aug 2009
Iron, intravenous	27 Jul 2009	31 Jul 2009
C-para, intravenous	30 Jul 2009	02 Aug 2009
Influenza vaccine, subcutaneous	23 Oct 2009	23 Oct 2009
Diflucortolone, topical	20 Aug 2009	Ongoing
Epinastine, oral	29 Oct 2009	Ongoing
Sodium chloride, intravenous	04 Aug 2009	04 Aug 2009
Nafamostat, intravenous	04 Aug 2009	04 Aug 2009
Glucose, intravenous	04 Aug 2009	04 Aug 2009
Sodium chloride, intravenous	07 Aug 2009	07 Aug 2009
Nafamostat, intravenous	07 Aug 2009	07 Aug 2009
Glucose, intravenous	07 Aug 2009	07 Aug 2009
Sodium chloride, intravenous	11 Aug 2009	11 Aug 2009

Nafamostat, intravenous	11 Aug 2009	11 Aug 2009
Glucose, intravenous	11 Aug 2009	11 Aug 2009
Sodium chloride, intravenous	14 Aug 2009	14 Aug 2009
Nafamostat, intravenous	14 Aug 2009	14 Aug 2009
Glucose, intravenous	14 Aug 2009	14 Aug 2009
Sodium chloride, intravenous	18 Aug 2009	18 Aug 2009
Nafamostat, intravenous	18 Aug 2009	18 Aug 2009
Glucose, intravenous	18 Aug 2009	18 Aug 2009
Sodium chloride, intravenous	21 Aug 2009	21 Aug 2009
Nafamostat, intravenous	21 Aug 2009	21 Aug 2009
Glucose, intravenous	21 Aug 2009	21 Aug 2009
Sodium chloride, intravenous	27 Aug 2009	27 Aug 2009
Nafamostat, intravenous	27 Aug 2009	27 Aug 2009
Glucose, intravenous	27 Aug 2009	27 Aug 2009
Sodium chloride, intravenous	03 Aug 2009	03 Sep 2009
Nafamostat, intravenous	10 Sep 2009	10 Sep 2009
Glucose, intravenous	03 Sep 2009	03 Sep 2009
Sodium chloride, intravenous	10 Sep 2009	10 Sep 2009
Nafamostat, intravenous	03 Sep 2009	03 Sep 2009
Glucose, intravenous	10 Sep 2009	10 Sep 2009
Sodium chloride, intravenous	17 Sep 2009	17 Sep 2009
Nafamostat, intravenous	17 Sep 2009	17 Sep 2009
Glucose, intravenous	17 Sep 2009	17 Sep 2009
Lidocaine, topical	13 Aug 2009	13 Aug 2009
Dimeticone, oral	13 Aug 2009	13 Aug 2009
Pronase, oral	13 Aug 2009	13 Aug 2009
Hyoscine, intravenous	13 Aug 2009	13 Aug 2009
Diazepam, intravenous	13 Aug 2009	13 Aug 2009
Lidocaine, topical	19 Aug 2009	19 Aug 2009
Dimeticone, oral	19 Aug 2009	19 Aug 2009
Hyoscine, intravenous	19 Aug 2009	19 Aug 2009
Betamethasone, intravenous	19 Aug 2009	19 Aug 2009
Olea europaea, topical	19 Aug 2009	19 Aug 2009
Mesalazine, oral	29 Oct 2009	Ongoing
Betamethasone, topical	20 Aug 2009	Ongoing
Pl gran., oral	16 Sep 2009	20 Sep 2009
Clarithromycin, oral	16 Sep 2009	20 Sep 2009

Treatment group in induction: Placebo SC.
Treatment group in maintenance: Nonresponder to placebo induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 22 May 2009 (Study Day -41)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 22 May 2009 (Study Day -41)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 22 May 2009 (Study Day -41)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 22 May 2009 (Study Day -41)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 04 Jun 2009 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 04 Jun 2009 (Study Day -28)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 2 (Ind), 04 Jun 2009 (Study Day -28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 0 (Main), 02 Jul 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 02 Jul 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 02 Jul 2009 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	02 Jul 2009.
Last scheduled study treatment visit in maintenance:	Week 0 (Main).
Date of study treatment discontinuation:	16 Jul 2009.

Study status:	
Date of disposition status:	29 Oct 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

c) ゴリムマブ寛解導入 non-responder

被験者識別コード：6004-00001

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
Permanent discontinuation of study agent due to AE	悪心 (Nausea)	Unlikely	12 Jul 2008 18 Jul 2008 (7 days)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Refractory ulcerative colitis)	Unlikely	15 Jul 2008 18 Aug 2008 (35 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 11 Mar [redacted]) Caucasian male. Weight: 55.2 kg; height: 183 cm.

Relevant medical history at baseline: 喫煙（過去），裂肛

Baseline smoking status: Prior smoker (stopped ≤ 1 year ago).

Ulcerative colitis history:
Date of diagnosis: April 1996.
UC disease duration: 12.0 years.

Prior/concomitant medication, route	**Start date**	**End date**
Allopurinol, oral	21 Mar 2008	19 Jun 2008
Mercaptopurine, oral	21 Mar 2008	26 Jun 2008
Allopurinol, oral	21 Mar 2008	Ongoing
Balsalazide, oral	Prior	Ongoing
Salbutamol, inhalation	08 May 2008	Ongoing
Seretide, inhalation	08 May 2008	Ongoing
Mercaptopurine, oral	26 Jun 2008	Ongoing
Mercaptopurine, oral	20 Mar 2008	19 Jun 2008
Mercaptopurine, oral	26 Jun 2008	15 Jul 2008
Allopurinol, oral	21 Mar 2008	19 Jun 2008
Balsalazide, oral	Prior	23 Jul 2008
Salbutamol, inhalation	08 May 2008	Ongoing
Seretide, inhalation	08 May 2008	Ongoing
Allopurinol, oral	26 Jun 2008	15 Jul 2008
Temazepam, oral	16 Jul 2008	05 Aug 2008
Paracetamol, oral	15 Jul 2008	Ongoing
Tramadol, oral	20 Jul 2008	Ongoing
Xylometazoline, intranasal	25 Jul 2008	27 Jul 2008
Loratadine, oral	26 Jul 2008	14 Aug 2008
Promethazine, oral	27 Jul 2008	13 Aug 2008
Betamethasone, intranasal	26 Jul 2008	04 Aug 2008
Diazepam, oral	29 Jul 2008	29 Jul 2008
Amoxicillin, intravenous	07 Aug 2008	11 Aug 2008
Gentamicin, intravenous	06 Aug 2008	10 Aug 2008
Heparin, intravenous	04 Aug 2008	14 Aug 2008
Pico-salax, oral	05 Aug 2008	05 Aug 2008
Morphine, intravenous	06 Aug 2008	09 Aug 2008
Metronidazole, intravenous	06 Aug 2008	10 Aug 2008
Magnesium aspartate, oral	08 Aug 2008	12 Aug 2008
Oxycodone, oral	09 Aug 2008	12 Aug 2008
Clotrimazole, topical	11 Aug 2008	14 Aug 2008
Furosemide, intravenous	09 Aug 2008	09 Aug 2008
Oxycodone, oral	09 Aug 2008	12 Aug 2008
Oxycodone, oral	13 Aug 2008	13 Aug 2008
Tropisetron, intravenous	07 Aug 2008	08 Aug 2008

Treatment group in induction:	1 mg/kg IV.
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 01 May 2008 (Study Day -42)	NA	Golimumab	1.1 mg/kg
Week 0 (Main), 12 Jun 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 12 Jun 2008 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 12 Jun 2008 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 03 Jul 2008 (Study Day 22)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 03 Jul 2008 (Study Day 22)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 03 Jul 2008 (Study Day 22)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 8 (Main)—dose not done	NA	NA	NA

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	03 Jul 2008.
Last scheduled study treatment visit in maintenance:	Week 4 (Main).
Date of study treatment discontinuation:	31 Jul 2008.

Study status:

Date of study discontinuation:	31 Jul 2008.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	SAE. Bowel resection surgery 6/8/2008.
Date of disposition status:	31 Jul 2008.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：6406-00004

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
Permanent discontinuation of study agent due to AE	発熱 (Fever of unknown origin)	Unlikely	05 Sep 2008 29 Sep 2008 (25 days)
SAE/ Permanent discontinuation of study agent due to AE/ Serious infection	潰瘍性大腸炎 (Exacerbation of ulcerative colitis)	Unlikely	12 Sep 2008 29 Sep 2008 (18 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 24 Feb [redacted]) Caucasian male.
Weight: 67 kg; height: 182 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:

Date of diagnosis:	01 Jan 2007.
UC disease duration:	1.5 years.

Prior/concomitant medication, route	Start date	End date
Mesalazine, oral	Prior	Ongoing
Prednisone, oral	Prior	Ongoing
Omeprazole, oral	15 Mar 2008	20 May 2008
Fleet /01605601/, oral	04 Jun 2008	04 Jun 2008
Fleet /01605601/, oral	22 Jun 2008	22 Jun 2008
Fleet /01605601/, oral	12 Aug 2008	12 Aug 2008
Mesalazine, oral	Prior	11 Sep 2008
Omeprazole, oral	15 Mar 2008	11 Sep 2008
Prednisone, oral	15 Mar 2008	11 Sep 2008
Augmentin /00756801/, oral	08 Sep 2008	11 Sep 2008
Pantoprazole, intravenous	12 Sep 2008	18 Sep 2008
Methylprednisolone, intravenous	12 Sep 2008	18 Sep 2008
Metronidazole, intravenous	12 Sep 2008	28 Sep 2008
Cefuroxime, intravenous	12 Sep 2008	20 Sep 2008

Hyoscine, intravenous	15 Sep 2008	18 Sep 2008
Mesalazine, rectal	16 Sep 2008	25 Sep 2008
Mesalazine, oral	16 Sep 2008	Ongoing
Loperamide, oral	16 Sep 2008	26 Sep 2008
Methylprednisolone, oral	18 Sep 2008	Ongoing
Pantoprazole, oral	18 Sep 2008	Ongoing
Metamizole, intravenous	20 Sep 2008	23 Sep 2008
Ciprofloxacin, intravenous	20 Sep 2008	23 Sep 2008
Amoxi-clavulanico, intravenous	23 Sep 2008	28 Sep 2008
Amoxi-clavulanico, oral	29 Sep 2008	07 Oct 2008
Nystatin, other	23 Sep 2008	30 Sep 2008
Ketoconazole, oral	24 Sep 2008	07 Oct 2008
Antiseptics and disinfectants, other	25 Sep 2008	29 Sep 2008
Azathioprine, oral	20 Nov 2008	Ongoing
Omeprazole, oral	20 Nov 2008	Ongoing
Ketoconazole, oral	20 Nov 2008	04 Dec 2008
Bactrim, oral	20 Nov 2008	04 Dec 2008
Iron, oral	20 Nov 2008	Ongoing

Treatment group in induction:	1 mg/kg IV.
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 04 Jul 2008 (Study Day -52)	NA	Golimumab	1.0 mg/kg
Week 0 (Main), 25 Aug 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 25 Aug 2008 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 25 Aug 2008 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	25 Aug 2008.
Last scheduled study treatment visit in maintenance:	Week 0 (Main).
Date of study treatment discontinuation:	29 Sep 2008.

Study status:

Date of study discontinuation:	08 Dec 2008.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	Serious adverse event.
Date of disposition status:	08 Dec 2008.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：6260-00002

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
Died/ SAE/ Serious infection	敗血症性ショック (Septic shock)	Not related	12 Jul 2009 13 Jul 2009 (2 days)
SAE	栄養障害 (Malnutrition)	Not related	11 Jul 2009 13 Jul 2009 (3 days)

Baseline demographic information: 5[redacted]-year-old (DOB: 01 Jan [redacted]) Asian female. Weight: 35 kg; height: 153 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not provided.

Ulcerative colitis history:

Date of diagnosis:	24 May 2006.
UC disease duration:	2.0 years.

Prior/concomitant medication, route	Start date	End date
Mesalazine, oral	28 Dec 2007	Ongoing
Isoniazid, oral	30 May 2008	Ongoing
Mesalazine, oral	28 Dec 2007	09 Jul 2009
Isoniazid, oral	30 May 2008	Ongoing
Norfloxacin, oral	30 Aug 2006	03 Sep 2006
Paracetamol, oral	11 May 2009	12 May 2009
All other therapeutic products, oral	21 May 2009	11 Jul 2009
Other nutrients, oral	21 May 2009	11 Jul 2009
Bromhexine, intravenous	11 Jul 2009	13 Jul 2009
Ciprofloxacin, intravenous	11 Jul 2009	13 Jul 2009
Metronidazole, intravenous	11 Jul 2009	13 Jul 2009
Pantoprazole, oral	11 Jul 2009	13 Jul 2009
Multivitamins, oral	11 Jul 2009	13 Jul 2009
Aglozyme /03191601/, oral	11 Jul 2009	13 Jul 2009
Fluoxetine, oral	11 Jul 2009	13 Jul 2009
Osmotically acting laxatives, oral	11 Jul 2009	13 Jul 2009
Fluconazole, oral	11 Jul 2009	13 Jul 2009
Epinephrine, intravenous	13 Jul 2009	13 Jul 2009
Hydrocortisone, intravenous	13 Jul 2009	13 Jul 2009
Atropine, intravenous	13 Jul 2009	13 Jul 2009
Dopamine, intravenous	13 Jul 2009	13 Jul 2009
Diprophylline, intravenous	13 Jul 2009	13 Jul 2009
Pantoprazole, intravenous	13 Jul 2009	13 Jul 2009
Ceftriaxone, intravenous	13 Jul 2009	13 Jul 2009

Treatment group in induction: 2 mg/kg IV.
Treatment group in maintenance: Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 30 May 2008 (Study Day -46)	NA	Golimumab	2 mg/kg
Week 0 (Main), 15 Jul 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 15 Jul 2008 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 15 Jul 2008 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 11 Aug 2008 (Study Day 28)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 11 Aug 2008 (Study Day 28)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 4 (Main), 11 Aug 2008 (Study Day 28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 09 Sep 2008 (Study Day 57)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 09 Sep 2008 (Study Day 57)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 09 Sep 2008 (Study Day 57)	Admin. 3/ Inj. 9	Golimumab	100 mg
Week 12 (Main), 11 Oct 2008 (Study Day 89)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 11 Oct 2008 (Study Day 89)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 11 Oct 2008 (Study Day 89)	Admin. 4/ Inj. 12	Golimumab	100 mg
Week 24 (Main), 06 Jan 2009 (Study Day 176)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 24 (Main), 06 Jan 2009 (Study Day 176)	Admin. 5/ Inj. 14	Golimumab	100 mg
Week 24 (Main), 06 Jan 2009 (Study Day 176)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 28 (Main), 30 Jan 2009 (Study Day 200)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 28 (Main), 30 Jan 2009 (Study Day 200)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 28 (Main), 30 Jan 2009 (Study Day 200)	Admin. 6/ Inj. 18	Golimumab	100 mg
Week 32 (Main), 02 Mar 2009 (Study Day 231)	Admin. 7/ Inj. 19	Placebo	0 mg
Week 32 (Main), 02 Mar 2009 (Study Day 231)	Admin. 7/ Inj. 20	Golimumab	100 mg
Week 32 (Main), 02 Mar 2009 (Study Day 231)	Admin. 7/ Inj. 21	Placebo	0 mg
Week 36 (Main), 26 Mar 2009 (Study Day 255)	Admin. 8/ Inj. 22	Placebo	0 mg
Week 36 (Main), 26 Mar 2009 (Study Day 255)	Admin. 8/ Inj. 23	Golimumab	100 mg
Week 36 (Main), 26 Mar 2009 (Study Day 255)	Admin. 8/ Inj. 24	Placebo	0 mg
Week 40 (Main), 28 Apr 2009 (Study Day 288)	Admin. 9/ Inj. 25	Placebo	0 mg
Week 40 (Main), 28 Apr 2009 (Study Day 288)	Admin. 9/ Inj. 26	Placebo	0 mg
Week 40 (Main), 28 Apr 2009 (Study Day 288)	Admin. 9/ Inj. 27	Golimumab	100 mg

Week 44 (Main), 21 May 2009 (Study Day 311)	Admin. 10/ Inj. 28	Placebo	0 mg
Week 44 (Main), 21 May 2009 (Study Day 311)	Admin. 10/ Inj. 29	Golimumab	100 mg
Week 44 (Main), 21 May 2009 (Study Day 311)	Admin. 10/ Inj. 30	Placebo	0 mg
Week 48 (Main), 17 Jun 2009 (Study Day 338)	Admin. 11/ Inj. 31	Placebo	0 mg
Week 48 (Main), 17 Jun 2009 (Study Day 338)	Admin. 11/ Inj. 32	Golimumab	100 mg
Week 48 (Main), 17 Jun 2009 (Study Day 338)	Admin. 11/ Inj. 33	Placebo	0 mg

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Death.
Date of last study agent administration in maintenance:	17 Jun 2009.
Last scheduled study treatment visit in maintenance:	Week 48 (Main).
Date of study treatment discontinuation:	13 Jul 2009.

Study status:

Date of study discontinuation:	13 Jul 2009.
Reason for noncompletion:	Death.
Date of disposition status:	13 Jul 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：6407-00012

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Progression of ulcerative colitis)	Not related	07 Mar 2009 18 Mar 2009 (12 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 13 Dec [redacted]) Caucasian male.
Weight: 64 kg; height: 174 cm.

Relevant medical history at baseline: 結節性紅斑，喫煙（過去）

Baseline smoking status: Prior smoker (stopped ≤ 1 year ago).

Ulcerative colitis history:

Date of diagnosis:	24 Nov 2005.
UC disease duration:	2.7 years.

Prior/concomitant medication, route	**Start date**	**End date**
Prednisone acetate, oral	25 Jul 2008	Ongoing
Azathioprine, oral	February 2008	Ongoing
Sulfasalazine, oral	25 Jul 2008	Ongoing
Folic acid, oral	24 Jul 2008	Ongoing
Prednisone, oral	25 Jul 2008	Ongoing
Paracetamol, oral	08 Dec 2008	Ongoing

Treatment group in induction:	2 mg/kg IV.
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:

Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 21 Aug 2008 (Study Day -42)	NA	Golimumab	2.0 mg/kg
Week 0 (Main), 02 Oct 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 02 Oct 2008 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 02 Oct 2008 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 30 Oct 2008 (Study Day 29)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 4 (Main), 30 Oct 2008 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 30 Oct 2008 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 27 Nov 2008 (Study Day 57)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 27 Nov 2008 (Study Day 57)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 27 Nov 2008 (Study Day 57)	Admin. 3/ Inj. 9	Golimumab	100 mg
Week 12 (Main), 23 Dec 2008 (Study Day 83)	Admin. 4/ Inj. 10	Golimumab	100 mg
Week 12 (Main), 23 Dec 2008 (Study Day 83)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 23 Dec 2008 (Study Day 83)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 20 Jan 2009 (Study Day 111)	Admin. 5/ Inj. 13	Placebo	0 mg

Week 16 (Main), 20 Jan 2009 (Study Day 111)	Admin. 5/ Inj. 14	Golimumab	100 mg
Week 16 (Main), 20 Jan 2009 (Study Day 111)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 17 Feb 2009 (Study Day 139)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 17 Feb 2009 (Study Day 139)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 20 (Main), 17 Feb 2009 (Study Day 139)	Admin. 6/ Inj. 18	Golimumab	100 mg

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	17 Feb 2009.
Last scheduled study treatment visit in maintenance:	Week 20 (Main).
Date of study treatment discontinuation:	25 Mar 2009.

Study status:

Date of study discontinuation:	25 Mar 2009.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	AE: UC exacerbation.
Date of disposition status:	25 Mar 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：6006-00008

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Refractory ulcerative colitis)	Unlikely	06 Mar 2009 16 Mar 2009 (11 days)

Baseline demographic information: 6[redacted]-year-old (DOB: 14 Dec [redacted]) Caucasian female. Weight: 56.5 kg; height: 157 cm.

Relevant medical history at baseline: ブドウ膜炎，喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:

Date of diagnosis:	27 Sep 1996.
UC disease duration:	12.2 years.

Prior/concomitant medication, route	Start date	End date
Calcitriol, oral	2002	Ongoing
Calcium carbonate, oral	2002	Ongoing
Estradiol, topical	1989	Ongoing
Azathioprine, oral	February 1998	Ongoing
Maxidex /00207701/, oral	30 May 2006	Ongoing
Esomeprazole magnesium, oral	2004	Ongoing
Estriol, topical	1988	Ongoing
Carmellose sodium, ophthalmic	2006	Ongoing
Mesalazine, oral	March 2006	Ongoing
Temazepam, oral	2006	Ongoing
Multivitamins w/minerals, oral	1988	19 Dec 2008
Paracetamol, oral	1988	Ongoing
Ascorbic acid, oral	1988	Ongoing
Fentanyl, intravenous	03 Dec 2008	03 Dec 2008
Propofol, intravenous	03 Dec 2008	03 Dec 2008
Anaesthetics, intrabuccal	02 Dec 2008	Ongoing
Roxithromycin, oral	13 Nov 2008	17 Nov 2008
Midazolam, intravenous	03 Dec 2008	03 Dec 2008
Anaesthetics, intradermal	18 Dec 2008	18 Dec 2008
Centrum /00554501/, oral	20 Dec 2008	22 Dec 2008
Centrum /00554501/, oral	23 Dec 2008	Ongoing
Fefol /00098901/, oral	20 Dec 2008	22 Dec 2008
Fefol /00098901/, oral	23 Dec 2008	Ongoing
Xylocaine-epinephrine, intradermal	09 Jan 2009	09 Jan 2009
Fentanyl, intravenous	14 Jan 2009	14 Jan 2009

Metoclopramide hydrochloride, intravenous	14 Jan 2009	14 Jan 2009
Midazolam hydrochloride, intravenous	14 Jan 2009	14 Jan 2009
Calcitrol/00508501/, oral	Prior	Ongoing
Calcium carbonate, oral	Prior	Ongoing
Estradiol, topical	Prior	Ongoing
Azathioprine, oral	Prior	Ongoing
Maxidex/00207701/, ophthalmic	Prior	Ongoing
Esomeprazole, oral	Prior	Ongoing
Estriol, topical	Prior	Ongoing
Tears plus, ophthalmic	Prior	Ongoing
Mesalazine, oral	Prior	Ongoing
Temazepam, oral	Prior	Ongoing
Paracetamol, oral	Prior	Ongoing
Ascorbic acid, oral	Prior	Ongoing
Fefol /00098901/, oral	Prior	26 Dec 2008
Metoclopramide, oral	14 Jan 2009	14 Jan 2009
Midazolam, oral	14 Jan 2009	14 Jan 2009
Fentanyl, oral	14 Jan 2009	14 Jan 2009
Nystatin, intravaginal	20 Feb 2009	02 Mar 2009
Ferric hydroxide polymaltose complex, intramuscular	27 Feb 2009	Ongoing
Midazolam, intravenous	06 Mar 2009	06 Mar 2009
Fentanyl, intravenous	06 Mar 2009	06 Mar 2009
Hydrocortisone, intravenous	06 Mar 2009	11 Mar 2009
Enoxaparin, subcutaneous	08 Mar 2009	16 Mar 2009
Prednisolone, oral	12 Mar 2009	16 Mar 2009
Prednisolone, oral	17 Mar 2009	Ongoing

Treatment group in induction: 4 mg/kg IV.
Treatment group in maintenance: Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 05 Dec 2008 (Study Day -40)	Admin. 1/ Inj.	Golimumab	4.1 mg/kg
Week 0 (Main), 14 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 14 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 14 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 11 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 11 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 4 (Main), 11 Feb 2009 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main)—dose not done	NA	NA	NA

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Adverse event.
Date of last study agent administration in maintenance: 11 Feb 2009.
Last scheduled study treatment visit in maintenance: Week 4 (Main).
Date of study treatment discontinuation: 05 Mar 2009

Study status:
Date of disposition status: 03 Jun 2009.
Ended study participation as of Week 54? Yes.
Entered extension study? No.

被験者識別コード：6052-00001

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Serious infection	毛巣嚢胞 (Pilonidal cyst, infected)	Not related	20 Jul 2008 21 Jul 2008 (2 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 13 Jan [redacted]) Caucasian male.
Weight: 72.5 kg; height: 180 cm.

Relevant medical history at baseline: 膿瘍の切開及びドレナージ，肛門周囲膿瘍			
Baseline smoking status: Nonsmoker.			
Ulcerative colitis history: Date of diagnosis: 2003. UC disease duration: 4.2 years.			
Prior/concomitant medication, route	**Start date**	**End date**	
Mesalazine, oral	11 Dec 2007	Ongoing	
Hydrocortisone med terramycin, topical	04 Mar 2008	11 Mar 2008	
Neo-cutigenol, topical	11 Mar 2008	March 2008	
Lidocaine, topical	04 Mar 2008	March 2008	
Clometocillin potassium, oral	28 Apr 2008	Ongoing	
Cetirizine, oral	26 May 2008	Ongoing	
Clometocillin, oral	28 Apr 2008	May 2008	
Paracetamol, oral	20 Jul 2008	August 2008	
Methylprednisolone, oral	20 Jul 2008	05 Sep 2008	
Treatment group in induction: 4 mg/kg IV. **Treatment group in maintenance:** Nonresponder to golimumab induction → received golimumab 100 mg maintenance. **Dose adjusted?** No.			
Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 19 Mar 2008 (Study Day -42)	NA	Golimumab	4 mg/kg
Week 0 (Main), 30 Apr 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 30 Apr 2008 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 30 Apr 2008 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 28 May 2008 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 28 May 2008 (Study Day 29)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 4 (Main), 28 May 2008 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main)—dose not done	NA	NA	NA
Treatment status: Study treatment discontinuation? Yes. Reason for treatment discontinuation: Unsatisfactory therapeutic effect. Date of last study agent administration in maintenance: 28 May 2008. Last scheduled study treatment visit in maintenance: Week 4 (Main). Date of study treatment discontinuation: 25 Jun 2008.			
Study status: Date of disposition status: 19 Sep 2008. Ended study participation as of Week 54? Yes. Entered extension study? No.			

被験者識別コード：6252-00009

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE/ Serious infection	播種性結核 (Miliary tuberculosis)	Probable	04 Apr 2009 20 Jan 2010 (292 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 10 Dec [redacted]) Asian male from India. Weight: 59 kg; height: 166 cm.			
Relevant medical history at baseline: 報告なし			
Baseline smoking status: Not reported.			
Ulcerative colitis history: Date of diagnosis: 28 Feb 2008. UC disease duration: 0.2 years.			
Prior/concomitant medication, route	**Start date**	**End date**	
Mesalazine, oral	02 Mar 2008	Ongoing	
Prednisolone, oral	02 Mar 2008	Ongoing	
Folic acid, oral	02 Mar 2008	Ongoing	
Pantoprazole sodium, oral	02 Mar 2008	Ongoing	

Amoxicillin, oral	18 May 2008	31 May 2008
Clavulanic acid, oral	18 May 2008	31 May 2008
Gemifloxacin, oral	18 May 2008	31 May 2008
Nimesulide, oral	18 May 2008	31 May 2008
Paracetamol, oral	18 May 2008	31 May 2008
Multivitamins, plain, oral	18 May 2008	31 May 2008
Lactobacillus sporogenes, oral	18 May 2008	31 May 2008
Prednisolone, oral	02 Mar 2008	19 Jun 2008
Folic acid, oral	02 Mar 2008	06 Aug 2009
Pantoprazole, oral	02 Mar 2008	Ongoing
Mesalazine, oral	02 Mar 2008	20 Jun 2008
Prednisolone, oral	20 Jun 2008	26 Jun 2008
Prednisolone, oral	27 Jun 2008	03 Jul 2008
Prednisolone, oral	04 Jul 2008	10 Jul 2008
Prednisolone, oral	11 Jul 2008	18 Jan 2009
Prednisolone, oral	19 Jan 2009	25 Jan 2009
Prednisolone, oral	26 Jan 2009	01 Feb 2009
Prednisolone, oral	02 Feb 2009	08 Feb 2009
Diclofenac, oral	19 Mar 2009	22 Mar 2009
Ofloxacin, oral	19 Mar 2009	22 Mar 2009
Paracetamol, oral	19 Mar 2009	22 Mar 2009
Rifinah, oral	17 Apr 2009	20 Jan 2010
Levofloxacin, oral	17 Apr 2009	06 Aug 2009
Pyridoxine, oral	17 Apr 2009	20 Jan 2010
Nimesulide, oral	17 Apr 2009	22 Apr 2009
Cough and cold preparations, oral	17 Apr 2009	22 Apr 2009
Zevit, oral	06 Aug 2009	20 Jan 2010
Treatment group in induction:	4 mg/kg IV.	
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.	
Dose adjusted?	No.	

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 07 May 2008 (Study Day -45)	NA	Golimumab	4.0 mg/kg
Week 0 (Main), 21 Jun 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 21 Jun 2008 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Main), 21 Jun 2008 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 25 Jul 2008 (Study Day 35)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 25 Jul 2008 (Study Day 35)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 4 (Main), 25 Jul 2008 (Study Day 35)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 28 Aug 2008 (Study Day 69)	Admin. 3/ Inj. 7	Golimumab	100 mg
Week 8 (Main), 28 Aug 2008 (Study Day 69)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 28 Aug 2008 (Study Day 69)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 22 Sep 2008 (Study Day 94)	Admin. 4/ Inj. 10	Golimumab	100 mg
Week 12 (Main), 22 Sep 2008 (Study Day 94)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 22 Sep 2008 (Study Day 94)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 13 Oct 2008 (Study Day 115)	Admin. 5/ Inj. 13	Golimumab	100 mg
Week 16 (Main), 13 Oct 2008 (Study Day 115)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 13 Oct 2008 (Study Day 115)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 12 Nov 2008 (Study Day 145)	Admin. 6/ Inj. 16	Golimumab	100 mg
Week 20 (Main), 12 Nov 2008 (Study Day 145)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 20 (Main), 12 Nov 2008 (Study Day 145)	Admin. 6/ Inj. 18	Placebo	0 mg
Week 24 (Main), 11 Dec 2008 (Study Day 174)	Admin. 7/ Inj. 19	Golimumab	100 mg
Week 24 (Main), 11 Dec 2008 (Study Day 174)	Admin. 7/ Inj. 20	Placebo	0 mg
Week 24 (Main), 11 Dec 2008 (Study Day 174)	Admin. 7/ Inj. 21	Placebo	0 mg
Week 28 (Main), 30 Dec 2008 (Study Day 193)	Admin. 8/ Inj. 22	Placebo	0 mg
Week 28 (Main), 30 Dec 2008 (Study Day 193)	Admin. 8/ Inj. 23	Golimumab	100 mg
Week 28 (Main), 30 Dec 2008 (Study Day 193)	Admin. 8/ Inj. 24	Placebo	0 mg
Week 32 (Main), 05 Feb 2009 (Study Day 230)	Admin. 9/ Inj. 25	Placebo	0 mg

Week 32 (Main), 05 Feb 2009 (Study Day 230)	Admin. 9/ Inj. 26	Placebo	0 mg
Week 32 (Main), 05 Feb 2009 (Study Day 230)	Admin. 9/ Inj. 27	Golimumab	100 mg
Week 36 (Main), 02 Mar 2009 (Study Day 255)	Admin. 10/ Inj. 28	Golimumab	100 mg
Week 36 (Main), 02 Mar 2009 (Study Day 255)	Admin. 10/ Inj. 29	Placebo	0 mg
Week 36 (Main), 02 Mar 2009 (Study Day 255)	Admin. 10/ Inj. 30	Placebo	0 mg
Week 40 (Main), 25 Mar 2009 (Study Day 278)	Admin. 11/ Inj. 31	Golimumab	100 mg
Week 40 (Main), 25 Mar 2009 (Study Day 278)	Admin. 11/ Inj. 32	Placebo	0 mg
Week 40 (Main), 25 Mar 2009 (Study Day 278)	Admin. 11/ Inj. 33	Placebo	0 mg
Unscheduled 1 (Main)—dose not done	NA	NA	NA

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	25 Mar 2009.
Last scheduled study treatment visit in maintenance:	Week 40 (Main).
Date of study treatment discontinuation:	17 Apr 2009.

Study status:

Date of study discontinuation:	04 May 2009.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	Due to positive tuberculosis test.
Date of disposition status:	04 May 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：6279-00003

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Exacerbation of UC)	Not related	23 Jan 2009 27 Feb 2009 (36 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 20 Jul [redacted]) Caucasian female.
Weight: 75 kg; height: 165 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 14 Feb 2006.
UC disease duration: 2.7 years.

Prior/concomitant medication, route	**Start date**	**End date**
Mesalazine, oral	11 Jan 2007	Ongoing
Loperamide, oral	04 Dec 2008	05 Dec 2008
Mesalazine, oral	11 Jan 2007	02 Feb 2009
Hydrocortisone, intravenous	23 Jan 2009	02 Feb 2009
Azathioprine, oral	23 Jan 2009	19 Feb 2009
Ceftriaxone, oral	19 Feb 2009	27 Feb 2009
Metronidazole, oral	19 Feb 2009	27 Feb 2009
Mercaptopurine, oral	17 Apr 2009	Ongoing
Infliximab, intravenous	15 Mar 2009	Ongoing
Prednisolone, oral	01 Feb 2009	19 Apr 2009

Treatment group in induction: 4 mg/kg IV.
Treatment group in maintenance: Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 05 Nov 2008 (Study Day -39)	NA	Golimumab	4 mg/kg
Week 0 (Main), 14 Dec 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 14 Dec 2008 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 14 Dec 2008 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 07 Jan 2009 (Study Day 25)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 4 (Main), 07 Jan 2009 (Study Day 25)	Admin. 2/ Inj. 5	Placebo	0 mg

Week 4 (Main), 07 Jan 2009 (Study Day 25)	Admin. 2/ Inj. 6	Placebo	0 mg
Treatment status:			
Study treatment discontinuation?	Yes.		
Reason for treatment discontinuation:	Adverse event.		
Date of last study agent administration in maintenance:	07 Jan 2009.		
Last scheduled study treatment visit in maintenance:	Week 4 (Main).		
Date of study treatment discontinuation:	23 Jan 2009.		
Study status:			
Date of disposition status:	10 Jun 2009.		
Ended study participation as of Week 54?	Yes.		
Entered extension study?	No.		

被験者識別コード：6407-00016

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Progression of ulcerative colitis)	Unlikely	27 Apr 2009 05 May 2009 (9 days)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Progression of ulcerative colitis)	Unlikely	18 May 2009 02 Jul 2009 (46 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 15 Jul [redacted]) Caucasian male.
Weight: 61.2 kg; height: 178 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:
Date of diagnosis: 28 Aug 2008.
UC disease duration: 0.4 years.

Prior/concomitant medication, route	**Start date**	**End date**
Methylprednisolone, oral	November 2008	Ongoing
Sulfasalazine, oral	29 Aug 2008	Ongoing
Methylprednisolone, oral	November 2008	27 Apr 2009
Sulfasalazine, oral	29 Aug 2008	18 May 2009
Prednisone, oral	27 Apr 2009	18 May 2009
Omeprazole, oral	27 Apr 2009	18 May 2009
Folic acid, oral	27 Apr 2009	Ongoing
Iron, oral	27 Apr 2009	Ongoing
Prednisone, oral	18 May 2009	02 Jul 2009
Sulfasalazine, oral	18 May 2009	28 May 2009
Omeprazole, oral	18 May 2009	Ongoing
Infliximab, intravenous	20 May 2009	20 May 2009
Metronidazole, intravenous	18 May 2009	22 May 2009
Infliximab, intravenous	30 May 2009	30 May 2009
Mesalazine, oral	28 May 2009	Ongoing
Azathioprine, oral	28 May 2009	15 Jun 2009
Azathioprine, oral	15 Jun 2009	Ongoing
Prednisone, oral	02 Jul 2009	Ongoing
Nystatin, oral	28 May 2009	28 Jun 2009

Treatment group in induction: 4 mg/kg IV.
Treatment group in maintenance: Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 07 Jan 2009 (Study Day -43)	NA	Golimumab	3.9 mg/kg
Week 0 (Main), 19 Feb 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 19 Feb 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 19 Feb 2009 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg

Week 4 (Main), 19 Mar 2009 (Study Day 29)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 4 (Main), 19 Mar 2009 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 19 Mar 2009 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 15 Apr 2009 (Study Day 56)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 15 Apr 2009 (Study Day 56)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 15 Apr 2009 (Study Day 56)	Admin. 3/ Inj. 9	Golimumab	100 mg

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	15 Apr 2009.
Last scheduled study treatment visit in maintenance:	Week 8 (Main).
Date of study treatment discontinuation:	27 Apr 2009.

Study status:

Date of disposition status:	03 Aug 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7003-00004

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Chronically active ulcerative colitis)	Not related	18 Dec 2008 25 Dec 2008 (8 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 31 Jan [redacted]) Caucasian female.
Weight: 68 kg; height: 168 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:

Date of diagnosis:	11 Jul 2008.
UC disease duration:	0.1 years.

Prior/concomitant medication, route	**Start date**	**End date**
Sulfasalazine, oral	16 Jan 2002	Ongoing
Mesalazine, oral	19 Dec 2006	Ongoing
Prednisolone, oral	19 Jul 2008	Ongoing
Balsalazide sodium, oral	11 Jul 2008	Ongoing
Eugynon /00022701/, oral	1994	Ongoing
Roxithromycin, oral	12 Aug 2008	14 Aug 2008
Paracetamol, oral	15 Aug 2008	15 Aug 2008
Paracetamol, oral	26 Aug 2008	29 Aug 2008
Paracetamol, oral	21 Aug 2008	21 Aug 2008
Galenic /ibuprofen/paracetamol, oral	21 Aug 2008	21 Aug 2008
Galenic /ibuprofen/paracetamol, oral	26 Sep 2008	26 Oct 2008
Sulfasalazine, oral	16 Jan 2002	18 Dec 2008
Mesalazine, oral	19 Dec 2006	18 Dec 2008
Prednisolone, oral	19 Jul 2008	11 May 2009
Balsalazide, oral	11 Jul 2005	18 Dec 2008
Eugynon /00022701/, oral	Prior	Ongoing
Alprazolam, oral	08 Oct 2008	28 Oct 2008
Panadeine co, oral	19 Oct 2008	19 Oct 2008
Panadeine co, oral	27 Oct 2008	Ongoing
Atropine, oral	23 Dec 2008	25 Dec 2008
Ceftriaxone, intravenous	19 Dec 2008	23 Dec 2008
Dexamethasone, intravenous	19 Dec 2008	25 Dec 2008
Diazepam, oral	18 Dec 2008	25 Dec 2008
Enoxaparin, subcutaneous	19 Dec 2008	25 Dec 2008
Granisetron, intravenous	18 Dec 2008	25 Dec 2008
Hyoscine, oral	23 Dec 2008	25 Dec 2008
Ibuprofen, oral	19 Dec 2008	25 Dec 2008

Morphine, intramuscular	18 Dec 2008	25 Dec 2008
Oxycodone, oral	18 Dec 2008	25 Dec 2008
Oxycodone, oral	22 Dec 2008	25 Dec 2008
Panadeine co, oral	22 Dec 2008	25 Dec 2008
Paracetamol, oral	18 Dec 2008	22 Dec 2008
Parecoxib, oral	21 Dec 2008	25 Dec 2008
Prednisolone, oral	20 Dec 2008	Ongoing
Promethazine, intramuscular	18 Dec 2008	25 Dec 2008
Treatment group in induction:	100 mg → 50 mg SC.	
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.	
Dose adjusted?	No.	

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 19 Aug 2008 (Study Day -42)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 19 Aug 2008 (Study Day -42)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 19 Aug 2008 (Study Day -42)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 19 Aug 2008 (Study Day -42)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 04 Sep 2008 (Study Day -26)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 04 Sep 2008 (Study Day -26)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 04 Sep 2008 (Study Day -26)	Admin. 2/ Inj. 7	Golimumab	50 mg
Week 0 (Main), 30 Sep 2008 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 30 Sep 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 30 Sep 2008 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 28 Oct 2008 (Study Day 29)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 4 (Main), 28 Oct 2008 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 28 Oct 2008 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 03 Dec 2008 (Study Day 65)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 03 Dec 2008 (Study Day 65)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 03 Dec 2008 (Study Day 65)	Admin. 3/ Inj. 9	Golimumab	100 mg

Treatment status:	
Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	03 Dec 2008.
Last scheduled study treatment visit in maintenance:	Week 8 (Main).
Date of study treatment discontinuation:	11 Dec 2008.
Study status:	
Date of disposition status:	14 May 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7204-00005

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of UC)	Not related	27 Jan 2009 17 Feb 2009 (22 days)
SAE	潰瘍性大腸炎 (Acute flare of UC)	Not related	06 Apr 2009 09 Apr 2009 (4 days)

Baseline demographic information: 5[redacted]-year-old (DOB: 01 Feb [redacted]) Caucasian female.
Weight: 75.5 kg; height: 158 cm.

Relevant medical history at baseline: ストーマ造設，関節痛

Baseline smoking status: Nonsmoker.

Ulcerative colitis history:
Date of diagnosis: March 1993.
UC disease duration: 15.7 years.

Prior/concomitant medication, route	Start date	End date
Mesalazine, oral	10 Dec 2007	Ongoing

Levothyroxine sodium, oral	September 2003	Ongoing
Loperamide hydrochloride, oral	29 Dec 2008	Ongoing
Loperamide, oral	29 Dec 2008	Ongoing
Azathioprine, oral	05 Feb 2009	09 Apr 2009
Prednisone, intravenous	02 Feb 2009	05 Feb 2009
Triamterene, oral	05 Feb 2009	Ongoing
Prednisone, oral	06 Feb 2009	09 Apr 2009
Metronidazole, oral	01 Feb 2009	10 Feb 2009
Betamethasone, topical	07 Feb 2009	11 Feb 2009
Optiderm /01148801, topical	12 Feb 2009	20 Feb 2009
Aciclovir, oral	15 Feb 2009	24 Feb 2009
Infliximab, intravenous	16 Feb 2009	Ongoing
Potassium, oral	15 Feb 2009	10 Apr 2009
Magnesium, oral	13 Feb 2009	Ongoing
Paracetamol, oral	25 Mar 2009	10 Apr 2009
Targin, oral	26 Feb 2009	02 Apr 2009
Dalteparin, subcutaneous	26 Mar 2009	02 Apr 2009
Cetirizine, oral	25 Apr 2009	Ongoing
Chlorhexidine, topical	07 Feb 2009	11 Feb 2009

Treatment group in induction:	100 mg → 50 mg SC.
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 02 Dec 2008 (Study Day -43)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 02 Dec 2008 (Study Day -43)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 02 Dec 2008 (Study Day -43)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 02 Dec 2008 (Study Day -43)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 18 Dec 2008 (Study Day -27)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 18 Dec 2008 (Study Day -27)	Admin. 2/ Inj. 6	Golimumab	50 mg
Week 2 (Ind), 18 Dec 2008 (Study Day -27)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 14 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 14 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 14 Jan 2009 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main)—dose not done	NA	NA	NA

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	14 Jan 2009.
Last scheduled study treatment visit in maintenance:	Week 0 (Main).
Date of study treatment discontinuation:	02 Feb 2009.

Study status:

Date of disposition status:	05 May 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7427-00004

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Not related	29 Jul 2009 21 Aug 2009 (24 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 11 Dec [redacted]) Caucasian female.
Weight: 47 kg; height: 165 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 06 Jan 2008.
UC disease duration: 1.1 years.

Prior/concomitant medication, route	Start date	End date
Prednisone, oral	Prior	Ongoing
Sulfasalazine, oral	Prior	Ongoing
Ferro-folgamma, oral	Prior	28 Feb 2009
Calcium-sandoz /00009901/, oral	10 Jan 2009	10 Feb 2009
Iron, oral	13 Mar 2009	Ongoing
Metamizole, intramuscular	28 Jul 2009	Ongoing
Calcium gluconate, intravenous	29 Jul 2009	Ongoing
Dexamethasone, intravenous	29 Jul 2009	Ongoing
Drotaverine, intramuscular	30 Jul 2009	Ongoing
Enoxaparin, subcutaneous	30 Jul 2009	Ongoing
Azathioprine, oral	30 Jul 2009	Ongoing

Treatment group in induction: 100 mg → 50 mg SC.
Treatment group in maintenance: Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 27 Jan 2009 (Study Day -43)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 27 Jan 2009 (Study Day -43)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 27 Jan 2009 (Study Day -43)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 27 Jan 2009 (Study Day -43)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 10 Feb 2009 (Study Day -29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 10 Feb 2009 (Study Day -29)	Admin. 2/ Inj. 6	Golimumab	50 mg
Week 2 (Ind), 10 Feb 2009 (Study Day -29)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 11 Mar 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 11 Mar 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 11 Mar 2009 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 08 Apr 2009 (Study Day 29)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 4 (Main), 08 Apr 2009 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 08 Apr 2009 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 05 May 2009 (Study Day 56)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 05 May 2009 (Study Day 56)	Admin. 3/ Inj. 8	Golimumab	100 mg
Week 8 (Main), 05 May 2009 (Study Day 56)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 09 Jun 2009 (Study Day 91)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 09 Jun 2009 (Study Day 91)	Admin. 4/ Inj. 11	Golimumab	100 mg
Week 12 (Main), 09 Jun 2009 (Study Day 91)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 07 Jul 2009 (Study Day 119)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 07 Jul 2009 (Study Day 119)	Admin. 5/ Inj. 14	Golimumab	100 mg
Week 16 (Main), 07 Jul 2009 (Study Day 119)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main)—dose not done	NA	NA	NA
Week 20 (Main)—dose not done	NA	NA	NA
Week 20 (Main)—dose not done	NA	NA	NA

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Adverse event.
Date of last study agent administration in maintenance: 07 Jul 2009.
Last scheduled study treatment visit in maintenance: Week 16 (Main).
Date of study treatment discontinuation: 31 Jul 2009.

Study status:
Date of disposition status: 28 Oct 2009.
Ended study participation as of Week 54? Yes.
Entered extension study? No.

被験者識別コード：6279-00006

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Serious infection	腎盂腎炎 (Pyelonephritis)	Possible	11 Oct 2010 18 Oct 2010 (8 days)

Baseline demographic information: 4[redacted]-year-old (DOB: 26 Jul [redacted]) Caucasian female.
Weight: 71 kg; height: 158 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 01 Apr 2007.
UC disease duration: 3.1 years.

Prior/concomitant medication, route	Start date	End date
Iron, oral	Prior	Ongoing
Mesalazine, oral	01 Jun 2008	Ongoing
Cefuroxime, oral	15 Jul 2010	24 Jul 2010
Roxithromycin, oral	15 Jul 2010	24 Jul 2010
Mercaptopurine, oral	19 Dec 2010	Ongoing
Prednisone, oral	07 Oct 2010	Ongoing
Cefuroxime, intravenous	11 Oct 2010	18 Oct 2010
Cefuroxime, oral	18 Oct 2010	25 Oct 2010

Treatment group in induction: 200 mg → 100 mg SC.
Treatment group in maintenance: Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 12 May 2010 (Study Day -46)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 12 May 2010 (Study Day -46)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 12 May 2010 (Study Day -46)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 12 May 2010 (Study Day -46)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 26 May 2010 (Study Day -32)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 26 May2010 (Study Day -32)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 0 (Main), 27 Jun 2010 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Main), 27 Jun 2010 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Unscheduled 1 (Main)—dose not done	NA	NA	NA
Unscheduled 1 (Main)—dose not done	NA	NA	NA
Week 4 (Main), 25 Jul 2010 (Study Day 29)	Admin. 2/ Inj. 3	Placebo	0 mg
Week 4 (Main), 25 Jul 2010 (Study Day 29)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 8 (Main), 19 Aug 2010 (Study Day 54)	Admin. 3/ Inj. 5	Placebo	0 mg
Week 8 (Main), 19 Aug 2010 (Study Day 54)	Admin. 3/ Inj. 6	Golimumab	100 mg
Week 12 (Main)—dose not done	NA	NA	NA

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Unsatisfactory therapeutic effect.
Date of last study agent administration in maintenance: 19 Aug 2010.
Last scheduled study treatment visit in maintenance: Week 8 (Main).
Date of study treatment discontinuation: 20 Sep 2010.

Study status:
Date of disposition status: 12 Jan 2011.
Ended study participation as of Week 54? Yes.
Entered extension study? No.

被験者識別コード：6501-00015

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Unlikely	27 May 2010 10 Jun 2010 (15 days)

Baseline demographic information: 5[redacted]-year-old (DOB: 07 Jun [redacted]) Caucasian male.
Weight: 72 kg; height: 168 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 12 Oct 2004
UC disease duration: 4.8 years.

Prior/concomitant medication, route	Start date	End date
Prednisone, oral	28 Jan 2009	Ongoing
Mesalazine, oral	28 Jan 2009	Ongoing
Ciprofloxacin, oral	21 Apr 2010	28 Apr 2010
Metronidazole, oral	21 Apr 2010	28 Apr 2010
Ciprofloxacin, oral	01 Jun 2010	08 Jun 2010
Metronidazole, oral	01 Jun 2010	08 Jun 2010
Hylak /01188001/, oral	01 Jun 2010	Ongoing
Omeprazole, oral	01 Jun 2010	Ongoing

Treatment group in induction: 200 mg → 100 mg SC.
Treatment group in maintenance: Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 07 Aug 2009 (Study Day -41)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 07 Aug 2009 (Study Day -41)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 07 Aug 2009 (Study Day -41)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 07 Aug 2009 (Study Day -41)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 20 Aug 2009 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 20 Aug 2009 (Study Day -28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 20 Aug 2009 (Study Day -28)	Admin. 2/ Inj. 7	Golimumab	100 mg
Week 0 (Main), 17 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 17 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 17 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 14 Oct 2009 (Study Day 28)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 14 Oct 2009 (Study Day 28)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 4 (Main), 14 Oct 2009 (Study Day 28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 11 Nov 2009 (Study Day 56)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 11 Nov 2009 (Study Day 56)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 11 Nov 2009 (Study Day 56)	Admin. 3/ Inj. 9	Golimumab	100 mg
Week 12 (Main), 09 Dec 2009 (Study Day 84)	Admin. 4/ Inj. 10	Golimumab	100 mg
Week 12 (Main), 09 Dec 2009 (Study Day 84)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 09 Dec 2009 (Study Day 84)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 07 Jan 2010 (Study Day 113)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 07 Jan 2010 (Study Day 113)	Admin. 5/ Inj. 14	Golimumab	100 mg
Week 16 (Main), 07 Jan 2010 (Study Day 113)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 03 Feb 2010 (Study Day 140)	Admin. 6/ Inj. 16	Golimumab	100 mg
Week 20 (Main), 03 Feb 2010 (Study Day 140)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 20 (Main), 03 Feb 2010 (Study Day 140)	Admin. 6/ Inj. 18	Placebo	0 mg
Week 24 (Main), 03 Mar 2010 (Study Day 168)	Admin. 7/ Inj. 19	Golimumab	100 mg
Week 24 (Main), 03 Mar 2010 (Study Day 168)	Admin. 7/ Inj. 20	Placebo	0 mg
Week 28 (Main), 31 Mar 2010 (Study Day 196)	Admin. 8/ Inj. 21	Placebo	0 mg
Week 28 (Main), 31 Mar 2010 (Study Day 196)	Admin. 8/ Inj. 22	Golimumab	100 mg
Week 32 (Main), 28 Apr 2010 (Study Day 224)	Admin. 9/ Inj. 23	Golimumab	100 mg
Week 32 (Main), 28 Apr 2010 (Study Day 224)	Admin. 9/ Inj. 24	Placebo	0 mg

Week 36 (Main), 27 May 2010 (Study Day 253)	Admin. 10/ Inj. 25	Golimumab	100 mg
Week 36 (Main), 27 May 2010 (Study Day 253)	Admin. 10/ Inj. 26	Placebo	0 mg
Week 40 (Main)—dose not done	NA	NA	NA

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	27 May 2010.
Last scheduled study treatment visit in maintenance:	Week 36 (Main).
Date of study treatment discontinuation:	24 Jun 2010.

Study status:

Date of study discontinuation:	24 Jun 2010.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	AE.
Date of disposition status:	24 Jun 2010.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7008-00011

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Not related	23 May 2010 01 Jun 2010 (10 days)

Baseline demographic information: 7[redacted]-year-old (DOB: 29 Nov [redacted]) Caucasian female.
Weight: 56 kg; height: 152 cm.

Relevant medical history at baseline: 関節炎，関節痛，アフタ性口内炎

Baseline smoking status: Nonsmoker.

Ulcerative colitis history:

Date of diagnosis:	22 Feb 2007.
UC disease duration:	2.4 years.

Prior/concomitant medication, route	**Start date**	**End date**
Pantoprazole, oral	Prior	Ongoing
Mesalazine, oral	June 2008	Ongoing
Azathioprine, oral	16 Mar 2009	Ongoing
Hydrocortisone acetate, rectal	January 2009	23 Jun 2009
Atorvastatin calcium, oral	July 1994	Ongoing
Midazolam, intravenous	22 Jul 2009	22 Jul 2009
Fentanyl, intravenous	22 Jul 2009	22 Jul 2009
Blood, whole, intravenous	29 Jul 2009	29 Jul 2009
Amoxicillin w/clavulanate potassium, oral	12 Aug 2009	22 Aug 2009
Midazolam, intravenous	02 Sep 2009	02 Sep 2009
Fentanyl, intravenous	02 Sep 2009	02 Sep 2009
Mesalazine, oral	June 2009	Ongoing
Atorvastatin, oral	July 1994	Ongoing
Paracetamol, oral	02 Sep 2009	16 Sep 2009
Amoxicillin, oral	14 Nov 2009	16 Nov 2009
Ferric hydroxide polymaltose complex, intravenous	10 Nov 2009	10 Nov 2009
Cefalexin, oral	29 Dec 2009	11 Jan 2010
Amoxi-clavulanico, oral	22 Feb 2010	09 Mar 2010
Cefalexin, oral	10 Mar 2010	22 Mar 2010
Amoxi-clavulanico, oral	17 Mar 2010	22 Mar 2010
Ciprofloxacin, oral	23 Mar 2010	06 Apr 2010
Midazolam, intravenous	14 Apr 2010	14 Apr 2010
Fentanyl, intravenous	14 Apr 2010	14 Apr 2010
Pico-salax, oral	23 May 2010	23 May 2010
Red blood cells, intravenous	24 May 2010	24 May 2010
Heparin, subcutaneous	25 May 2010	01 Jun 2010
Paracetamol, oral	24 May 2010	27 May 2010

Cefoxitin, oral	24 May 2010	27 May 2010
Metronidazole, oral	24 May 2010	27 May 2010
Panadeine co, oral	27 May 2010	01 Jun 2010

Treatment group in induction:	200 mg → 100 mg SC.
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 22 Jul 2009 (Study Day -42)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 22 Jul 2009 (Study Day -42)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 22 Jul 2009 (Study Day -42)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 22 Jul 2009 (Study Day -42)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 05 Aug 2009 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 05 Aug 2009 (Study Day -28)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 2 (Ind), 05 Aug 2009 (Study Day -28)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 02 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 02 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 02 Sep 2009 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 30 Sep 2009 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 30 Sep 2009 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 30 Sep 2009 (Study Day 29)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 8 (Main), 28 Oct 2009 (Study Day 57)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 28 Oct 2009 (Study Day 57)	Admin. 3/ Inj. 8	Golimumab	100 mg
Week 8 (Main), 28 Oct 2009 (Study Day 57)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 25 Nov 2009 (Study Day 85)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 25 Nov 2009 (Study Day 85)	Admin. 4/ Inj. 11	Golimumab	100 mg
Week 12 (Main), 25 Nov 2009 (Study Day 85)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 23 Dec 2009 (Study Day 113)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 23 Dec 2009 (Study Day 113)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 23 Dec 2009 (Study Day 113)	Admin. 5/ Inj. 15	Golimumab	100 mg
Week 20 (Main), 27 Jan 2010 (Study Day 148)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 27 Jan 2010 (Study Day 148)	Admin. 6/ Inj. 17	Golimumab	100 mg
Week 20 (Main), 27 Jan 2010 (Study Day 148)	Admin. 6/ Inj. 18	Placebo	0 mg
Week 24 (Main), 17 Feb 2010 (Study Day 169)	Admin. 7/ Inj. 19	Placebo	0 mg
Week 24 (Main), 17 Feb 2010 (Study Day 169)	Admin. 7/ Inj. 20	Placebo	0 mg
Week 24 (Main), 17 Feb 2010 (Study Day 169)	Admin. 7/ Inj. 21	Golimumab	100 mg
Week 28 (Main)—dose not done	NA	NA	NA

Treatment status:	
Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Unsatisfactory therapeutic effect.
Date of last study agent administration in maintenance:	17 Feb 2010.
Last scheduled study treatment visit in maintenance:	Week 24 (Main).
Date of study treatment discontinuation:	14 Apr 2010.
Study status:	
Date of study discontinuation:	14 Apr 2010.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	Lack of efficacy.
Date of disposition status:	14 Apr 2010.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7129-00005

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE	潰瘍性大腸炎 (Worsening of ulcerative colitis necessitating colectomy)	Not related	02 Sep 2009 11 Sep 2009 (10 days)

SAE	イレウス (Ileus)	Not related	12 Sep 2009 13 Sep 2009 (2 days)
SAE/ Serious infection	敗血症 (Sepsis)	Possible	13 Sep 2009 19 Sep 2009 (7 days)
SAE/ Event of interest: GI abscess/ stricture/ colectomy	処置後合併症 (Rupture vulneris postoperativa = rupture of the postoperative scar after colectomy [removal of the colon])	Unlikely	22 Sep 2009 14 Oct 2009 (23 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 29 Nov [redacted]) Caucasian male.
Weight: 89.8 kg; height: 190 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 2004.
UC disease duration: 4.4 years.

Prior/concomitant medication, route	Start date	End date
Prednisolone, oral	16 Apr 2009	Ongoing
Azathioprine, oral	02 Jan 2007	Ongoing
Calcium, oral	16 Apr 2009	Ongoing
Prednisolone, oral	16 Apr 2009	11 Sep 2009
Azathioprine, oral	02 Feb 2007	01 Sep 2009
Calcium, oral	16 Apr 2009	11 Sep 2009
Loperamide, oral	09 Sep 2009	Ongoing
Warfarin, oral	01 Oct 2009	Ongoing
Cefuroxime, intravenous	13 Sep 2009	18 Sep 2009
Gentamicin, intravenous	13 Sep 2009	14 Sep 2009
Tinzaparin, subcutaneous	22 Sep 2009	30 Sep 2009

Treatment group in induction: 200 mg → 100 mg SC.
Treatment group in maintenance: Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 19 May 2009 (Study Day -37)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 19 May 2009 (Study Day -37)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 19 May 2009 (Study Day -37)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 19 May 2009 (Study Day -37)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 28 May 2009 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 28 May 2009 (Study Day -28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 28 May 2009 (Study Day -28)	Admin. 2/ Inj. 7	Golimumab	100 mg
Week 0 (Main), 25 Jun 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 25 Jun 2009 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Main), 25 Jun 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 24 Jul 2009 (Study Day 30)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 24 Jul 2009 (Study Day 30)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 24 Jul 2009 (Study Day 30)	Admin. 2/ Inj. 6	Golimumab	100 mg
Unscheduled 2 (Main)—dose not done	NA	NA	NA

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Unsatisfactory therapeutic effect.
Date of last study agent administration in maintenance: 24 Jul 2009.
Last scheduled study treatment visit in maintenance: Week 4 (Main).
Date of study treatment discontinuation: 24 Jul 2009.

Study status:
Date of disposition status: 24 Nov 2009.
Ended study participation as of Week 54? Yes.
Entered extension study? No.

被験者識別コード：7407-00007

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Exacerbation of ulcerative colitis)	Not related	30 Nov 2009 16 Dec 2009 (17 days)

Baseline demographic information: 5[redacted]-year-old (DOB: 13 Feb [redacted]) Caucasian male.
Weight: 99.2 kg; height: 174 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:
Date of diagnosis: 08 Nov 2007.
UC disease duration: 1.1 years.

Prior/concomitant medication, route	Start date	End date
Gliclazide, oral	23 Apr 2008	Ongoing
Perindopril, oral	1993	Ongoing
Bisoprolol fumarate, oral	1993	Ongoing
Latanoprost, ophthalmic	1998	Ongoing
Methylprednisolone, oral	10 Nov 2008	Ongoing
Sulfasalazine, oral	10 Nov 2008	Ongoing
Fortrans /01064301/, oral	22 Dec 2008	22 Dec 2008
Fortrans /01064301/, oral	09 Feb 2009	09 Feb 2009
Sulfasalazine, oral	10 Nov 2008	29 Nov 2009
Methylprednisolone, oral	10 Nov 2008	24 Feb 2009
Bisoprolol, oral	1993	Ongoing
Latanoprost, topical	1998	Ongoing
Fortrans /01064301/, oral	09 Sep 2009	09 Sep 2009
Paracetamol, oral	19 Oct 2009	26 Oct 2009
Fortrans /01064301/, oral	06 Jan 2010	06 Jan 2010
Hydrocortisone, intravenous	30 Nov 2009	15 Dec 2009
Metronidazole, intravenous	30 Nov 2009	15 Dec 2009
Azathioprine, oral	04 Dec 2009	Ongoing
Pancreatin, oral	30 Nov 2009	Ongoing
Mesalazine, oral	30 Nov 2009	Ongoing
Prednisone, oral	16 Dec 2009	Ongoing
Glucose, intravenous	30 Nov 2009	15 Dec 2009
Sodium chloride, intravenous	30 Nov 2009	15 Dec 2009

Treatment group in induction: 200 mg → 100 mg SC.
Treatment group in maintenance: Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 29 Dec 2008 (Study Day -43)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 29 Dec 2008 (Study Day -43)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 29 Dec 2008 (Study Day -43)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 29 Dec 2008 (Study Day -43)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 12 Jan 2009 (Study Day -29)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 12 Jan 2009 (Study Day -29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 12 Jan 2009 (Study Day -29)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 10 Feb 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 10 Feb 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 10 Feb 2009 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 10 Mar 2009 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 10 Mar 2009 (Study Day 29)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 4 (Main), 10 Mar 2009 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 08 Apr 2009 (Study Day 58)	Admin. 3/ Inj. 7	Golimumab	100 mg
Week 8 (Main), 08 Apr 2009 (Study Day 58)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 08 Apr 2009 (Study Day 58)	Admin. 3/ Inj. 9	Placebo	0 mg

Week 12 (Main), 05 May 2009 (Study Day 85)	Admin. 4/ Inj. 10	Golimumab	100 mg
Week 12 (Main), 05 May 2009 (Study Day 85)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 05 May 2009 (Study Day 85)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 02 Jun 2009 (Study Day 113)	Admin. 5/ Inj. 13	Golimumab	100 mg
Week 16 (Main), 02 Jun 2009 (Study Day 113)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 02 Jun 2009 (Study Day 113)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 30 Jun 2009 (Study Day 141)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 30 Jun 2009 (Study Day 141)	Admin. 6/ Inj. 17	Golimumab	100 mg
Week 20 (Main), 30 Jun 2009 (Study Day 141)	Admin. 6/ Inj. 18	Placebo	0 mg
Week 24 (Main), 28 Jul 2009 (Study Day 169)	Admin. 7/ Inj. 19	Placebo	0 mg
Week 24 (Main), 28 Jul 2009 (Study Day 169)	Admin. 7/ Inj. 20	Golimumab	100 mg
Week 24 (Main), 28 Jul 2009 (Study Day 169)	Admin. 7/ Inj. 21	Placebo	0 mg
Week 28 (Main), 26 Aug 2009 (Study Day 198)	Admin. 8/ Inj. 22	Placebo	0 mg
Week 28 (Main), 26 Aug 2009 (Study Day 198)	Admin. 8/ Inj. 23	Golimumab	100 mg
Week 28 (Main), 26 Aug 2009 (Study Day 198)	Admin. 8/ Inj. 24	Placebo	0 mg
Week 32 (Main), 23 Sep 2009 (Study Day 226)	Admin. 9/ Inj. 25	Placebo	0 mg
Week 32 (Main), 23 Sep 2009 (Study Day 226)	Admin. 9/ Inj. 26	Golimumab	100 mg
Week 32 (Main), 23 Sep 2009 (Study Day 226)	Admin. 9/ Inj. 27	Placebo	0 mg
Week 36 (Main), 21 Oct 2009 (Study Day 254)	Admin. 10/ Inj. 28	Golimumab	100 mg
Week 36 (Main), 21 Oct 2009 (Study Day 254)	Admin. 10/ Inj. 29	Placebo	0 mg
Week 36 (Main), 21 Oct 2009 (Study Day 254)	Admin. 10/ Inj. 30	Placebo	0 mg
Week 40 (Main), 18 Nov 2009 (Study Day 282)	Admin. 11/ Inj. 31	Placebo	0 mg
Week 40 (Main), 18 Nov 2009 (Study Day 282)	Admin. 11/ Inj. 32	Placebo	0 mg
Week 40 (Main), 18 Nov 2009 (Study Day 282)	Admin. 11/ Inj. 33	Golimumab	100 mg
Unscheduled 1 (Main)—dose not done	NA	NA	NA
Treatment status:			
Study treatment discontinuation?	Yes.		
Reason for treatment discontinuation:	Adverse event.		
Date of last study agent administration in maintenance:	18 Nov 2009.		
Last scheduled study treatment visit in maintenance:	Week 40 (Main).		
Date of study treatment discontinuation:	16 Dec 2009.		
Study status:			
Date of disposition status:	11 Mar 2010.		
Ended study participation as of Week 54?	No.		
Entered extension study?	No.		

被験者識別コード：7528-00001

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Serious infection / Event of interest: Opportunistic infection	脳膿瘍 (Multiple brain abscesses)	Not related	24 Nov 2010 21 Jan 2011 (59 days)
Baseline demographic information: 6[redacted]-year-old (DOB: 02 Jun [redacted]) Caucasian male from South Africa. Weight: 92 kg; height: 183 cm.			
Relevant medical history at baseline: 報告なし			
Baseline smoking status: Not reported.			
Ulcerative colitis history: Date of diagnosis: 1975. UC disease duration: 34.4 years.			
Prior/concomitant medication, route	**Start date**	**End date**	
Mesalazine, oral	Prior	Ongoing	
Anilides, oral	03 May 2010	09 May 2010	
Metronidazole, oral	24 Jun 2010	29 Jun 2010	
Spektramox, oral	24 Jun 2010	30 Jun 2010	
Paracetamol, oral	24 Jun 2010	26 Jun 2010	
Ultracet, oral	24 Jun 2010	26 Jun 2010	
Loperamide hydrochloride, oral	13 Jul 2010	18 Jul 2010	
Bactrim, oral	17 Dec 2010	22 Dec 2010	

Augmentin/00756801, oral	17 Dec 2010	17 Dec 2010
Metronidazole, oral	17 Dec 2010	22 Dec 2010
Treatment group in induction:	200 mg → 100 mg SC.	
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.	
Dose adjusted?	No.	

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 08 Jun 2010 (Study Day -42)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 08 Jun 2010 (Study Day -42)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 08 Jun 2010 (Study Day -42)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 08 Jun 2010 (Study Day -42)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 22 Jun 2010 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 22 Jun 2010 (Study Day -28)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 20 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 20 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Unsatisfactory therapeutic effect.
Date of last study agent administration in maintenance:	20 Jul 2010.
Last scheduled study treatment visit in maintenance:	Week 0 (Main).
Date of study treatment discontinuation:	17 Aug 2010.

Study status:

Date of study discontinuation:	19 Aug 2010.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	Subject's decision due to lack of efficacy.
Date of disposition status:	19 Aug 2010.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7530-00011

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Serious infection	胸水 (Pleural effusion left)	Not related	14 Feb 2011 25 Feb 2011 (12 days)
SAE/ Permanent discontinuation of study agent due to AE/ Event of interest: Hepatotoxicity	肝炎 (Drug induced hepatitis)	Not related	10 Mar 2011 07 Apr 2011 (29 days)

Baseline demographic information: 6[redacted]-year-old (DOB: 16 Mar [redacted]) female (race: Other).
Weight: 81 kg; height: 171 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:

Date of diagnosis:	04 Apr 2008.
UC disease duration:	2.1 years.

Prior/concomitant medication, route	Start date	End date
Mesalazine, oral	08 Feb 2010	Ongoing
Omeprazole, oral	20 Jan 2009	Ongoing
Pethidine, intravenous	13 May 2010	13 May 2010
Midazolam, intravenous	13 May 2010	13 May 2010
Paracetamol, oral	07 Jul 2010	Ongoing
Norfloxacin, oral	21 Dec 2010	24 Dec 2010
Ciprofloxacin, oral	18 Jan 2011	22 Jan 2011
Mefenamic acid, oral	18 Jan 2011	21 Jan 2011
Blood, whole, intravenous	20 Jan 2011	20 Jan 2011
Augmentin /00756801/, intravenous	14 Feb 2011	21 Feb 2011
Bactrim, oral	18 Feb 2011	24 Feb 2011
Myrin plus, oral	25 Feb 2011	15 Mar 2011

Pyridoxine, oral	25 Feb 2011	17 Mar 2011
Ethambutol, intramuscular	15 Mar 2011	Ongoing
Streptomycin, intramuscular	15 Mar 2011	Ongoing
Simvastatin, oral	20 Feb 2011	Ongoing
Metoclopramide, intravenous	11 Mar 2011	20 Mar 2011
Magnesium chloride anhydrous, oral	13 Mar 2011	17 Mar 2011
Potassium, oral	19 Mar 2011	23 Mar 2011
Augmentin /00756801/, oral	22 Mar 2011	24 Mar 2011
Lactulose, oral	19 Mar 2011	19 Mar 2011
Isoniazid, oral	01 Apr 2011	Ongoing
Pyrazinamide, oral	01 Apr 2011	Ongoing

Treatment group in induction: 200 mg → 100 mg SC.
Treatment group in maintenance: Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 24 May 2010 (Study Day -42)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 24 May 2010 (Study Day -42)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 24 May 2010 (Study Day -42)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 24 May 2010 (Study Day -42)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 07 Jun 2010 (Study Day -28)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 07 Jun 2010 (Study Day -28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 0 (Main), 05 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 05 Jul 2010 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 4 (Main), 03 Aug 2010 (Study Day 30)	Admin. 2/ Inj. 3	Placebo	0 mg
Week 4 (Main), 03 Aug 2010 (Study Day 30)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 8 (Main), 30 Aug 2010 (Study Day 57)	Admin. 3/ Inj. 5	Golimumab	100 mg
Week 8 (Main), 30 Aug 2010 (Study Day 57)	Admin. 3/ Inj. 6	Placebo	0 mg
Week 12 (Main), 27 Sep 2010 (Study Day 85)	Admin. 4/ Inj. 7	Golimumab	100 mg
Week 12 (Main), 27 Sep 2010 (Study Day 85)	Admin. 4/ Inj. 8	Placebo	0 mg
Week 16 (Main), 22 Oct 2010 (Study Day 110)	Admin. 5/ Inj. 9	Placebo	0 mg
Week 16 (Main), 22 Oct 2010 (Study Day 110)	Admin. 5/ Inj. 10	Golimumab	100 mg
Week 20 (Main), 25 Nov 2010 (Study Day 144)	Admin. 6/ Inj. 11	Golimumab	100 mg
Week 20 (Main), 25 Nov 2010 (Study Day 144)	Admin. 6/ Inj. 12	Placebo	0 mg
Week 24 (Main), 21 Dec 2010 (Study Day 170)	Admin. 7/ Inj. 13	Golimumab	100 mg
Week 24 (Main), 21 Dec 2010 (Study Day 170)	Admin. 7/ Inj. 14	Placebo	0 mg
Week 28 (Main), 20 Jan 2011 (Study Day 200)	Admin. 8/ Inj. 15	Placebo	0 mg
Week 28 (Main), 20 Jan 2011 (Study Day 200)	Admin. 8/ Inj. 16	Golimumab	100 mg
Week 32 (Main), 14 Feb 2011 (Study Day 225)	Admin. 9/ Inj. 17	Golimumab	100 mg
Week 32 (Main), 14 Feb 2011 (Study Day 225)	Admin. 9/ Inj. 18	Placebo	0 mg
Unscheduled 1 (Main)	NA	NA	NA

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	14 Feb 2011.
Last scheduled study treatment visit in maintenance:	Week 32 (Main).
Date of study treatment discontinuation:	07 Apr 2011.

Study status:

Date of study discontinuation:	07 Apr 2011.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	Due to SAE.
Date of disposition status:	07 Apr 2011.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7739-00001

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Unlikely	26 Feb 2008 08 Mar 2008 (12 days)
SAE/ Serious infection	尿路感染 (Urinary tract infection)	Possible	26 Feb 2008 08 Mar 2008 (12 days)
Permanent discontinuation of study agent due to AE	結節性紅斑 (Erythema nodosum)	Possible	27 Feb 2008 08 Mar 2008 (11 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 26 Jun [redacted]) Caucasian female.
Weight: 60.3 kg; height: 162 cm.

Relevant medical history at baseline: 喫煙（現在）

Baseline smoking status: Current smoker.

Ulcerative colitis history:
Date of diagnosis: 29 Jun 2006.
UC disease duration: 1.4 years.

Prior/concomitant medication, route	Start date	End date
Mesalazine, oral	09 Oct 2007	Ongoing
Succinic acid, oral	12 Oct 2007	Ongoing
Promethazine, oral	09 Oct 2007	Ongoing
Hydrocortisone, topical	09 Oct 2007	Ongoing
Prednisone, oral	12 Oct 2007	30 Oct 2007
Prednisone, oral	31 Oct 2007	Ongoing
Paracetamol, oral	01 Jan 2007	Ongoing
Fleet enema/00129701/, rectal	25 Oct 2007	26 Oct 2007
Pethidine hydrochloride, intravenous	26 Oct 2007	26 Oct 2007
Midazolam hydrochloride, intravenous	26 Oct 2007	26 Oct 2007
Fleet enema/00129701/, rectal	14 Nov 2007	14 Nov 2007
Fentanyl, intravenous	14 Nov 2007	14 Nov 2007
Midazolam hydrochloride, intravenous	14 Nov 2007	14 Nov 2007
Fleet enema/00129701/, rectal	09 Jan 2008	09 Jan 2008
Midazolam hydrochloride, intravenous	09 Jan 2008	09 Jan 2008
Fentanyl, intravenous	09 Jan 2008	09 Jan 2008
Mesalazine, oral	09 Oct 2007	Ongoing
Succinic acid, oral	12 Oct 2007	02 Mar 2008
Promethazine, oral	09 Oct 2007	Ongoing
Paracetamol, oral	01 Jan 2007	Ongoing
Hydrocortisone, topical	09 Oct 2007	15 Feb 2008
Prednisone, oral	31 Oct 2007	02 Mar 2008
Midazolam, intravenous	09 Jan 2008	09 Jan 2008
Fentanyl, intravenous	09 Jan 2008	09 Jan 2008
Fluconazole, oral	06 Feb 2008	06 Feb 2008
Hydrocortisone, topical	19 Feb 2008	Ongoing
Ciprofloxacin, oral	26 Feb 2008	27 Feb 2008
Tramadol, oral	26 Feb 2008	29 Feb 2008
Phenazopyridine, oral	26 Feb 2008	02 Mar 2008
Bactrim, oral	27 Feb 2008	02 Mar 2008
Levofloxacin, intravenous	02 Mar 2008	06 Mar 2008
Methylprednisolone, intravenous	02 Mar 2008	07 Mar 2008
Paracetamol, oral	02 Mar 2008	02 Mar 2008
Hydromorphone, intravenous	02 Mar 2008	07 Mar 2008
Ondansetron, intravenous	02 Mar 2008	07 Mar 2008
Infliximab, intravenous	06 Mar 2008	Ongoing
Docusate, oral	08 Mar 2008	Ongoing
Ondansetron, oral	08 Mar 2008	Ongoing
Oxycocet, oral	08 Mar 2008	12 Mar 2008
Vicodin, oral	06 Mar 2008	06 Mar 2008

Docusate, oral	07 Mar 2008	07 Mar 2008
Prednisone, oral	07 Mar 2008	Ongoing
Treatment group in induction:	200 mg → 100 mg SC.	
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.	
Dose adjusted?	No.	

Treatment received:

Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 26 Nov 2007 (Study Day -44)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 26 Nov 2007 (Study Day -44)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 26 Nov 2007 (Study Day -44)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 26 Nov 2007 (Study Day -44)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 10 Dec 2007 (Study Day -30)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 10 Dec 2007 (Study Day -30)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 10 Dec 2007 (Study Day -30)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 09 Jan 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 09 Jan 2008 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 09 Jan 2008 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 06 Feb 2008 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 06 Feb 2008 (Study Day 29)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 4 (Main), 06 Feb 2008 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main)—dose not done	NA	NA	NA

Treatment status:	
Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	06 Feb 2008.
Last scheduled study treatment visit in maintenance:	Week 4 (Main).
Date of study treatment discontinuation:	03 Mar 2008.
Study status:	
Date of disposition status:	19 Jun 2008.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7741-00002

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Serious infection	潰瘍性大腸炎 (Ulcerative colitis with possible flare)	Not related	06 Aug 2009 09 Aug 2009 (4 days)

Baseline demographic information: 5[redacted]-year-old (DOB: 12 Jun [redacted]) Caucasian male.
Weight: 137.3 kg; height: 178 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 12 Mar 1996.
UC disease duration: 13.3 years.

Prior/concomitant medication, route	**Start date**	**End date**
Mesalazine, oral	31 May 2006	Ongoing
Paracetamol, oral	10 Jun 2009	Ongoing
Fentanyl, intravenous	28 Jul 2009	28 Jul 2009
Midazolam hydrochloride, intravenous	28 Jul 2009	28 Jul 2009
Macrogol, oral	27 Jul 2009	27 Jul 2009
Bisacodyl, oral	27 Jul 2009	27 Jul 2009
Prednisone, oral	09 Aug 2009	Ongoing
Metronidazole, oral	09 Aug 2009	Ongoing
Treatment group in induction:	200 mg → 100 mg SC.	
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.	
Dose adjusted?	No.	

Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 22 Jun 2009 (Study Day -43)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 22 Jun 2009 (Study Day -43)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 22 Jun 2009 (Study Day -43)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 22 Jun 2009 (Study Day -43)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 07 Jul 2009 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 07 Jul 2009 (Study Day -28)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 07 Jul 2009 (Study Day -28)	Admin. 2/ Inj. 7	Golimumab	100 mg
Week 0 (Main), 04 Aug 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 04 Aug 2009 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Main), 04 Aug 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 01 Sep 2009 (Study Day 29)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 4 (Main), 01 Sep 2009 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 01 Sep 2009 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg

Treatment status:	
Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Other.
Other reason for treatment discontinuation:	PI chose to remove subject from study due to active UC after colonoscopy.
Date of last study agent administration in maintenance:	01 Sep 2009.
Last scheduled study treatment visit in maintenance:	Week 4 (Main).
Date of study treatment discontinuation:	17 Sep 2009.
Study status:	
Date of disposition status:	13 Jan 2010.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7746-00005

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Serious infection	急性膵炎 (Acute pancreatitis)	Unlikely	09 Apr 2009 13 Apr 2009 (5 days)

Baseline demographic information: 4[redacted]-year-old (DOB: 24 Aug [redacted]) Caucasian male.
Weight: 77.7 kg; height: 178 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:
Date of diagnosis: 1991.
UC disease duration: 17.1 years.

Prior/concomitant medication, route	**Start date**	**End date**
Mesalazine, oral	April 2007	Ongoing
Budesonide, oral	April 2007	Ongoing
Esomeprazole magnesium, oral	September 2007	Ongoing
Loperamide hydrochloride, oral	1991	Ongoing
Paracetamol, oral	10 Feb 2009	11 Feb 2009
Acetylsalicylic acid, oral	09 Apr 2009	09 Apr 2009
Glyceryl trinitrate, sublingual	09 Apr 2009	09 Apr 2009
Morphine, intravenous	09 Apr 2009	09 Apr 2009
Ondansetron, intravenous	09 Apr 2009	09 Apr 2009
Sodium chloride, intravenous	09 Apr 2009	12 Apr 2009
Ringer-lactate, intravenous	11 Apr 2009	13 Apr 2009
Meropenem, intravenous	11 Apr 2009	13 Apr 2009
Pantoprazole, intravenous	09 Apr 2009	12 Apr 2009
Alprazolam, oral	09 Apr 2009	13 Apr 2009
Hydromorphone, intravenous	09 Apr 2009	13 Apr 2009
Potassium, oral	09 Apr 2009	13 Apr 2009
Mesalazine, oral	Prior	28 Apr 2011

Budesonide, oral	Prior	15 Jan 2010
Esomeprazole, oral	Prior	15 Dec 2010
Loperamide, oral	Prior	Ongoing
Promethazine, intravenous	09 Apr 2009	09 Apr 2009
Pseudoephedrine, oral	10 Dec 2009	15 Dec 2009
Treatment group in induction:	200 mg → 100 mg SC.	
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.	
Dose adjusted?	No.	

Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 09 Feb 2009 (Study Day -44)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 09 Feb 2009 (Study Day -44)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 09 Feb 2009 (Study Day -44)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 09 Feb 2009 (Study Day -44)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 23 Feb 2009 (Study Day -30)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 23 Feb 2009 (Study Day -30)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 2 (Ind), 23 Feb 2009 (Study Day -30)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 25 Mar 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 25 Mar 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 25 Mar 2009 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 22 Apr 2009 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 22 Apr 2009 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 22 Apr 2009 (Study Day 29)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 8 (Main), 20 May 2009 (Study Day 57)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 20 May 2009 (Study Day 57)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 20 May 2009 (Study Day 57)	Admin. 3/ Inj. 9	Golimumab	100 mg
Week 12 (Main), 15 Jun 2009 (Study Day 83)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 15 Jun 2009 (Study Day 83)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 15 Jun 2009 (Study Day 83)	Admin. 4/ Inj. 12	Golimumab	100 mg
Week 16 (Main), 21 Jul 2009 (Study Day 119)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 21 Jul 2009 (Study Day 119)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 21 Jul 2009 (Study Day 119)	Admin. 5/ Inj. 15	Golimumab	100 mg
Week 20 (Main), 12 Aug 2009 (Study Day 141)	Admin. 6/ Inj. 16	Golimumab	100 mg
Week 20 (Main), 12 Aug 2009 (Study Day 141)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 20 (Main), 12 Aug 2009 (Study Day 141)	Admin. 6/ Inj. 18	Placebo	0 mg
Week 24 (Main), 09 Sep 2009 (Study Day 169)	Admin. 7/ Inj. 19	Golimumab	100 mg
Week 24 (Main), 09 Sep 2009 (Study Day 169)	Admin. 7/ Inj. 20	Placebo	0 mg
Week 24 (Main), 09 Sep 2009 (Study Day 169)	Admin. 7/ Inj. 21	Placebo	0 mg
Week 28 (Main), 07 Oct 2009 (Study Day 197)	Admin. 8/ Inj. 22	Golimumab	100 mg
Week 28 (Main), 07 Oct 2009 (Study Day 197)	Admin. 8/ Inj. 23	Placebo	0 mg
Week 28 (Main), 07 Oct 2009 (Study Day 197)	Admin. 8/ Inj. 24	Placebo	0 mg
Week 32 (Main), 04 Nov 2009 (Study Day 225)	Admin. 9/ Inj. 25	Placebo	0 mg
Week 32 (Main), 04 Nov 2009 (Study Day 225)	Admin. 9/ Inj. 26	Placebo	0 mg
Week 32 (Main), 04 Nov 2009 (Study Day 225)	Admin. 9/ Inj. 27	Golimumab	100 mg
Week 36 (Main), 30 Nov 2009 (Study Day 251)	Admin. 10/ Inj. 28	Placebo	0 mg
Week 36 (Main), 30 Nov 2009 (Study Day 251)	Admin. 10/ Inj. 29	Placebo	0 mg
Week 36 (Main), 30 Nov 2009 (Study Day 251)	Admin. 10/ Inj. 30	Golimumab	100 mg
Week 40 (Main), 23 Dec 2009 (Study Day 274)	Admin. 11/ Inj. 31	Placebo	0 mg
Week 40 (Main), 23 Dec 2009 (Study Day 274)	Admin. 11/ Inj. 32	Placebo	0 mg
Week 40 (Main), 23 Dec 2009 (Study Day 274)	Admin. 11/ Inj. 33	Golimumab	100 mg
Week 44 (Main), 18 Jan 2010 (Study Day 300)	Admin. 12/ Inj. 34	Placebo	0 mg
Week 44 (Main), 18 Jan 2010 (Study Day 300)	Admin. 12/ Inj. 35	Golimumab	100 mg
Week 44 (Main), 18 Jan 2010 (Study Day 300)	Admin. 12/ Inj. 36	Placebo	0 mg
Week 48 (Main), 16 Feb 2010 (Study Day 329)	Admin. 13/ Inj. 37	Placebo	0 mg
Week 48 (Main), 16 Feb 2010 (Study Day 329)	Admin. 13/ Inj. 38	Golimumab	100 mg
Week 48 (Main), 16 Feb 2010 (Study Day 329)	Admin. 13/ Inj. 39	Placebo	0 mg
Week 52 (Main), 16 Mar 2010 (Study Day 357)	Admin. 14/ Inj. 40	Placebo	0 mg
Week 52 (Main), 16 Mar 2010 (Study Day 357)	Admin. 14/ Inj. 41	Golimumab	100 mg

Treatment status:	
Study treatment discontinuation?	No.
Date of last study agent administration in maintenance:	16 Mar 2010.
Last scheduled study treatment visit in maintenance:	Week 52 (Main).
Study status:	
Date of disposition status:	30 Mar 2010.
Ended study participation as of Week 54?	No.
Entered extension study?	Yes.

被験者識別コード：7746-00010

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Serious infection	レンサ球菌性敗血症 (Streptococcal pneumonia sepsis)	Not related	29 Oct 2010 02 Nov 2010 (5 days)

Baseline demographic information: 6[redacted]-year-old (DOB: 30 May [redacted]) Caucasian male.
Weight: 108.6 kg; height: 183 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:
Date of diagnosis: 06 Aug 2009.
UC disease duration: 0.6 years.

Prior/concomitant medication, route	**Start date**	**End date**
Prednisone, oral	24 Nov 2009	Ongoing
Mesalazine, oral	July 2009	Ongoing
Mercaptopurine, oral	2009	Ongoing
Dutasteride, oral	04 Sep 2008	Ongoing
Loperamide hydrochloride, oral	October 2009	Ongoing
Vitamin B12 nos, sublingual	Prior	Ongoing
Vitamins with minerals, oral	May 2008	Ongoing
Midazolam hydrochloride, intravenous	11 Mar 2010	11 Mar 2010
Fleet enema /00129701/, rectal	10 Mar 2010	10 Mar 2010
Lisinopril, oral	03 May 2010	Ongoing
Prednisone, oral	24 Nov 2009	27 Aug 2010
Mesalazine, oral	July 2009	02 Nov 2010
Mercaptopurine, oral	2009	October 2010
Icaps, oral	May 2008	Ongoing
Loperamide, oral	October 2009	Ongoing
Prednisone, oral	27 Aug 2010	Ongoing
Fleet enema /00129701/, rectal	27 Aug 2010	27 Aug 2010
Midazolam, intravenous	27 Aug 2010	27 Aug 2010
Fentanyl, intravenous	27 Aug 2010	27 Aug 2010
Infliximab, intravenous	07 Oct 2010	Ongoing
Mercaptopurine, oral	October 2010	Ongoing
Ceftriaxone, intravenous	29 Oct 2010	31 Oct 2010
Methylprednisolone, intravenous	29 Oct 2010	30 Oct 2010
Cefdinir, oral	01 Nov 2010	01 Nov 2010
Prednisone, oral	01 Nov 2010	02 Nov 2010
Insulin aspart, subcutaneous	29 Oct 2010	01 Nov 2010
Lisinopril, oral	03 Nov 2010	Ongoing
Mesalazine, oral	02 Nov 2010	Ongoing
Moxifloxacin, oral	02 Nov 2010	07 Nov 2010
Pantoprazole, oral	03 Nov 2010	Ongoing
Alprazolam, oral	29 Oct 2010	Ongoing
Prednisone, oral	03 Nov 2010	07 Nov 2010
Prednisone, oral	08 Nov 2010	12 Nov 2010
Prednisone, oral	12 Nov 2010	November 2010
Prednisone, oral	November 2010	30 Nov 2010
Prednisone, oral	01 Dec 2010	Ongoing

Treatment group in induction:	200 mg → 100 mg SC.
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 25 Mar 2010 (Study Day -42)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Ind), 25 Mar 2010 (Study Day -42)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Ind), 25 Mar 2010 (Study Day -42)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 25 Mar 2010 (Study Day -42)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 08 Apr 2010 (Study Day -28)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 08 Apr 2010 (Study Day -28)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 06 May 2010 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 06 May 2010 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 4 (Main), 03 Jun 2010 (Study Day 29)	Admin. 2/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 03 Jun 2010 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 8 (Main), 24 Jun 2010 (Study Day 50)	Admin. 3/ Inj. 5	Golimumab	100 mg
Week 8 (Main), 24 Jun 2010 (Study Day 50)	Admin. 3/ Inj. 6	Placebo	0 mg
Week 12 (Main), 22 Jul 2010 (Study Day 78)	Admin. 4/ Inj. 7	Golimumab	100 mg
Week 12 (Main), 22 Jul 2010 (Study Day 78)	Admin. 4/ Inj. 8	Placebo	0 mg
Week 16 (Main), 26 Aug 2010 (Study Day 113)	Admin. 5/ Inj. 9	Placebo	0 mg
Week 16 (Main), 26 Aug 2010 (Study Day 113)	Admin. 5/ Inj. 10	Golimumab	100 mg

Treatment status:	
Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Unsatisfactory therapeutic effect.
Date of last study agent administration in maintenance:	26 Aug 2010.
Last scheduled study treatment visit in maintenance:	Week 16 (Main).
Date of study treatment discontinuation:	27 Aug 2010.
Study status:	
Date of disposition status:	16 Dec 2010.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7755-00001

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Serious infection	ブドウ球菌性菌血症 (Methicillin sensitive *Staphylococcus aureus* bacteremia)	Unlikely	15 Oct 2008 21 Oct 2008 (7 days)

Baseline demographic information: 4[redacted]-year-old (DOB: 01 Jan [redacted]) Caucasian male.
Weight: 88.6 kg; height: 188 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 01 Aug 2004.
UC disease duration: 3.8 years.

Prior/concomitant medication, route	Start date	End date
Azathioprine, oral	Prior	Ongoing
Mesalazine, oral	Prior	Ongoing
Folic acid, oral	14 Dec 2007	Ongoing
Vitamin B12 nos, oral	17 Dec 2007	Ongoing
Multivitamin /00831701, oral	17 Dec 2007	Ongoing
Calcium carbonate, oral	17 Dec 2007	Ongoing
Loperamide hydrochloride, oral	01 Aug 2006	Ongoing
Lomotil, oral	08 May 2008	Ongoing
Magnesium citrate, oral	07 May 2008	07 May 2008
Bisacodyl, rectal	08 May 2008	08 May 2008

Magnesium citrate, oral	31 May 2008	31 May 2008
Bisacodyl, rectal	01 Jul 2008	01 Jul 2008
Prednisone, oral	15 Jul 2008	Ongoing
Enoxaparin, subcutaneous	16 Oct 2008	21 Oct 2008
Lotrisone, topical	17 Oct 2008	21 Oct 2008
Gastrografin, intravenous	15 Oct 2008	15 Oct 2008
Pantoprazole, oral	16 Oct 2008	21 Oct 2008
Infliximab, intravenous	15 Aug 2008	Ongoing
Levofloxacin, intravenous	15 Oct 2008	17 Oct 2008
Metronidazole, intravenous	15 Oct 2008	17 Oct 2008
Vancomycin, intravenous	17 Oct 2008	18 Oct 2008
Cefazolin, intravenous	18 Oct 2008	21 Oct 2008
Paracetamol, oral	15 Oct 2008	21 Oct 2008
Temazepam, oral	19 Oct 2008	21 Oct 2008
Omeprazole, oral	14 Aug 2008	15 Oct 2008
Omeprazole, oral	22 Oct 2008	Ongoing

Treatment group in induction: 200 mg → 100 mg SC.
Treatment group in maintenance: Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 20 May 2008 (Study Day -42)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 20 May 2008 (Study Day -42)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 20 May 2008 (Study Day -42)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 0 (Ind), 20 May 2008 (Study Day -42)	Admin. 1/ Inj. 4	Placebo	0 mg
Week 2 (Ind), 05 Jun 2008 (Study Day -26)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 05 Jun 2008 (Study Day -26)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 05 Jun 2008 (Study Day -26)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 01 Jul 2008 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 01 Jul 2008 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 01 Jul 2008 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Unscheduled 1 (Main)—dose not done	NA	NA	NA

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Unsatisfactory therapeutic effect.
Date of last study agent administration in maintenance: 01 Jul 2008.
Last scheduled study treatment visit in maintenance: Week 0 (Main).
Date of study treatment discontinuation: 15 Jul 2008.

Study status:
Date of study discontinuation: 15 Jul 2008.
Reason for noncompletion: Withdrawal of consent.
Date of disposition status: 15 Jul 2008.
Ended study participation as of Week 54? Yes.
Entered extension study? No.

被験者識別コード：6112-00013

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	薬効欠如 (Ulcerative colitis, lack of efficacy of study drug)	Unlikely	04 Dec 2009 11 Dec 2009 (8 days)

Baseline demographic information: 4[redacted]-year-old (DOB: 07 Aug [redacted]) Caucasian male.
Weight: 117 kg; height: 181 cm.

Relevant medical history at baseline: 関節痛，喫煙（現在）

Baseline smoking status: Current smoker.

Ulcerative colitis history:
Date of diagnosis: 28 Aug 2008.
UC disease duration: 0.8 years.

Prior/concomitant medication, route	Start date	End date
Mesalazine, oral	16 Mar 2009	Ongoing
Valsartan, oral	Prior	Ongoing
Magnesium citrate, oral	02 Jun 2009	02 Jun 2009
Fleet enema/00129701/, rectal	03 Jun 2009	03 Jun 2009
Magnesium citrate, oral	21 Jul 2009	21 Jul 2009
Fleet enema/00129701/, rectal	22 Jul 2009	22 Jul 2009
Mesalazine, oral	16 Mar 2009	03 Dec 2009

Treatment group in induction: 400 mg → 200 mg SC.
Treatment group in maintenance: Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 11 Jun 2009 (Study Day -41)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 11 Jun 2009 (Study Day -41)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 11 Jun 2009 (Study Day -41)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 11 Jun 2009 (Study Day -41)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 24 Jun 2009 (Study Day -28)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 24 Jun 2009 (Study Day -28	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 2 (Ind), 24 Jun 2009 (Study Day -28)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 22 Jul 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 22 Jul 2009 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Main), 22 Jul 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 25 Aug 2009 (Study Day 35)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 4 (Main), 25 Aug 2009 (Study Day 35)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 25 Aug 2009 (Study Day 35)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 08 Sep 2009 (Study Day 49)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 08 Sep 2009 (Study Day 49)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 08 Sep 2009 (Study Day 49)	Admin. 3/ Inj. 9	Golimumab	100 mg
Week 12 (Main), 11 Oct 2009 (Study Day 82)	Admin. 4/ Inj. 10	Golimumab	100 mg
Week 12 (Main), 11 Oct 2009 (Study Day 82)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 11 Oct 2009 (Study Day 82)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main)—dose not done	NA	NA	NA

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Unsatisfactory therapeutic effect.
Date of last study agent administration in maintenance: 11 Oct 2009.
Last scheduled study treatment visit in maintenance: Week 12 (Main).
Date of study treatment discontinuation: 25 Nov 2009.

Study status:
Date of disposition status: 02 Mar 2010.
Ended study participation as of Week 54? Yes.
Entered extension study? No.

被験者識別コード：6112-00016

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Unlikely	18 Feb 2010 27 Feb 2010 (10 days)
SAE/ Serious infection	術後膿瘍 (Post-colectomy pelvic abscess)	Not related	01 Mar 2010 10 Mar 2010 (10 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 08 Aug [redacted]) Caucasian female.
Weight: 61.2 kg; height: 161 cm.

Relevant medical history at baseline: アフタ性口内炎，喫煙（過去），裂肛

Baseline smoking status: Prior smoker (stopped > 1 year ago)

Ulcerative colitis history:
Date of diagnosis: 17 Jan 2006.
UC disease duration: 3.9 years.

Prior/concomitant medication, route	Start date	End date
Mesalazine, oral	Prior	Ongoing
Loperamide hydrochloride, oral	07 Mar 2008	Ongoing
Calcium carbonate, oral	21 Mar 2008	Ongoing
Vitamin D nos, oral	21 Mar 2008	Ongoing
Azathioprine, oral	Prior	Ongoing
Magnesium citrate, oral	02 Nov 2009	02 Nov 2009
Fleet enema /00129701/, rectal	03 Nov 2009	03 Nov 2009
Fleet enema /00129701/, rectal	02 Dec 2009	02 Dec 2009
Clindamycin, oral	13 Nov 2009	15 Nov 2009
Amoxicillin, oral	17 Nov 2009	26 Nov 2009
Hydrocortisone, rectal	10 Nov 2009	10 Nov 2009
Clindamycin, oral	15 Dec 2009	22 Dec 2009
Fleet enema /00129701/, rectal	19 Jan 2010	19 Jan 2010
Loperamide, oral	07 Mar 2008	Ongoing
Contraceptives, intravaginal	Prior	Ongoing

Treatment group in induction: 400 mg → 200 mg SC.
Treatment group in maintenance: Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 09 Dec 2009 (Study Day -41)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 09 Dec 2009 (Study Day -41)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 09 Dec 2009 (Study Day -41)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 09 Dec 2009 (Study Day -41)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 22 Dec 2009 (Study Day -28)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 22 Dec 2009 (Study Day -28)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 19 Jan 2010 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 19 Jan 2010 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 19 Jan 2010 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Unsatisfactory therapeutic effect.
Date of last study agent administration in maintenance: 19 Jan 2010.
Last scheduled study treatment visit in maintenance: Week 0 (Main).
Date of study treatment discontinuation: 04 Feb 2010.

Study status:
Date of disposition status: 20 May 2010.
Ended study participation as of Week 54? Yes.
Entered extension study? No.

被験者識別コード：6115-00003

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Lack of improvement in ulcerative colitis)	Not related	10 May 2010 29 Jun 2010 (51 days)

Baseline demographic information: 1[redacted]-year-old (DOB: 11 Jul [redacted]) Caucasian female.
Weight: 61 kg; height: 172 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: 16 Nov 2009.
UC disease duration: 0.3 years.

Prior/concomitant medication, route	Start date	End date
Prednisone, oral	17 Feb 2010	Ongoing
Eugynon /00022701/, oral	March 2009	Ongoing
Saccharated iron oxide, intravenous	06 Jan 2010	26 Feb 2010
Propofol, intravenous	22 Feb 2010	22 Feb 2010

Treatment group in induction: 400 mg → 200 mg SC.
Treatment group in maintenance: Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 08 Mar 2010 (Study Day -39)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 08 Mar 2010 (Study Day -39)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 08 Mar 2010 (Study Day -39)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 08 Mar 2010 (Study Day -39)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 23 Mar 2010 (Study Day -24)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 23 Mar 2010 (Study Day -24)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 16 Apr 2010 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 16 Apr 2010 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg

Treatment status:
Study treatment discontinuation? Yes.
Reason for treatment discontinuation: Unsatisfactory therapeutic effect.
Date of last study agent administration in maintenance: 16 Apr 2010.
Last scheduled study treatment visit in maintenance: Week 0 (Main).
Date of study treatment discontinuation: 10 May 2010.

Study status:
Date of study discontinuation: 16 Jul 2010.
Reason for noncompletion: Withdrawal of consent.
Date of disposition status: 16 Jul 2010.
Ended study participation as of Week 54? Yes.
Entered extension study? No.

被験者識別コード：6207-00001

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Severe flare of ulcerative colitis)	Not related	03 May 2010 19 May 2010 (17 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 01 Apr [redacted]) Caucasian male.
Weight: 61 kg; height: 178 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:
Date of diagnosis: 14 Feb 2007.
UC disease duration: 3.0 years.

Prior/concomitant medication, route	Start date	End date
Mesalazine, oral	2007	Ongoing
Prednisolone, oral	2006	2009
Azathioprine, oral	2009	November 2009
Loperamide hydrochloride, oral	2009	Ongoing
Metronidazole, oral	12 Feb 2010	18 Feb 2010
Ferrous glycine sulfate, oral	21 Jan 2010	Ongoing
Paracetamol, oral	23 Feb 2010	23 Feb 2010
Iron, oral	21 Jan 2010	Ongoing
Loperamide, oral	2009	Ongoing
Mercaptopurine, oral	May 2010	Ongoing
Prednisolone	05 May 2010	May 2010
Ciprofloxacin	05 May 2010	May 2010

Treatment group in induction:	400 mg → 200 mg SC.
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 23 Feb 2010 (Study Day -44)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 23 Feb 2010 (Study Day -44)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 23 Feb 2010 (Study Day -44)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 23 Feb 2010 (Study Day -44)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 10 Mar 2010 (Study Day -29)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 10 Mar 2010 (Study Day -29)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 08 Apr 2010 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 08 Apr 2010 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 4 (Main)—dose not done	NA	NA	NA
Week 4 (Main)—dose not done	NA	NA	NA

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	08 Apr 2010.
Last scheduled study treatment visit in maintenance:	Week 0 (Main).
Date of study treatment discontinuation:	03 May 2010.

Study status:

Date of study discontinuation:	03 May 2010.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	Due to SAE (severe flare of UC).
Date of disposition status:	03 May 2010.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7116-00006

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Exacerbation of ulcerative colitis leading to colectomy)	Not related	06 Nov 2009 16 Nov 2009 (11 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 27 Mar [redacted]) Caucasian female.
Weight: 51 kg; height: 163 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:

Date of diagnosis:	October 2004.
UC disease duration:	4.9 years.

Prior/concomitant medication, route	Start date	End date
Azathioprine, oral	June 2005	Ongoing
Iron, oral	26 Sep 2009	03 Oct 2009
Azathioprine, oral	June 2005	07 Nov 2009
Methylprednisolone, intravenous	06 Nov 2009	07 Nov 2009
Calcium carbonate, oral	06 Nov 2009	08 Nov 2009
Vitamin D nos, oral	06 Nov 2009	08 Nov 2009
Cefazolin, intravenous	08 Nov 2009	08 Nov 2009
Metronidazole, intravenous	08 Nov 2009	09 Nov 2009
Paracetamol, oral	08 Nov 2009	16 Nov 2009
Hydromorphone, intravenous	08 Nov 2009	10 Nov 2009
Bupivacaine, intravenous	08 Nov 2009	13 Nov 2009
Red blood cells, intravenous	10 Nov 2009	10 Nov 2009
Hydrocortisone, intravenous	10 Nov 2009	11 Nov 2009
Ciprofloxacin, intravenous	08 Nov 2009	09 Nov 2009
Heparin, subcutaneous	09 Nov 2009	16 Nov 2009

Potassium, oral	13 Nov 2009	13 Nov 2009
Pip/tazo, intravenous	13 Nov 2009	15 Nov 2009
Fentanyl, intravenous	10 Nov 2009	11 Nov 2009
Diclofenac, oral	09 Nov 2009	09 Nov 2009
Dimenhydrinate, intravenous	09 Nov 2009	10 Nov 2009
Panadeine co, oral	15 Nov 2009	16 Nov 2009
Ondansetron, intravenous	10 Nov 2009	13 Nov 2009
Prochlorperazine, intravenous	09 Nov 2009	10 Nov 2009
Zopiclone, oral	08 Nov 2009	08 Nov 2009
Lorazepam, sublingual	13 Nov 2009	14 Nov 2009
Treatment group in induction:	400 mg → 200 mg SC.	
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.	
Dose adjusted?	No.	

Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 09 Sep 2009 (Study Day -43)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 09 Sep 2009 (Study Day -43)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 09 Sep 2009 (Study Day -43)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 09 Sep 2009 (Study Day -43)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 25 Sep 2009 (Study Day -27)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 25 Sep 2009 (Study Day -27)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 22 Oct 2009 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 22 Oct 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 22 Oct 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main)—dose not done	NA	NA	NA

Treatment status:	
Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	22 Oct 2009.
Last scheduled study treatment visit in maintenance:	Week 0 (Main).
Date of study treatment discontinuation:	06 Nov 2009.

Study status:	
Date of disposition status:	03 Mar 2010.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7206-00004

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Exacerbation of ulcerative colitis)	Not related	29 Jan 2010 09 Feb 2010 (12 days)

Baseline demographic information: 2[redacted]-year-old (DOB: 01 Jul [redacted]) Caucasian female.
Weight: 90 kg; height: 176 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:	
Date of diagnosis:	December 2007.
UC disease duration:	1.8 years.

Prior/concomitant medication, route	**Start date**	**End date**
Metamizole, oral	January 2010	January 2010
Prednisolone, intravenous	01 Feb 2010	03 Feb 2010
Treatment group in induction:	400 mg → 200 mg SC.	
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.	
Dose adjusted?	No.	

Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 12 Oct 2009 (Study Day -50)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 12 Oct 2009 (Study Day -50)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 12 Oct 2009 (Study Day -50)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 12 Oct 2009 (Study Day -50)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 04 Nov 2009 (Study Day -27)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 04 Nov 2009 (Study Day -27)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 0 (Main), 01 Dec 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 01 Dec 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 01 Dec 2009 (Study Day 1)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 4 (Main), 30 Dec 2009 (Study Day 30)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 4 (Main), 30 Dec 2009 (Study Day 30)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 30 Dec 2009 (Study Day 30)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 27 Jan 2010 (Study Day 58)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 27 Jan 2010 (Study Day 58)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 27 Jan 2010 (Study Day 58)	Admin. 3/ Inj. 9	Golimumab	100 mg
Treatment status:			
Study treatment discontinuation?	Yes.		
Reason for treatment discontinuation:	Adverse event.		
Date of last study agent administration in maintenance:	27 Jan 2010.		
Last scheduled study treatment visit in maintenance:	Week 8 (Main).		
Date of study treatment discontinuation:	29 Jan 2010.		
Study status:			
Date of study discontinuation:	01 Feb 2010.		
Reason for noncompletion:	Withdrawal of consent.		
Date of disposition status:	01 Feb 2010.		
Ended study participation as of Week 54?	Yes.		
Entered extension study?	No.		

被験者識別コード：7207-00001

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Unlikely	24 May 2008 04 Jun 2008 (12 days)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Unlikely	08 Jun 2008 25 Jun 2008 (18 days)
Baseline demographic information: 3[redacted]-year-old (DOB: 01 Feb [redacted]) Caucasian male. Weight: 97 kg; height: 182 cm.			
Relevant medical history at baseline: アフタ性口内炎			
Baseline smoking status: Nonsmoker.			
Ulcerative colitis history: Date of diagnosis: November 2006. UC disease duration: 1.4 years.			

Prior/concomitant medication, route	**Start date**	**End date**
Prednisolone, oral	26 Feb 2008	07May2008
Mesalazine, oral	November 2007	Ongoing
Lekovit Ca, oral	2007	Ongoing
Omeprazole, oral	2004	Ongoing
Pethidine hydrochloride, subcutaneous	02 May 2008	02 May 2008
Ibuprofen, oral	02 May 2008	04 May 2008
Tramadol hydrochloride, oral	04 May 2008	05 May 2008
Metamizole sodium, oral	05 May 2008	05 May 2008
Co-dafalgan, oral	06 May 2008	Ongoing
Prednisolone, oral	08 May 2008	14 May 2008
Prednisolone, oral	15 May 2008	Ongoing

Risedronate sodium, oral	19 May 2008	Ongoing
Bactrim, oral	08 May 2008	13 May 2008
Lekovit Ca, oral	04 Jun 2008	Ongoing
Lekovit Ca, oral	2007	03 Jun 2008
Risedronic acid, oral	19 May 2008	Ongoing
Prednisolone, oral	15 May 2008	Ongoing
Bactrim, oral	Jun 2008	25 Sep 2008
Infliximab, intravenous	18 Jun 2008	Ongoing

Treatment group in induction: 400 mg → 200 mg SC.
Treatment group in maintenance: Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted? No.

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 09 Apr 2008 (Study Day -43)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 09 Apr 2008 (Study Day -43)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 09 Apr 2008 (Study Day -43)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 09 Apr 2008 (Study Day -43)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 23 Apr 2008 (Study Day -29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 23 Apr 2008 (Study Day -29)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 2 (Ind), 23 Apr 2008 (Study Day -29)	Admin. 2/ Inj. 7	Golimumab	100 mg
Week 0 (Main), 22 May 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 22 May 2008 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Main), 22 May 2008 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Unscheduled 1 (Main)—dose not done	NA	NA	NA

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	22 May 2008.
Last scheduled study treatment visit in maintenance:	Week 0 (Main).
Date of study treatment discontinuation:	03 Jul 2008.

Study status:

Date of study discontinuation:	03 Jul 2008.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	Lack of efficacy (AE 2).
Date of disposition status:	03 Jul 2008.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7264-00002

Reasons	Preferred term (Verbatim term)	Relation to study agent	AE onset date AE end date (duration)
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Idiopathic ulcerative colitis)	Possible	30 Sep 2009 07 Nov 2009 (39 days)
SAE/ Permanent discontinuation of study agent due to AE	溶血性貧血 (Drug induced haemolytic anaemia)	Possible	30 Sep 2009 07 Nov 2009 (39 days)
SAE/ Permanent discontinuation of study agent due to AE	多発性関節炎 (Seronegative polyarthritis)	Probable	30 Sep 2009 07 Nov 2009 (39 days)
Permanent discontinuation of study agent due to AE	無力症 (Generalised weakness)	Unlikely	29 Oct 2009 07 Nov 2009 (10 days)

Baseline demographic information: 4[redacted]-year-old (DOB: 05 Sep [redacted]) Asian male. Weight: 55 kg; height: not provided.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history: Date of diagnosis: 20 May 2005. UC disease duration: 3.5 years.		
Prior/concomitant medication, route	**Start date**	**End date**
Balsalazide, oral	08 Apr 2007	Ongoing
Rifinah, oral	28 Sep 2008	12 Oct 2008
Isoniazid, oral	12 Oct 2008	Ongoing
Domperidone, oral	12 Oct 2008	22 Oct 2008
Colyte /00751601/, oral	20 Oct 2008	20 Oct 2008
Colyte /00751601/, oral	17 Dec 2008	17 Dec 2008
Balsalazide, oral	08 Apr 2008	01 Nov 2009
Isoniazid, oral	12 Oct 2008	20 May 2009
Pheniramine, intramuscular	13 Apr 2009	13 Apr 2009
Fexofenadine, oral	13 Apr 2009	19 Apr 2009
Colyte /00751601/, oral	21 Jul 2009	21 Jul 2009
Multivitamins with minerals /90003801/, oral	03 Aug 2009	Ongoing
Fleet enema /00129701/, oral	27 Sep 2009	27 Sep 2009
Paracetamol, oral	29 Oct 2009	02 Nov 2009
Cefonicide, intravenous	02 Nov 2009	07 Nov 2009
Ondansetron, intravenous	02 Nov 2009	07 Nov 2009
Pantoprazole, oral	02 Nov 2009	07 Nov 2009
Ultracet, oral	02 Nov 2009	07 Nov 2009
Paracetamol, oral	02 Nov 2009	07 Nov 2009
Balsalazide, oral	02 Nov 2009	08 Nov 2009
Balsalazide, oral	09 Nov 2009	Ongoing
Treatment group in induction: 400 mg → 200 mg SC. **Treatment group in maintenance:** Nonresponder to golimumab induction → received golimumab 100 mg maintenance. **Dose adjusted?** No.		

Treatment received:			
Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 31 Oct 2008 (Study Day -52)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 31 Oct 2008 (Study Day -52)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 31 Oct 2008 (Study Day -52)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 31 Oct 2008 (Study Day -52)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 19 Nov 2008 (Study Day -33)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 19 Nov 2008 (Study Day -33)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 2 (Ind), 19 Nov 2008 (Study Day -33)	Admin. 2/ Inj. 7	Golimumab	100 mg
Week 0 (Main), 22 Dec 2008 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 22 Dec 2008 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Main), 22 Dec 2008 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 19 Jan 2009 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 19 Jan 2009 (Study Day 29)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 4 (Main), 19 Jan 2009 (Study Day 29)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 18 Feb 2009 (Study Day 59)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 18 Feb 2009 (Study Day 59)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 18 Feb 2009 (Study Day 59)	Admin. 3/ Inj. 9	Golimumab	100 mg
Week 12 (Main), 16 Mar 2009 (Study Day 85)	Admin. 4/ Inj. 10	Golimumab	100 mg
Week 12 (Main), 16 Mar 2009 (Study Day 85)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 16 Mar 2009 (Study Day 85)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 13 Apr 2009 (Study Day 113)	Admin. 5/ Inj. 13	Golimumab	100 mg
Week 16 (Main), 13 Apr 2009 (Study Day 113)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 13 Apr 2009 (Study Day 113)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 11 May 2009 (Study Day 141)	Admin. 6/ Inj. 16	Placebo	0 mg
Week 20 (Main), 11 May 2009 (Study Day 141)	Admin. 6/ Inj. 17	Golimumab	100 mg
Week 20 (Main), 11 May 2009 (Study Day 141)	Admin. 6/ Inj. 18	Placebo	0 mg
Week 24 (Main), 09 Jun 2009 (Study Day 170)	Admin. 7/ Inj. 19	Placebo	0 mg
Week 24 (Main), 09 Jun 2009 (Study Day 170)	Admin. 7/ Inj. 20	Golimumab	100 mg
Week 24 (Main), 09 Jun 2009 (Study Day 170)	Admin. 7/ Inj. 21	Placebo	0 mg

Week 28 (Main), 06 Jul 2009 (Study Day 197)	Admin. 8/ Inj. 22	Golimumab	100 mg
Week 28 (Main), 06 Jul 2009 (Study Day 197)	Admin. 8/ Inj. 23	Placebo	0 mg
Week 28 (Main), 06 Jul 2009 (Study Day 197)	Admin. 8/ Inj. 24	Placebo	0 mg
Week 32 (Main), 03 Aug 2009 (Study Day 225)	Admin. 9/ Inj. 25	Placebo	0 mg
Week 32 (Main), 03 Aug 2009 (Study Day 225)	Admin. 9/ Inj. 26	Golimumab	100 mg
Week 32 (Main), 03 Aug 2009 (Study Day 225)	Admin. 9/ Inj. 27	Placebo	0 mg
Week 36 (Main), 31 Aug 2009 (Study Day 253)	Admin. 10/ Inj. 28	Placebo	0 mg
Week 36 (Main), 31 Aug 2009 (Study Day 253)	Admin. 10/ Inj. 29	Golimumab	100 mg
Week 36 (Main), 31 Aug 2009 (Study Day 253)	Admin. 10/ Inj. 30	Placebo	0 mg
Week 40 (Main), 30 Sep 2009 (Study Day 283)	Admin. 11/ Inj. 31	Placebo	0 mg
Week 40 (Main), 30 Sep 2009 (Study Day 283)	Admin. 11/ Inj. 32	Placebo	0 mg
Week 40 (Main), 30 Sep 2009 (Study Day 283)	Admin. 11/ Inj. 33	Golimumab	100 mg
Unscheduled 1 (Main)—dose not done	NA	NA	NA

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	30 Sep 2009.
Last scheduled study treatment visit in maintenance:	Week 40 (Main).
Date of study treatment discontinuation:	09 Nov 2009.

Study status:

Date of disposition status:	08 Feb 2010.
Ended study participation as of Week 54?	No.
Entered extension study?	No.

被験者識別コード：7354-00004

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Progression of ulcerative colitis)	Not related	04 May 2009 01 Jun 2009 (29 days)

Baseline demographic information: 6[redacted]-year-old (DOB: 10 May [redacted]) Caucasian male.
Weight: 82.8 kg; height: 178 cm.

Relevant medical history at baseline: 喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:

Date of diagnosis:	21 Apr 2005.
UC disease duration:	3.9 years.

Prior/concomitant medication, route	**Start date**	**End date**
Insulin aspart, subcutaneous	Prior	Ongoing
Insulin detemir, subcutaneous	Prior	Ongoing
Mesalazine, oral	15 Mar 2007	Ongoing
Prednisone, oral	04 May 2009	25 May 2009
Beclometasone, rectal	05 May 2009	13 Jul 2009
Calcium carbonate, oral	04 May 2009	08 Jul 2009
Mesalazine, rectal	05 May 2009	13 Jul 2009
Prednisone, intravenous	25 May 2009	01 Jun 2009

Treatment group in induction:	400 mg → 200 mg SC.
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:

Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 09 Mar 2009 (Study Day -42)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 09 Mar 2009 (Study Day -42)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 09 Mar 2009 (Study Day -42)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 09 Mar 2009 (Study Day -42)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 24 Mar 2009 (Study Day -27)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 2 (Ind), 24 Mar 2009 (Study Day -27)	Admin. 2/ Inj. 6	Golimumab	100 mg

Week 2 (Ind), 24 Mar 2009 (Study Day -27)	Admin. 2/ Inj. 7	Golimumab	100 mg
Week 0 (Main), 20 Apr 2009 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 20 Apr 2009 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 20 Apr 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Unscheduled 1 (Main)—dose not done	NA	NA	NA
Unscheduled 1 (Main)—dose not done	NA	NA	NA

Treatment status:

Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	20 Apr 2009.
Last scheduled study treatment visit in maintenance:	Week 0 (Main).
Date of study treatment discontinuation:	04 May 2009.

Study status:

Date of study discontinuation:	11 May 2009.
Reason for noncompletion:	Withdrawal of consent.
Date of disposition status:	11 May 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

被験者識別コード：7701-00002

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Not related	28 Jul 2009 04 Aug 2009 (8 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 21 Oct [redacted]) Caucasian male. Weight: 111 kg; height: 192 cm.

Relevant medical history at baseline: 関節痛，喫煙（過去）

Baseline smoking status: Prior smoker (stopped > 1 year ago).

Ulcerative colitis history:

Date of diagnosis:	10 Oct 1994.
UC disease duration:	14.3 years.

Prior/concomitant medication, route	**Start date**	**End date**
Paracetamol, oral	August 2007	Ongoing
Fentanyl, intravenous	14 Jan 2009	14 Jan 2009
Diphenhydramine, intravenous	14 Jan 2009	14 Jan 2009
Midazolam, intravenous	14 Jan 2009	14 Jan 2009
Prednisone, oral	August 2007	Ongoing
Mesalazine, oral	October 2007	Ongoing
Fentanyl, intravenous	11 Mar 2009	11 Mar 2009
Midazolam, intravenous	11 Mar 2009	11 Mar 2009
Methylprednisolone, intravenous	28 Jul 2009	29 Jul 2009
Sodium chloride, intravenous	29 Jul 2009	29 Jul 2009

Treatment group in induction:	400 mg → 200 mg SC.
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.
Dose adjusted?	No.

Treatment received:

Visit, Date (Study Day)	**Admin. /Inj. No.**	**Agent**	**Dose/Unit**
Week 0 (Ind), 28 Jan 2009 (Study Day -42)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 28 Jan 2009 (Study Day -42)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 28 Jan 2009 (Study Day -42)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 28 Jan 2009 (Study Day -42)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 11 Feb 2009 (Study Day -28)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 11 Feb 2009 (Study Day -28)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 2 (Ind), 11 Feb 2009 (Study Day -28)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 11 Mar 2009 (Study Day 1)	Admin. 1/ Inj. 1	Placebo	0 mg
Week 0 (Main), 11 Mar 2009 (Study Day 1)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Main), 11 Mar 2009 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg

Week 4 (Main), 08 Apr 2009 (Study Day 29)	Admin. 2/ Inj. 4	Placebo	0 mg
Week 4 (Main), 08 Apr 2009 (Study Day 29)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 08 Apr 2009 (Study Day 29)	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 8 (Main), 06 May 2009 (Study Day 57)	Admin. 3/ Inj. 7	Placebo	0 mg
Week 8 (Main), 06 May 2009 (Study Day 57)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 06 May 2009 (Study Day 57)	Admin. 3/ Inj. 9	Golimumab	100 mg
Week 12 (Main), 03 Jun 2009 (Study Day 85)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 03 Jun 2009 (Study Day 85)	Admin. 4/ Inj. 11	Golimumab	100 mg
Week 12 (Main), 03 Jun 2009 (Study Day 85)	Admin. 4/ Inj. 12	Placebo	0 mg
Week 16 (Main), 01 Jul 2009 (Study Day 113)	Admin. 5/ Inj. 13	Placebo	0 mg
Week 16 (Main), 01 Jul 2009 (Study Day 113)	Admin. 5/ Inj. 14	Golimumab	100 mg
Week 16 (Main), 01 Jul 2009 (Study Day 113)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main)—dose not done	NA	NA	NA
Treatment status:			
Study treatment discontinuation?	Yes.		
Reason for treatment discontinuation:	Adverse event.		
Date of last study agent administration in maintenance:	01 Jul 2009.		
Last scheduled study treatment visit in maintenance:	Week 16 (Main).		
Date of study treatment discontinuation:	28 Jul 2009.		
Study status:			
Date of study discontinuation:	30 Jul 2009.		
Reason for noncompletion:	Withdrawal of consent.		
Date of disposition status:	30 Jul 2009.		
Ended study participation as of Week 54?	Yes.		
Entered extension study?	No.		

被験者識別コード：7703-00001

Reasons	**Preferred term (Verbatim term)**	**Relation to study agent**	**AE onset date AE end date (duration)**
SAE/ Permanent discontinuation of study agent due to AE	潰瘍性大腸炎 (Worsening of ulcerative colitis)	Not related	28 Jan 2009 23 Feb 2009 (27 days)

Baseline demographic information: 3[redacted]-year-old (DOB: 12 Jul [redacted]) Caucasian female.
Weight: 74 kg; height: 168 cm.

Relevant medical history at baseline: 報告なし

Baseline smoking status: Not reported.

Ulcerative colitis history:
Date of diagnosis: February 1998.
UC disease duration: 9.8 years.

Prior/concomitant medication, route	**Start date**	**End date**
Cirrus, oral	1997	Ongoing
Evra, transdermal	2001	Ongoing
Zolpidem tartrate, oral	May 2007	09 Jan 2008
Paracetamol, oral	1990	Ongoing
Multivitamins w/minerals, oral	April 2007	Ongoing
Temazepam, oral	Prior	Ongoing
Propofol, intravenous	07 Dec 2007	07 Dec 2007
Midazolam hydrochloride, intravenous	07 Dec 2007	07 Dec 2007
Mesalazine, oral	February 1998	Ongoing
Magnesium citrate, oral	07 Dec 2007	07 Dec 2007
Propofol, intravenous	29 Jan 2008	29 Jan 2008
Midazolam hydrochloride, intravenous	29 Jan 2008	29 Jan 2008
Mesalazine, oral	Prior	Ongoing
Paracetamol, oral	Prior	Ongoing
Cirrus, oral	Prior	Ongoing
Evra, transdermal	Prior	Ongoing
Multivitamins w/minerals, oral	Prior	Ongoing
Clindamycin, oral	28 Aug 2008	29 Aug 2008

Clindamycin, oral	30 Aug 2008	02 Sep 2008
Vicodin, oral	28 Aug 2008	01 Sep 2008
Bisacodyl, oral	03 Oct 2008	03 Oct 2008
Magnesium citrate, oral	28 Jan 2009	28 Jan 2009
Prednisone, oral	30 Jan 2009	Ongoing
Clonazepam, oral	03 Feb 2009	Ongoing
Midazolam, intravenous	29 Jan 2009	29 Jan 2009
Propofol, intravenous	29 Jan 2009	29 Jan 2009
Treatment group in induction:	400 mg →200 mg SC.	
Treatment group in maintenance:	Nonresponder to golimumab induction → received golimumab 100 mg maintenance.	
Dose adjusted?	No.	

Treatment received:

Visit, Date (Study Day)	Admin. /Inj. No.	Agent	Dose/Unit
Week 0 (Ind), 19 Dec 2007 (Study Day -41)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Ind), 19 Dec 2007 (Study Day -41)	Admin. 1/ Inj. 2	Golimumab	100 mg
Week 0 (Ind), 19 Dec 2007 (Study Day -41)	Admin. 1/ Inj. 3	Golimumab	100 mg
Week 0 (Ind), 19 Dec 2007 (Study Day -41)	Admin. 1/ Inj. 4	Golimumab	100 mg
Week 2 (Ind), 03 Jan 2008 (Study Day -26	Admin. 2/ Inj. 6	Golimumab	100 mg
Week 2 (Ind), 03 Jan 2008 (Study Day -26)	Admin. 2/ Inj. 5	Golimumab	100 mg
Week 2 (Ind), 03 Jan 2008 (Study Day -26)	Admin. 2/ Inj. 7	Placebo	0 mg
Week 0 (Main), 29 Jan 2008 (Study Day 1)	Admin. 1/ Inj. 1	Golimumab	100 mg
Week 0 (Main), 29 Jan 2008 (Study Day 1)	Admin. 1/ Inj. 2	Placebo	0 mg
Week 0 (Main), 29 Jan 2008 (Study Day 1)	Admin. 1/ Inj. 3	Placebo	0 mg
Week 4 (Main), 28 Feb 2008 (Study Day 31)	Admin. 2/ Inj. 4	Golimumab	100 mg
Week 4 (Main), 28 Feb 2008 (Study Day 31)	Admin. 2/ Inj. 5	Placebo	0 mg
Week 4 (Main), 28 Feb 2008 (Study Day 31)	Admin. 2/ Inj. 6	Placebo	0 mg
Week 8 (Main), 26 Mar 2008 (Study Day 58)	Admin. 3/ Inj. 7	Golimumab	100 mg
Week 8 (Main), 26 Mar 2008 (Study Day 58)	Admin. 3/ Inj. 8	Placebo	0 mg
Week 8 (Main), 26 Mar 2008 (Study Day 58)	Admin. 3/ Inj. 9	Placebo	0 mg
Week 12 (Main), 23 Apr 2008 (Study Day 86)	Admin. 4/ Inj. 10	Placebo	0 mg
Week 12 (Main), 23 Apr 2008 (Study Day 86)	Admin. 4/ Inj. 11	Placebo	0 mg
Week 12 (Main), 23 Apr 2008 (Study Day 86)	Admin. 4/ Inj. 12	Golimumab	100 mg
Week 16 (Main), 21 May 2008 (Study Day 114)	Admin. 5/ Inj. 13	Golimumab	100 mg
Week 16 (Main), 21 May 2008 (Study Day 114)	Admin. 5/ Inj. 14	Placebo	0 mg
Week 16 (Main), 21 May 2008 (Study Day 114)	Admin. 5/ Inj. 15	Placebo	0 mg
Week 20 (Main), 18 Jun 2008 (Study Day 142)	Admin. 6/ Inj. 16	Golimumab	100 mg
Week 20 (Main), 18 Jun 2008 (Study Day 142)	Admin. 6/ Inj. 17	Placebo	0 mg
Week 20 (Main), 18 Jun 2008 (Study Day 142)	Admin. 6/ Inj. 18	Placebo	0 mg
Week 24 (Main), 16 Jul 2008 (Study Day 170)	Admin. 7/ Inj. 19	Placebo	0 mg
Week 24 (Main), 16 Jul 2008 (Study Day 170)	Admin. 7/ Inj. 20	Golimumab	100 mg
Week 24 (Main), 16 Jul 2008 (Study Day 170)	Admin. 7/ Inj. 21	Placebo	0 mg
Week 28 (Main), 13 Aug 2008 (Study Day 198)	Admin. 8/ Inj. 22	Placebo	0 mg
Week 28 (Main), 13 Aug 2008 (Study Day 198)	Admin. 8/ Inj. 23	Golimumab	100 mg
Week 28 (Main), 13 Aug 2008 (Study Day 198)	Admin. 8/ Inj. 24	Placebo	0 mg
Week 32 (Main), 16 Sep 2008 (Study Day 232)	Admin. 9/ Inj. 25	Golimumab	100 mg
Week 32 (Main), 16 Sep 2008 (Study Day 232)	Admin. 9/ Inj. 26	Placebo	0 mg
Week 32 (Main), 16 Sep 2008 (Study Day 232)	Admin. 9/ Inj. 27	Placebo	0 mg
Week 36 (Main), 08 Oct 2008 (Study Day 254)	Admin. 10/ Inj. 28	Golimumab	100 mg
Week 36 (Main), 08 Oct 2008 (Study Day 254)	Admin. 10/ Inj. 29	Placebo	0 mg
Week 36 (Main), 08 Oct 2008 (Study Day 254)	Admin. 10/ Inj. 30	Placebo	0 mg
Week 40 (Main), 05 Nov 2008 (Study Day 282)	Admin. 11/ Inj. 31	Placebo	0 mg
Week 40 (Main), 05 Nov 2008 (Study Day 282)	Admin. 11/ Inj. 32	Placebo	0 mg
Week 40 (Main), 05 Nov 2008 (Study Day 282)	Admin. 11/ Inj. 33	Golimumab	100 mg
Week 44 (Main), 03 Dec 2008 (Study Day 310)	Admin. 12/ Inj. 34	Placebo	0 mg
Week 44 (Main), 03 Dec 2008 (Study Day 310)	Admin. 12/ Inj. 35	Golimumab	100 mg
Week 44 (Main), 03 Dec 2008 (Study Day 310)	Admin. 12/ Inj. 36	Placebo	0 mg
Week 48 (Main), 05 Jan 2009 (Study Day 343)	Admin. 13/ Inj. 37	Placebo	0 mg
Week 48 (Main), 05 Jan 2009 (Study Day 343)	Admin. 13/ Inj. 38	Golimumab	100 mg

Week 48 (Main), 05 Jan 2009 (Study Day 343)	Admin. 13/ Inj. 39	Placebo	0 mg
Week 52 (Main)—dose not done	NA	NA	NA

Treatment status:	
Study treatment discontinuation?	Yes.
Reason for treatment discontinuation:	Adverse event.
Date of last study agent administration in maintenance:	05 Jan 2009.
Last scheduled study treatment visit in maintenance:	Week 48 (Main).
Date of study treatment discontinuation:	30 Jan 2009.
Study status:	
Date of study discontinuation:	30 Jan 2009.
Reason for noncompletion:	Other.
Other reason for noncompletion/details:	Worsening of disease.
Date of disposition status:	30 Jan 2009.
Ended study participation as of Week 54?	Yes.
Entered extension study?	No.

2.7.6.4.2　C0524T18 試験（継続投与試験）（評価資料：5.3.5.1.3-2）

実施期間：2007 年 9 月 ■日～2015 年 2 月 ■日

試験の目的：

継続投与試験の目的は，54 週間の寛解維持試験を完了し継続投与試験に組み入れられた，中等症から重症の活動期潰瘍性大腸炎（以下 UC）患者を対象に，更に 3 年間ゴリムマブを投与したときの有効性，薬物動態及び安全性を評価することであった。

試験方法：

本継続投与試験では，52 週までの投与を完了し，54 週での有効性及び安全性の評価を完了した被験者のうち，治験担当医師により継続投与で効果が得られると判断された被験者を参加可能とした。寛解維持試験［プラセボ，ゴリムマブ 50 mg，100 mg 又は 200 mg（治験実施計画書 改訂 3 版発行後に 200 mg を投与していた被験者には 100 mg へ減量）］の 52 週と同じ用量を，56 週から 212 週まで継続投与し，治験薬の最終投与から 16 週後の 228 週に安全性を最終評価した。寛解維持試験の盲検性は，継続投与試験開始後においても，寛解維持試験の最後の被験者が 54 週の評価を完了し，54 週の解析が完了するまで維持された。プラセボを投与されていた被験者は，開鍵後に試験を中止したため，追跡期間が短かった。

継続投与試験中に，UC の疾患活動性が悪化したと治験担当医師が判断した場合，以下のように治験薬を 1 回だけ増量可能とした。

- ゴリムマブ 50 mg を 4 週ごとに投与していた被験者には，ゴリムマブ 100 mg を 4 週ごとに投与可能とした。
- ゴリムマブ 100 mg を 4 週ごとに投与していた被験者には，治験実施計画書 改訂 3 版の発行後，増量不可とした。
- プラセボを 4 週ごとに投与していた被験者には，ゴリムマブ 100 mg を 4 週ごとに投与可能とした。

用量調節後の初回投与後 16 週までに UC の疾患活動性に改善が認められないと治験担当医師が判断した場合は，当該被験者への治験薬投与を中止した。

<u>対象患者集団</u>

寛解導入試験［C0524T16 試験（以下 T16 試験）又は C0524T17 試験（以下 T17 試験）］のゴリムマブ群で 6 週に clinical response が認められた中等症から重症の活動期 UC 患者を，寛解維持試験の 0 週にランダムに割り付けた。

「投与被験者」は，以下のとおり構成された。

- 寛解維持試験の 0 週にランダム割付けされた被験者
- 寛解維持試験の 0 週にランダム割付けされなかった被験者
    - 寛解導入試験（T16 試験又は T17 試験）の 6 週にプラセボにより clinical response が認められた被験者（以下プラセボ寛解導入 responder）

・ 寛解導入試験（T16 試験又は T17 試験）の 6 週にプラセボにより clinical response を認めなかった被験者（以下プラセボ寛解導入 non-responder）又はゴリムマブにより clinical response を認めなかった被験者（以下ゴリムマブ寛解導入 non-responder）

被験者数：

計画時

本継続投与試験では，52 週までの投与を完了し，54 週の有効性及び安全性の評価を完了した被験者のうち，治験担当医師により継続投与で効果が得られると判断された被験者を参加可能とした。

解析時

寛解維持試験の 0 週にランダム割付けされた被験者 464 例及びランダム割付けされなかった 764 例のうち，継続投与試験で治験薬を投与された被験者は 666 例であった。試験結果の項で詳述する。

診断及び主な組入れ基準：

52 週までの投与を完了し，54 週の有効性及び安全性の評価を完了した被験者のうち，治験担当医師により継続投与で効果が得られると判断された被験者を，継続投与試験に参加可能とした。

投与期間：

寛解維持試験の投与期間は 52 週間であった。継続投与試験では 56 週から 212 週まで投与した。

評価：

薬物動態及び免疫原性

血清中ゴリムマブ濃度並びに抗ゴリムマブ抗体及び中和抗体

有効性

Physician’s Global Assessment（以下 PGA），コルチコステロイドの使用の変更，C-反応性たんぱく（以下 CRP），Inflammatory Bowel Disease Questionnaire（以下 IBDQ）

安全性

バイタルサイン，身体所見（皮膚所見を含む），臨床検査，有害事象，抗核抗体及び抗 dsDNA 抗体，結核（以下 TB）検査，妊娠検査（治験担当医師又は被験者が必要と判断した場合）

なお，有害事象名は MedDRA ver.17.1 を用いてコーディングした。また，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」又は不明の有害事象を治験薬の使用と関連性のある有害事象とした。

統計手法：

人口統計学的特性及びベースラインの疾患特性，有効性並びに安全性の解析は，継続投与試験で 1 回以上治験薬を投与されたすべての被験者を対象とした。連続変数の要約には記述統計量

（例：平均値，中央値，標準偏差，四分位範囲，最小値及び最大値）を用いた。カテゴリー変数の要約には計数及びパーセンテージを用いた。

薬物動態及び免疫原性

薬物動態は，寛解維持試験でランダム割付けされた被験者及び投与被験者ごとに要約した。免疫原性（抗ゴリムマブ抗体）は，継続投与試験の投与被験者を対象として要約した。

有効性

有効性は，寛解維持試験の 0 週にランダム割付けされた被験者及び投与被験者を対象としてそれぞれ解析し，要約した。

安全性

安全性は，投与被験者を対象として解析し，要約した。

試験結果：

対象患者集団

寛解維持試験の 0 週にランダム割付けされた 464 例は，継続投与試験で以下のように投与を継続した。

- プラセボにランダム割付けされた被験者 156 例のうち，継続投与試験では 103 例に治験薬が投与された。
- ゴリムマブ 50 mg にランダム割付けされた被験者 154 例のうち，継続投与試験では 100 例に治験薬が投与された。
- ゴリムマブ 100 mg にランダム割付けされた被験者 154 例のうち，継続投与試験では 100 例に治験薬が投与された。

寛解維持試験の 0 週にランダム割付けされなかった被験者 764 例は，継続投与試験で以下のように投与を継続した。

- プラセボ寛解導入 responder であり，プラセボが継続して投与された被験者 129 例のうち，継続投与試験では 78 例に治験薬が投与された。
- プラセボ寛解導入 non-responder であり，ゴリムマブ 100 mg が投与された被験者 230 例のうち，継続投与試験では 113 例に治験薬が投与された。
- ゴリムマブ寛解導入 non-responder であり，ゴリムマブ 100 mg が投与された被験者 405 例のうち，継続投与試験では 172 例に治験薬が投与された。

寛解維持試験の 0 週にランダム割付けされた被験者及びランダム割付けされなかった被験者で継続投与試験に移行した被験者を，「継続投与試験の投与被験者」とした。56 週より前の用量調節に基づく被験者の内訳は，以下のとおりである。

- プラセボ群：96 例
    - ゴリムマブ寛解導入 responder であり，寛解維持試験の 0 週にプラセボにランダム割付けされた被験者：52 例

・ プラセボ寛解導入 responder（ランダム割付けされなかった被験者）であり，寛解維持試験でプラセボを投与された被験者：44 例

・ 50 mg 群：93 例

・ ゴリムマブ寛解導入 responder であり，寛解維持試験の 0 週にゴリムマブ 50 mg にランダム割付けされ，増量されなかった被験者：93 例

・ 100 mg 群：477 例

・ ゴリムマブ寛解導入 responder であり，寛解維持試験の 0 週にゴリムマブ 100 mg にランダム割付けされ，増量されなかった被験者：91 例

・ ゴリムマブ寛解導入 responder であり，寛解維持試験の 0 週にプラセボ又はゴリムマブ 50 mg にランダム割付けされ，継続投与試験の前に 100 mg に増量された被験者：58 例

・ ゴリムマブ寛解導入 responder であり，寛解維持試験の 0 週にゴリムマブ 100 mg にランダム割付けされ，継続投与試験の前に 200 mg に増量後，治験実施計画書 改訂 3 版発行後に 100 mg に減量された被験者：9 例

・ プラセボ寛解導入 responder であり，継続投与試験の前に 100 mg に増量された被験者：34 例

・ ランダム割付けされなかったプラセボ寛解導入 non-responder であり，ゴリムマブ 100 mg を投与された被験者：113 例

・ ランダム割付けされなかったゴリムマブ寛解導入 non-responder であり，ゴリムマブ 100 mg を投与された被験者：172 例

継続投与試験で治験薬を投与された 666 例のうち，43.8%（292/666 例）［（プラセボ群 83.3%（80/96 例），併合ゴリムマブ群 37.2%（212/570 例）］が治験薬投与を中止した。

・ 併合ゴリムマブ群の 10.9%（62/570 例）及びプラセボ群の 10.4%（10/96 例）が，「有害事象」により治験薬投与を中止した。

・ 併合ゴリムマブ群の 7.4%（42/570 例）及びプラセボ群の 5.2%（5/96 例）が，「効果不十分」により治験薬投与を中止した。

・ 併合ゴリムマブ群の 17.7%（101/570 例）及びプラセボ群の 65.6%（63/96 例）が，「その他」により治験薬投与を中止した。

継続投与試験で治験薬を投与された 666 例のうち，19.7%（131/666 例）［プラセボ群 33.3%（32/96 例），50 mg 群 14.0%（13/93 例）及び 100 mg 群 18.0%（86/477 例）］が試験を中止した。継続投与試験で最も高頻度にみられた試験中止理由は，「同意撤回」及び「その他」であった。

投与被験者の人口統計学的特性，ベースラインの疾患特性及び UC 治療薬を併用していた被験者の割合は，寛解維持試験でランダム割付けされた被験者とおおむね同様であった。

継続投与試験で治験薬を投与された被験者のうち，8.7%（58/666 例）は以下のように増量した。

・ 継続投与試験でプラセボを投与された被験者のうち，30.2%（29/96 例）がゴリムマブ 100 mg を 4 週ごとに投与された。

・ 継続投与試験でゴリムマブ 50 mg を 4 週ごとに投与された被験者のうち，20.4%（19/93 例）が 100 mg に増量し 4 週ごとに投与された。

・ 継続投与試験でゴリムマブ 100 mg を 4 週ごとに投与された被験者のうち，2.1%（10/477 例）が 200 mg に増量し 4 週ごとに投与された。

薬物動態及び免疫原性

・ ゴリムマブ 50 mg 又は 100 mg を 4 週ごとに 212 週まで投与された被験者で，定常状態時の血清中ゴリムマブのトラフ濃度は維持された。

・ ゴリムマブ 50 mg 又は 100 mg の 4 週ごとの皮下投与による寛解維持療法において，血清中ゴリムマブ濃度は，用量にほぼ比例していた。継続投与試験中の血清中ゴリムマブ濃度は，大部分の被験者で定量可能であった。

・ 継続投与試験で抗ゴリムマブ抗体が陽性であった被験者の割合は，ゴリムマブ 50 mg を投与された被験者［4.4%（4/90 例）］とゴリムマブ 100 mg を投与された被験者［3.7%（19/514 例）］で同様であった。

・ 継続投与試験で抗ゴリムマブ抗体が陽性で中和抗体評価用の検体が適切に得られた 22 例のうち，18/22 例（81.8%）が中和抗体陽性であった。

有効性

寛解維持試験の 0 週にランダム割付けされ，継続投与試験で 212 週までゴリムマブを投与された被験者において：

・ 54 週の PGA スコアが疾患活動性なし又は軽度であった被験者の割合［90%以上（177/195 例）は，継続投与試験の 216 週まで維持された。

・ 54 週の CRP 濃度の中央値（約 1.5 mg/L）は，継続投与試験の 216 週まで維持された。

・ 56 週の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［約 88%（170/194 例）］は，継続投与試験の 216 週まで維持された。

・ 54 週の IBDQ スコアが 170 以上であった被験者の割合［約 73%（140/193 例）］は，継続投与試験の 216 週まで維持された。

継続投与試験のゴリムマブ投与被験者においても，同様のパターンが認められた。

安全性

継続投与試験でのゴリムマブ 50 mg 又は 100 mg の 4 週ごとの皮下投与による寛解維持療法では，おおむね良好な忍容性が認められた。

有害事象及び重篤な有害事象

全投与被験者：

・ 有害事象を発現した被験者の割合は，いずれのゴリムマブ群でも同様であったが，プラセボ群と比較してやや高かった。しかしながら，プラセボ群は開鍵後に継続投与試験が中止されたことから，プラセボ群の追跡期間は顕著に短かった。

・ 各投与群で最も高頻度に認められた有害事象はいずれも UC であり，プラセボ群 20.8%（20/96 例），50 mg 群 19.1%（18/94 例）及び 100 mg 群 26.9%（141/524 例）であった。

・ 治験薬の投与中止に至った有害事象の発現割合，治験担当医師により感染症と判断された有害事象及び重篤な有害事象は，総じてプラセボ群及び 50 mg 群と比較し 100 mg 群で高かった。

・ 重篤な有害事象が認められた被験者の割合は，プラセボ群及び 50 mg 群と比較し 100 mg 群で高かった。

・ 各投与群で最も高頻度に認められた重篤な有害事象はいずれも UC であり，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）であった。

・ 投与群間の追跡期間の差を調整するために，追跡期間 100 人年あたりの有害事象の発現率を算出した。このうち，治験担当医師により感染症と判断された有害事象の発現率は，50 mg 群及びプラセボ群と比較し 100 mg 群で高かった。一方で，有害事象，重篤な有害事象，治験担当医師により感染症と判断された重篤な有害事象及び治験薬の投与中止に至った有害事象の発現率は，50 mg 群と比較し 100 mg 群で数値的に高かったが，信頼区間は重なっていた。併合ゴリムマブ群とプラセボ群でも，おおむね同様のパターンが認められた。

<u>他の重要な有害事象及び注目すべき有害事象</u>

全投与被験者：

・ 継続投与試験で，死亡は 9 例認められた。9 例には，心不全及び呼吸不全が認められたプラセボ群の被験者 1 例，寛解維持試験を完了したが継続投与試験で治験薬を投与されなかった 50 mg 群の被験者で認められた両心室機能不全 1 例が含まれる。ほかの 7 例は 100 mg 群の被験者であった。死因の内訳は，心筋梗塞，胆嚢癌，結腸直腸癌 2 例，敗血症，偶発的な亜酸化窒素の過量投与，結腸切除後の誤嚥であった。

・ 追跡期間 100 人年あたりの死亡の発現率は，継続投与試験のプラセボ群とゴリムマブ群で同程度であった。また，54 週までと比較し，継続投与試験でのゴリムマブ継続投与により発現率の上昇は認められなかった。

・ 継続投与試験で，悪性腫瘍は 13 例で 14 件認められた。悪性腫瘍の内訳は，非黒色腫皮膚癌［以下 NMSC，5 件：50 mg 群 1 例及び 100 mg 群 3 例（うち 1 例で 2 件発現）］，リンパ腫（2 件：100 mg 群 2 例）及び固形癌（7 件：50 mg 群 2 例及び 100 mg 群 5 例）であった。

・ NMSC を含むすべての悪性腫瘍の追跡期間 100 人年あたりの発現率は，継続投与試験のゴリムマブ群間で同程度であった。

・ NMSC を除く悪性腫瘍の発現割合は，ゴリムマブ群間で同様であり，監視疫学遠隔成績に基づいて予想した一般的な UC 患者集団での発現割合と同様であった。

・ 継続投与試験で，4 例に活動性 TB（肺結核 3 例及び肺外結核 1 例）が認められた。すべての被験者がゴリムマブ 100 mg を投与されており，TB 流行地域に居住していた。すべての被験者が適切に治療され，入手可能な最新の追跡調査結果で肺結核 3 例の回復が確認された。

・ 継続投与試験で，日和見感染は 3 件（レジオネラ菌性肺炎，水痘帯状疱疹ウイルス性髄膜炎，サイトメガロウイルス一次感染，100 mg 群で各 1 例）が重篤な有害事象として報告された。すべての被験者が治療され回復した。

・ 継続投与試験で，中枢神経系脱髄疾患は 2 例（いずれも 100 mg 群）で 2 件（脱髄及び多発性硬化症）認められた。

・ 継続投与試験で，ゴリムマブ投与による注射部位反応は高頻度に認められた。重篤な注射部位反応又はアナフィラキシー反応若しくは血清病様反応の事象は認められなかった。非重篤の薬物過敏症反応 1 件が 100 mg 群の被験者 1 例で認められた。

臨床検査

血液学的検査及び血液生化学検査の顕著な異常変動に，投与群間に特筆すべき差はほぼ認められなかった。

試験の限界（Study limitations）

継続投与試験の結果の解釈にはいくつかの限界がある。第一に，選択バイアスが結果に影響を及ぼした可能性がある。継続投与試験に参加した被験者は，54 週間の寛解維持試験を完了し，治験担当医師により継続投与で効果が得られると判断された被験者である。したがって，初めの 1 年でゴリムマブに対する反応性及び忍容性が得られた被験者への継続投与に関する所見を一般化するには限界がある。第二に，継続投与試験のプラセボ群の被験者数は限定されており，プラセボ群の追跡期間は短く，特に低頻度の安全性事象においては，ゴリムマブ群とプラセボ群を直接比較することには限界がある。加えて，継続投与試験のプラセボ群は，ゴリムマブ寛解導入 responder で長期にわたって効果が維持された被験者，又は有効性及びおそらく安全性もゴリムマブ群との比較に限界があるプラセボ寛解導入 responder で長期にわたって効果が維持された（疾患活動性が長期にわたって潜在化した）被験者である。さらに，有効性評価は Mayo スコアの PGA サブスコアを使用し，寛解維持試験時の Mayo スコアの総スコアに基づく clinical response 又は clinical remission を使用しなかった。最後に，炎症性バイオマーカーの評価による患者の疾患活動性の確認には，CRP のみを使用した。

結論

寛解維持試験の 52 週の治験薬投与により反応性が得られ，更に 3 年間 4 週ごとにゴリムマブを皮下投与した中等症から重症の活動期 UC 患者において，以下の事項が確認された。

・ PGA により定義した臨床的な効果の維持

・ コルチコステロイド非投与下での臨床的な効果の持続

・ IBDQ により評価した，健康に関する QOL の改善の維持

・ 最新の SIMPONI の添付文書に記載されている安全性プロファイルとの一致

表 2.7.6.4-9 すべての有害事象（継続投与試験の投与被験者）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	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 adverse events	52 (54.2%)	72 (76.6%)	416 (79.4%)	479 (80.0%)
System-organ class/preferred term				
感染症および寄生虫症	28 (29.2%)	44 (46.8%)	294 (56.1%)	335 (55.9%)
鼻咽頭炎	5 (5.2%)	11 (11.7%)	84 (16.0%)	95 (15.9%)
上気道感染	4 (4.2%)	6 (6.4%)	46 (8.8%)	51 (8.5%)
副鼻腔炎	3 (3.1%)	6 (6.4%)	43 (8.2%)	49 (8.2%)
インフルエンザ	3 (3.1%)	9 (9.6%)	38 (7.3%)	47 (7.8%)
胃腸炎	0	5 (5.3%)	28 (5.3%)	33 (5.5%)
咽頭炎	1 (1.0%)	6 (6.4%)	24 (4.6%)	30 (5.0%)
気管支炎	1 (1.0%)	4 (4.3%)	24 (4.6%)	28 (4.7%)
口腔ヘルペス	1 (1.0%)	1 (1.1%)	25 (4.8%)	26 (4.3%)
帯状疱疹	0	1 (1.1%)	17 (3.2%)	18 (3.0%)
尿路感染	2 (2.1%)	3 (3.2%)	15 (2.9%)	18 (3.0%)
ウイルス感染	2 (2.1%)	3 (3.2%)	12 (2.3%)	15 (2.5%)
ウイルス性上気道感染	1 (1.0%)	1 (1.1%)	13 (2.5%)	14 (2.3%)
ウイルス性胃腸炎	0	2 (2.1%)	11 (2.1%)	13 (2.2%)
肺炎	2 (2.1%)	2 (2.1%)	9 (1.7%)	11 (1.8%)
鼻炎	1 (1.0%)	2 (2.1%)	7 (1.3%)	9 (1.5%)
結膜炎	0	3 (3.2%)	5 (1.0%)	8 (1.3%)
毛包炎	0	1 (1.1%)	7 (1.3%)	8 (1.3%)
麦粒腫	0	1 (1.1%)	6 (1.1%)	7 (1.2%)
喉頭炎	3 (3.1%)	2 (2.1%)	5 (1.0%)	7 (1.2%)
扁桃炎	1 (1.0%)	2 (2.1%)	5 (1.0%)	7 (1.2%)
外陰部腟カンジダ症	0	1 (1.1%)	6 (1.1%)	7 (1.2%)
急性副鼻腔炎	0	1 (1.1%)	5 (1.0%)	6 (1.0%)
下気道感染	1 (1.0%)	1 (1.1%)	5 (1.0%)	6 (1.0%)
爪真菌症	0	2 (2.1%)	4 (0.8%)	6 (1.0%)
気道感染	0	1 (1.1%)	5 (1.0%)	6 (1.0%)
歯膿瘍	0	1 (1.1%)	5 (1.0%)	6 (1.0%)
肛門膿瘍	0	0	5 (1.0%)	5 (0.8%)
耳感染	0	2 (2.1%)	3 (0.6%)	5 (0.8%)
単純ヘルペス	1 (1.0%)	2 (2.1%)	3 (0.6%)	5 (0.8%)
足部白癬	0	0	5 (1.0%)	5 (0.8%)
外陰腟真菌感染	0	0	5 (1.0%)	5 (0.8%)
クロストリジウム・ディフィシレ感染	0	0	4 (0.8%)	4 (0.7%)
膀胱炎	0	0	4 (0.8%)	4 (0.7%)
中耳炎	1 (1.0%)	1 (1.1%)	3 (0.6%)	4 (0.7%)
レンサ球菌性咽頭炎	0	0	4 (0.8%)	4 (0.7%)
ウイルス性気道感染	0	1 (1.1%)	3 (0.6%)	4 (0.7%)
皮膚感染	0	1 (1.1%)	3 (0.6%)	4 (0.7%)
白癬感染	0	0	4 (0.8%)	4 (0.7%)
癜風	0	0	4 (0.8%)	4 (0.7%)
急性扁桃炎	0	0	3 (0.6%)	3 (0.5%)
蜂巣炎	1 (1.0%)	1 (1.1%)	2 (0.4%)	3 (0.5%)
感染性腸炎	0	0	3 (0.6%)	3 (0.5%)
精巣上体炎	0	0	3 (0.6%)	3 (0.5%)
眼感染	0	1 (1.1%)	2 (0.4%)	3 (0.5%)
真菌感染	1 (1.0%)	0	3 (0.6%)	3 (0.5%)
歯肉炎	0	0	3 (0.6%)	3 (0.5%)
限局性感染	0	0	3 (0.6%)	3 (0.5%)
肺結核	0	0	3 (0.6%)	3 (0.5%)
四肢膿瘍	0	0	2 (0.4%)	2 (0.3%)
虫垂炎	0	0	2 (0.4%)	2 (0.3%)

表 2.7.6.4-9 すべての有害事象（継続投与試験の投与被験者）（続き）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
細菌感染	0	0	2 (0.4%)	2 (0.3%)
カンジダ感染	0	0	2 (0.4%)	2 (0.3%)
エンテロウイルス感染	0	0	2 (0.4%)	2 (0.3%)
消化管感染	0	0	2 (0.4%)	2 (0.3%)
ジアルジア症	0	0	2 (0.4%)	2 (0.3%)
膿痂疹	0	0	2 (0.4%)	2 (0.3%)
感染性皮膚嚢腫	0	0	2 (0.4%)	2 (0.3%)
ウイルス性髄膜炎	0	0	2 (0.4%)	2 (0.3%)
外耳炎	0	0	2 (0.4%)	2 (0.3%)
爪囲炎	0	0	2 (0.4%)	2 (0.3%)
歯周炎	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
毛巣嚢胞	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
処置後感染	0	0	2 (0.4%)	2 (0.3%)
ブドウ球菌感染	0	0	2 (0.4%)	2 (0.3%)
皮下組織膿瘍	0	0	2 (0.4%)	2 (0.3%)
股部白癬	0	0	2 (0.4%)	2 (0.3%)
尿道炎	0	0	2 (0.4%)	2 (0.3%)
腟感染	0	0	2 (0.4%)	2 (0.3%)
ウイルス性咽頭炎	0	0	2 (0.4%)	2 (0.3%)
真菌性肛門感染	0	1 (1.1%)	0	1 (0.2%)
細菌性敗血症	0	0	1 (0.2%)	1 (0.2%)
ブラストシスティス感染	0	0	1 (0.2%)	1 (0.2%)
ボルデテラ感染	0	0	1 (0.2%)	1 (0.2%)
ボレリア感染	0	0	1 (0.2%)	1 (0.2%)
ウイルス性気管支炎	0	0	1 (0.2%)	1 (0.2%)
カンピロバクター胃腸炎	0	0	1 (0.2%)	1 (0.2%)
クラミジア感染	0	0	1 (0.2%)	1 (0.2%)
ウイルス性結膜炎	0	1 (1.1%)	0	1 (0.2%)
サイトメガロウイルス感染	0	0	1 (0.2%)	1 (0.2%)
憩室炎	0	0	1 (0.2%)	1 (0.2%)
細菌性耳感染	0	0	1 (0.2%)	1 (0.2%)
真菌性耳感染	0	0	1 (0.2%)	1 (0.2%)
脳炎	0	0	1 (0.2%)	1 (0.2%)
蟯虫症	0	0	1 (0.2%)	1 (0.2%)
丹毒	0	0	1 (0.2%)	1 (0.2%)
遊走性紅斑	0	1 (1.1%)	0	1 (0.2%)
大腸菌性腎盂腎炎	0	0	1 (0.2%)	1 (0.2%)
肺外結核	0	0	1 (0.2%)	1 (0.2%)
眼瞼感染	0	0	1 (0.2%)	1 (0.2%)
皮膚真菌感染	0	1 (1.1%)	0	1 (0.2%)
せつ	0	0	1 (0.2%)	1 (0.2%)
ウイルス性胃炎	0	0	1 (0.2%)	1 (0.2%)
大腸菌性胃腸炎	0	0	1 (0.2%)	1 (0.2%)
陰部ヘルペス	0	0	1 (0.2%)	1 (0.2%)
歯肉膿瘍	0	0	1 (0.2%)	1 (0.2%)
鼠径部膿瘍	0	1 (1.1%)	0	1 (0.2%)
A型肝炎	0	0	1 (0.2%)	1 (0.2%)
C型肝炎	0	0	1 (0.2%)	1 (0.2%)
切開部位感染	0	1 (1.1%)	0	1 (0.2%)
咬傷感染	1 (1.0%)	0	1 (0.2%)	1 (0.2%)
感染性嚢腫	0	0	1 (0.2%)	1 (0.2%)
感染	0	0	1 (0.2%)	1 (0.2%)
原虫感染	0	0	1 (0.2%)	1 (0.2%)
感染性大腸炎	0	0	1 (0.2%)	1 (0.2%)
腎感染	0	0	1 (0.2%)	1 (0.2%)
迷路炎	0	0	1 (0.2%)	1 (0.2%)
大葉性肺炎	0	1 (1.1%)	0	1 (0.2%)

表 2.7.6.4-9 すべての有害事象（継続投与試験の投与被験者）（続き）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
肺感染	0	0	1 (0.2%)	1 (0.2%)
ライム病	0	0	1 (0.2%)	1 (0.2%)
リンパ節感染	0	0	1 (0.2%)	1 (0.2%)
口腔カンジダ症	0	0	1 (0.2%)	1 (0.2%)
細菌の過剰増殖	0	0	1 (0.2%)	1 (0.2%)
骨盤内敗血症	0	0	1 (0.2%)	1 (0.2%)
直腸周囲膿瘍	0	0	1 (0.2%)	1 (0.2%)
百日咳	0	0	1 (0.2%)	1 (0.2%)
細菌性咽頭炎	0	0	1 (0.2%)	1 (0.2%)
咽頭扁桃炎	0	0	1 (0.2%)	1 (0.2%)
インフルエンザ性肺炎	0	0	1 (0.2%)	1 (0.2%)
レジオネラ菌性肺炎	0	0	1 (0.2%)	1 (0.2%)
偽膜性大腸炎	0	0	1 (0.2%)	1 (0.2%)
歯髄炎	0	0	1 (0.2%)	1 (0.2%)
腎盂腎炎	0	0	1 (0.2%)	1 (0.2%)
膿疱性皮疹	0	0	1 (0.2%)	1 (0.2%)
レトロウイルス感染	0	0	1 (0.2%)	1 (0.2%)
卵管炎	0	0	1 (0.2%)	1 (0.2%)
敗血症	0	0	1 (0.2%)	1 (0.2%)
皮膚細菌感染	0	0	1 (0.2%)	1 (0.2%)
汗腺感染	0	0	1 (0.2%)	1 (0.2%)
ダニ媒介ウイルス脳炎	0	0	1 (0.2%)	1 (0.2%)
気管気管支炎	0	0	1 (0.2%)	1 (0.2%)
結核	0	0	1 (0.2%)	1 (0.2%)
膣膿瘍	0	0	1 (0.2%)	1 (0.2%)
水痘	1 (1.0%)	0	1 (0.2%)	1 (0.2%)
前庭神経炎	0	0	1 (0.2%)	1 (0.2%)
創傷感染	0	0	1 (0.2%)	1 (0.2%)
気管炎	1 (1.0%)	0	0	0
胃腸障害	31 (32.3%)	40 (42.6%)	259 (49.4%)	293 (48.9%)
潰瘍性大腸炎	20 (20.8%)	18 (19.1%)	141 (26.9%)	157 (26.2%)
下痢	4 (4.2%)	7 (7.4%)	36 (6.9%)	43 (7.2%)
腹痛	4 (4.2%)	7 (7.4%)	29 (5.5%)	36 (6.0%)
悪心	4 (4.2%)	2 (2.1%)	22 (4.2%)	24 (4.0%)
消化不良	1 (1.0%)	1 (1.1%)	18 (3.4%)	19 (3.2%)
痔核	2 (2.1%)	3 (3.2%)	16 (3.1%)	19 (3.2%)
便秘	0	4 (4.3%)	14 (2.7%)	18 (3.0%)
嘔吐	3 (3.1%)	0	17 (3.2%)	17 (2.8%)
上腹部痛	1 (1.0%)	4 (4.3%)	11 (2.1%)	15 (2.5%)
血便排泄	2 (2.1%)	4 (4.3%)	10 (1.9%)	14 (2.3%)
直腸出血	2 (2.1%)	1 (1.1%)	10 (1.9%)	11 (1.8%)
腹部膨満	1 (1.0%)	1 (1.1%)	8 (1.5%)	9 (1.5%)
排便回数増加	0	2 (2.1%)	7 (1.3%)	9 (1.5%)
胃食道逆流性疾患	2 (2.1%)	0	9 (1.7%)	9 (1.5%)
大腸ポリープ	0	1 (1.1%)	8 (1.5%)	9 (1.5%)
下腹部痛	0	1 (1.1%)	6 (1.1%)	7 (1.2%)
裂肛	0	2 (2.1%)	5 (1.0%)	7 (1.2%)
アフタ性口内炎	0	2 (2.1%)	5 (1.0%)	7 (1.2%)
口内炎	0	0	7 (1.3%)	7 (1.2%)
歯痛	1 (1.0%)	1 (1.1%)	6 (1.1%)	7 (1.2%)
胃炎	2 (2.1%)	0	6 (1.1%)	6 (1.0%)
直腸炎	0	0	6 (1.1%)	6 (1.0%)
鼡径ヘルニア	0	1 (1.1%)	4 (0.8%)	5 (0.8%)
肛門周囲痛	0	1 (1.1%)	4 (0.8%)	5 (0.8%)
偽性ポリポーシス	0	0	5 (1.0%)	5 (0.8%)
口唇炎	0	0	4 (0.8%)	4 (0.7%)
齲歯	1 (1.0%)	0	4 (0.8%)	4 (0.7%)

表 2.7.6.4-9 すべての有害事象（継続投与試験の投与被験者）（続き）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
放屁	1 (1.0%)	0	4 (0.8%)	4 (0.7%)
腹部不快感	1 (1.0%)	1 (1.1%)	2 (0.4%)	3 (0.5%)
便意切迫	0	1 (1.1%)	2 (0.4%)	3 (0.5%)
食中毒	1 (1.0%)	0	3 (0.6%)	3 (0.5%)
口腔内潰瘍形成	0	0	3 (0.6%)	3 (0.5%)
埋伏歯	0	0	3 (0.6%)	3 (0.5%)
結腸異形成	0	0	2 (0.4%)	2 (0.3%)
血性下痢	0	0	2 (0.4%)	2 (0.3%)
胃腸音異常	0	0	2 (0.4%)	2 (0.3%)
歯肉の炎症	0	0	2 (0.4%)	2 (0.3%)
過敏性腸症候群	0	0	2 (0.4%)	2 (0.3%)
大腸狭窄	0	0	2 (0.4%)	2 (0.3%)
粘液便	1 (1.0%)	0	2 (0.4%)	2 (0.3%)
直腸ポリープ	0	0	2 (0.4%)	2 (0.3%)
腹部ヘルニア	0	1 (1.1%)	0	1 (0.2%)
腹部硬直	0	0	1 (0.2%)	1 (0.2%)
腹部圧痛	0	0	1 (0.2%)	1 (0.2%)
痔瘻	0	0	1 (0.2%)	1 (0.2%)
肛門の炎症	0	0	1 (0.2%)	1 (0.2%)
肛門そう痒症	0	0	1 (0.2%)	1 (0.2%)
肛門直腸不快感	1 (1.0%)	0	1 (0.2%)	1 (0.2%)
慢性胃炎	0	0	1 (0.2%)	1 (0.2%)
大腸炎	0	0	1 (0.2%)	1 (0.2%)
クローン病	0	0	1 (0.2%)	1 (0.2%)
十二指腸潰瘍	0	1 (1.1%)	0	1 (0.2%)
嚥下障害	2 (2.1%)	0	1 (0.2%)	1 (0.2%)
小腸炎	0	0	1 (0.2%)	1 (0.2%)
腸炎	0	1 (1.1%)	0	1 (0.2%)
心窩部不快感	0	0	1 (0.2%)	1 (0.2%)
びらん性十二指腸炎	0	0	1 (0.2%)	1 (0.2%)
おくび	0	0	1 (0.2%)	1 (0.2%)
胃障害	0	0	1 (0.2%)	1 (0.2%)
びらん性胃炎	0	0	1 (0.2%)	1 (0.2%)
消化器痛	0	0	1 (0.2%)	1 (0.2%)
歯肉増殖	0	0	1 (0.2%)	1 (0.2%)
歯肉痛	0	0	1 (0.2%)	1 (0.2%)
舌炎	0	0	1 (0.2%)	1 (0.2%)
痔出血	0	0	1 (0.2%)	1 (0.2%)
血栓性痔核	0	0	1 (0.2%)	1 (0.2%)
嚥下痛	0	1 (1.1%)	0	1 (0.2%)
口腔内痛	0	0	1 (0.2%)	1 (0.2%)
口内丘疹	0	0	1 (0.2%)	1 (0.2%)
歯の障害	0	0	1 (0.2%)	1 (0.2%)
歯の脱落	0	0	1 (0.2%)	1 (0.2%)
歯奇形	0	0	1 (0.2%)	1 (0.2%)
筋骨格系および結合組織障害	9 (9.4%)	18 (19.1%)	99 (18.9%)	117 (19.5%)
関節痛	5 (5.2%)	9 (9.6%)	28 (5.3%)	37 (6.2%)
背部痛	1 (1.0%)	2 (2.1%)	32 (6.1%)	34 (5.7%)
筋骨格痛	1 (1.0%)	1 (1.1%)	12 (2.3%)	13 (2.2%)
四肢痛	0	1 (1.1%)	7 (1.3%)	8 (1.3%)
筋肉痛	1 (1.0%)	1 (1.1%)	6 (1.1%)	7 (1.2%)
関節炎	0	0	6 (1.1%)	6 (1.0%)
椎間板突出	0	0	6 (1.1%)	6 (1.0%)
筋痙縮	0	0	6 (1.1%)	6 (1.0%)
変形性関節症	0	2 (2.1%)	4 (0.8%)	6 (1.0%)
筋力低下	1 (1.0%)	1 (1.1%)	3 (0.6%)	4 (0.7%)
頚部痛	0	0	4 (0.8%)	4 (0.7%)

表 2.7.6.4-9 すべての有害事象（継続投与試験の投与被験者）（続き）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
筋骨格系胸痛	0	1 (1.1%)	2 (0.4%)	3 (0.5%)
滑液包炎	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
骨減少症	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
骨粗鬆症	0	0	2 (0.4%)	2 (0.3%)
関節周囲炎	0	0	2 (0.4%)	2 (0.3%)
脊椎痛	0	0	2 (0.4%)	2 (0.3%)
腱鞘炎	0	0	2 (0.4%)	2 (0.3%)
反応性関節炎	0	1 (1.1%)	0	1 (0.2%)
骨障害	0	1 (1.1%)	0	1 (0.2%)
骨痛	0	1 (1.1%)	0	1 (0.2%)
腱付着部症	0	1 (1.1%)	0	1 (0.2%)
外骨腫	0	0	1 (0.2%)	1 (0.2%)
椎間板変性症	0	0	1 (0.2%)	1 (0.2%)
関節腫脹	0	1 (1.1%)	0	1 (0.2%)
筋緊張	0	1 (1.1%)	0	1 (0.2%)
筋骨格硬直	0	1 (1.1%)	0	1 (0.2%)
骨炎	0	0	1 (0.2%)	1 (0.2%)
骨壊死	0	0	1 (0.2%)	1 (0.2%)
顎痛	0	0	1 (0.2%)	1 (0.2%)
足底筋膜炎	0	0	1 (0.2%)	1 (0.2%)
肩回旋筋腱板症候群	0	0	1 (0.2%)	1 (0.2%)
脊椎炎	0	0	1 (0.2%)	1 (0.2%)
腱炎	0	0	1 (0.2%)	1 (0.2%)
狭窄性腱鞘炎	0	0	1 (0.2%)	1 (0.2%)
筋骨格不快感	1 (1.0%)	0	0	0
呼吸器、胸郭および縦隔障害	8 (8.3%)	13 (13.8%)	104 (19.8%)	116 (19.4%)
咳嗽	8 (8.3%)	4 (4.3%)	38 (7.3%)	42 (7.0%)
口腔咽頭痛	0	4 (4.3%)	22 (4.2%)	26 (4.3%)
鼻閉	0	1 (1.1%)	10 (1.9%)	11 (1.8%)
副鼻腔うっ血	1 (1.0%)	1 (1.1%)	8 (1.5%)	9 (1.5%)
呼吸困難	0	0	8 (1.5%)	8 (1.3%)
アレルギー性鼻炎	0	1 (1.1%)	6 (1.1%)	7 (1.2%)
鼻出血	0	1 (1.1%)	5 (1.0%)	6 (1.0%)
鼻漏	0	1 (1.1%)	5 (1.0%)	6 (1.0%)
喘息	0	0	5 (1.0%)	5 (0.8%)
上気道うっ血	1 (1.0%)	0	4 (0.8%)	4 (0.7%)
湿性咳嗽	0	0	3 (0.6%)	3 (0.5%)
呼吸障害	0	0	3 (0.6%)	3 (0.5%)
気道うっ血	0	1 (1.1%)	2 (0.4%)	3 (0.5%)
間質性肺疾患	0	0	2 (0.4%)	2 (0.3%)
鼻潰瘍	0	0	2 (0.4%)	2 (0.3%)
胸膜炎	0	0	2 (0.4%)	2 (0.3%)
肺塞栓症	0	0	2 (0.4%)	2 (0.3%)
肺腫瘤	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
上気道の炎症	0	0	2 (0.4%)	2 (0.3%)
上気道咳症候群	0	0	2 (0.4%)	2 (0.3%)
喘鳴	0	0	2 (0.4%)	2 (0.3%)
アレルギー性気管支炎	0	0	1 (0.2%)	1 (0.2%)
アレルギー性咳嗽	0	1 (1.1%)	0	1 (0.2%)
アレルギー性咽頭炎	0	0	1 (0.2%)	1 (0.2%)
誤嚥	0	0	1 (0.2%)	1 (0.2%)
無気肺	0	0	1 (0.2%)	1 (0.2%)
カタル	0	0	1 (0.2%)	1 (0.2%)
発声障害	1 (1.0%)	1 (1.1%)	0	1 (0.2%)
労作性呼吸困難	0	0	1 (0.2%)	1 (0.2%)
肺気腫	0	0	1 (0.2%)	1 (0.2%)
鼻部不快感	0	0	1 (0.2%)	1 (0.2%)

表 2.7.6.4-9 すべての有害事象（継続投与試験の投与被験者）（続き）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
口腔咽頭不快感	0	0	1 (0.2%)	1 (0.2%)
副鼻腔分泌過多	0	0	1 (0.2%)	1 (0.2%)
咽頭の炎症	0	0	1 (0.2%)	1 (0.2%)
胸水	0	0	1 (0.2%)	1 (0.2%)
胸膜痛	0	0	1 (0.2%)	1 (0.2%)
肺臓炎	0	0	1 (0.2%)	1 (0.2%)
肺線維症	0	1 (1.1%)	0	1 (0.2%)
ラ音	0	0	1 (0.2%)	1 (0.2%)
呼吸不全	0	0	1 (0.2%)	1 (0.2%)
気道出血	0	0	1 (0.2%)	1 (0.2%)
睡眠時無呼吸症候群	0	0	1 (0.2%)	1 (0.2%)
くしゃみ	0	0	1 (0.2%)	1 (0.2%)
咽喉刺激感	0	0	1 (0.2%)	1 (0.2%)
皮膚および皮下組織障害	6 (6.3%)	17 (18.1%)	92 (17.6%)	108 (18.0%)
発疹	1 (1.0%)	3 (3.2%)	19 (3.6%)	22 (3.7%)
湿疹	0	0	11 (2.1%)	11 (1.8%)
脱毛症	0	2 (2.1%)	6 (1.1%)	8 (1.3%)
アレルギー性皮膚炎	0	1 (1.1%)	7 (1.3%)	8 (1.3%)
紅斑	0	0	8 (1.5%)	8 (1.3%)
ざ瘡	0	0	7 (1.3%)	7 (1.2%)
寝汗	0	0	5 (1.0%)	5 (0.8%)
そう痒症	2 (2.1%)	0	5 (1.0%)	5 (0.8%)
皮膚病変	1 (1.0%)	1 (1.1%)	4 (0.8%)	5 (0.8%)
皮膚乾燥	0	3 (3.2%)	1 (0.2%)	4 (0.7%)
乾癬	0	0	4 (0.8%)	4 (0.7%)
蕁麻疹	0	0	4 (0.8%)	4 (0.7%)
日光角化症	0	0	3 (0.6%)	3 (0.5%)
光線過敏性反応	0	1 (1.1%)	2 (0.4%)	3 (0.5%)
皮膚亀裂	0	0	3 (0.6%)	3 (0.5%)
皮膚嚢腫	0	0	2 (0.4%)	2 (0.3%)
皮膚炎	1 (1.0%)	0	2 (0.4%)	2 (0.3%)
アトピー性皮膚炎	0	0	2 (0.4%)	2 (0.3%)
接触性皮膚炎	0	0	2 (0.4%)	2 (0.3%)
薬疹	0	0	2 (0.4%)	2 (0.3%)
結節性紅斑	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
汗疹	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
丘疹	0	0	2 (0.4%)	2 (0.3%)
斑状皮疹	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
そう痒性皮疹	0	0	2 (0.4%)	2 (0.3%)
皮膚刺激	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
皮膚腫瘤	0	2 (2.1%)	0	2 (0.3%)
円形脱毛症	0	0	1 (0.2%)	1 (0.2%)
水疱	0	0	1 (0.2%)	1 (0.2%)
冷汗	0	0	1 (0.2%)	1 (0.2%)
乾癬様皮膚炎	0	1 (1.1%)	0	1 (0.2%)
異汗性湿疹	0	0	1 (0.2%)	1 (0.2%)
多形紅斑	0	0	1 (0.2%)	1 (0.2%)
多汗症	1 (1.0%)	0	1 (0.2%)	1 (0.2%)
過角化	0	0	1 (0.2%)	1 (0.2%)
過敏性血管炎	0	0	1 (0.2%)	1 (0.2%)
扁平苔癬	0	0	1 (0.2%)	1 (0.2%)
硬化性苔癬	0	1 (1.1%)	0	1 (0.2%)
苔癬様角化症	0	0	1 (0.2%)	1 (0.2%)
メラノーシス	0	0	1 (0.2%)	1 (0.2%)
爪痛	0	0	1 (0.2%)	1 (0.2%)
粃糠疹	0	1 (1.1%)	0	1 (0.2%)
ばら色粃糠疹	0	1 (1.1%)	0	1 (0.2%)

表 2.7.6.4-9 すべての有害事象（継続投与試験の投与被験者）（続き）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
壊疽性膿皮症	0	0	1 (0.2%)	1 (0.2%)
紅斑性皮疹	0	0	1 (0.2%)	1 (0.2%)
丘疹性皮疹	0	0	1 (0.2%)	1 (0.2%)
酒さ	0	0	1 (0.2%)	1 (0.2%)
脂漏性皮膚炎	0	0	1 (0.2%)	1 (0.2%)
皮膚剥脱	0	0	1 (0.2%)	1 (0.2%)
日光皮膚炎	0	1 (1.1%)	0	1 (0.2%)
神経皮膚炎	1 (1.0%)	0	0	0
一般・全身障害および投与部位の状態	6 (6.3%)	12 (12.8%)	88 (16.8%)	100 (16.7%)
発熱	3 (3.1%)	7 (7.4%)	32 (6.1%)	39 (6.5%)
疲労	1 (1.0%)	2 (2.1%)	13 (2.5%)	15 (2.5%)
胸痛	0	2 (2.1%)	10 (1.9%)	12 (2.0%)
注射部位紅斑	0	1 (1.1%)	10 (1.9%)	11 (1.8%)
インフルエンザ様疾患	1 (1.0%)	2 (2.1%)	7 (1.3%)	9 (1.5%)
末梢性浮腫	0	1 (1.1%)	8 (1.5%)	9 (1.5%)
無力症	1 (1.0%)	0	7 (1.3%)	7 (1.2%)
注射部位疼痛	0	1 (1.1%)	3 (0.6%)	4 (0.7%)
疼痛	0	0	2 (0.4%)	2 (0.3%)
恥骨上痛	0	0	2 (0.4%)	2 (0.3%)
胸部不快感	0	0	1 (0.2%)	1 (0.2%)
悪寒	0	0	1 (0.2%)	1 (0.2%)
嚢胞	0	0	1 (0.2%)	1 (0.2%)
歩行障害	0	0	1 (0.2%)	1 (0.2%)
注射部位内出血	0	0	1 (0.2%)	1 (0.2%)
注射部位硬結	0	0	1 (0.2%)	1 (0.2%)
注射部位浮腫	0	0	1 (0.2%)	1 (0.2%)
注射部位そう痒感	0	0	1 (0.2%)	1 (0.2%)
注射部位発疹	0	0	1 (0.2%)	1 (0.2%)
倦怠感	0	0	1 (0.2%)	1 (0.2%)
非心臓性胸痛	0	0	1 (0.2%)	1 (0.2%)
穿刺部位疼痛	0	0	1 (0.2%)	1 (0.2%)
神経系障害	6 (6.3%)	12 (12.8%)	70 (13.4%)	82 (13.7%)
頭痛	1 (1.0%)	7 (7.4%)	40 (7.6%)	47 (7.8%)
浮動性めまい	0	0	8 (1.5%)	8 (1.3%)
錯感覚	0	0	6 (1.1%)	6 (1.0%)
振戦	0	0	4 (0.8%)	4 (0.7%)
感覚鈍麻	0	0	3 (0.6%)	3 (0.5%)
片頭痛	1 (1.0%)	0	3 (0.6%)	3 (0.5%)
失神	0	0	3 (0.6%)	3 (0.5%)
手根管症候群	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
脱髄	0	0	2 (0.4%)	2 (0.3%)
知覚過敏	0	0	2 (0.4%)	2 (0.3%)
坐骨神経痛	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
傾眠	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
無嗅覚	0	0	1 (0.2%)	1 (0.2%)
平衡障害	0	1 (1.1%)	0	1 (0.2%)
頚動脈狭窄	0	0	1 (0.2%)	1 (0.2%)
頚腕症候群	0	0	1 (0.2%)	1 (0.2%)
協調運動異常	0	0	1 (0.2%)	1 (0.2%)
書字障害	0	0	1 (0.2%)	1 (0.2%)
脳症	0	0	1 (0.2%)	1 (0.2%)
てんかん	0	0	1 (0.2%)	1 (0.2%)
筋緊張低下	0	0	1 (0.2%)	1 (0.2%)
嗜眠	0	0	1 (0.2%)	1 (0.2%)
意識消失	0	1 (1.1%)	0	1 (0.2%)
前兆を伴う片頭痛	0	0	1 (0.2%)	1 (0.2%)
多発性硬化症	0	0	1 (0.2%)	1 (0.2%)

表 2.7.6.4-9 すべての有害事象（継続投与試験の投与被験者）（続き）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
不随意性筋収縮	0	0	1 (0.2%)	1 (0.2%)
パーキンソン病	0	0	1 (0.2%)	1 (0.2%)
回復性虚血性神経脱落症候	0	1 (1.1%)	0	1 (0.2%)
感覚障害	0	0	1 (0.2%)	1 (0.2%)
感覚消失	0	0	1 (0.2%)	1 (0.2%)
副鼻腔炎に伴う頭痛	0	0	1 (0.2%)	1 (0.2%)
一過性脳虚血発作	1 (1.0%)	1 (1.1%)	0	1 (0.2%)
群発頭痛	1 (1.0%)	0	0	0
体位性めまい	1 (1.0%)	0	0	0
記憶障害	1 (1.0%)	0	0	0
傷害、中毒および処置合併症	10 (10.4%)	12 (12.8%)	45 (8.6%)	57 (9.5%)
節足動物咬傷	0	2 (2.1%)	4 (0.8%)	6 (1.0%)
靭帯捻挫	2 (2.1%)	0	6 (1.1%)	6 (1.0%)
挫傷	1 (1.0%)	2 (2.1%)	3 (0.6%)	5 (0.8%)
半月板損傷	0	2 (2.1%)	2 (0.4%)	4 (0.7%)
肋骨骨折	0	0	4 (0.8%)	4 (0.7%)
骨挫傷	0	2 (2.1%)	1 (0.2%)	3 (0.5%)
上顆炎	1 (1.0%)	0	3 (0.6%)	3 (0.5%)
関節損傷	0	0	3 (0.6%)	3 (0.5%)
裂傷	1 (1.0%)	0	3 (0.6%)	3 (0.5%)
処置による疼痛	0	1 (1.1%)	2 (0.4%)	3 (0.5%)
歯牙破折	0	1 (1.1%)	2 (0.4%)	3 (0.5%)
動物咬傷	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
手骨折	0	0	2 (0.4%)	2 (0.3%)
関節脱臼	0	0	2 (0.4%)	2 (0.3%)
処置による悪心	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
熱傷	0	0	2 (0.4%)	2 (0.3%)
偶発的過量投与	0	0	1 (0.2%)	1 (0.2%)
足関節部骨折	0	0	1 (0.2%)	1 (0.2%)
節足動物刺傷	0	0	1 (0.2%)	1 (0.2%)
咬刺傷	0	1 (1.1%)	0	1 (0.2%)
脳振盪	0	0	1 (0.2%)	1 (0.2%)
顔面骨骨折	0	0	1 (0.2%)	1 (0.2%)
足骨折	1 (1.0%)	0	1 (0.2%)	1 (0.2%)
損傷	0	0	1 (0.2%)	1 (0.2%)
企図的過量投与	0	0	1 (0.2%)	1 (0.2%)
顎の骨折	0	0	1 (0.2%)	1 (0.2%)
靭帯断裂	0	0	1 (0.2%)	1 (0.2%)
四肢損傷	1 (1.0%)	1 (1.1%)	0	1 (0.2%)
下肢骨折	0	0	1 (0.2%)	1 (0.2%)
爪損傷	0	1 (1.1%)	0	1 (0.2%)
神経損傷	0	0	1 (0.2%)	1 (0.2%)
過量投与	0	0	1 (0.2%)	1 (0.2%)
処置後合併症	0	0	1 (0.2%)	1 (0.2%)
処置後出血	0	0	1 (0.2%)	1 (0.2%)
外傷後頚部症候群	0	1 (1.1%)	0	1 (0.2%)
外傷後疼痛	0	0	1 (0.2%)	1 (0.2%)
漿液腫	0	0	1 (0.2%)	1 (0.2%)
外傷性脊椎症	0	0	1 (0.2%)	1 (0.2%)
刺創	0	0	1 (0.2%)	1 (0.2%)
各種物質毒性	0	0	1 (0.2%)	1 (0.2%)
外傷性関節炎	0	0	1 (0.2%)	1 (0.2%)
ワクチン接種合併症	0	0	1 (0.2%)	1 (0.2%)
血管偽動脈瘤	0	0	1 (0.2%)	1 (0.2%)
創傷	0	0	1 (0.2%)	1 (0.2%)
手首関節骨折	1 (1.0%)	1 (1.1%)	0	1 (0.2%)
腱断裂	1 (1.0%)	0	0	0

表 2.7.6.4-9 すべての有害事象（継続投与試験の投与被験者）（続き）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
胸椎骨折	1 (1.0%)	0	0	0
臨床検査	2 (2.1%)	9 (9.6%)	48 (9.2%)	57 (9.5%)
アラニンアミノトランスフェラーゼ増加	0	2 (2.1%)	9 (1.7%)	11 (1.8%)
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (1.1%)	8 (1.5%)	9 (1.5%)
ヘモグロビン減少	0	0	6 (1.1%)	6 (1.0%)
肝機能検査異常	0	0	5 (1.0%)	5 (0.8%)
血中クレアチニン増加	0	1 (1.1%)	3 (0.6%)	4 (0.7%)
体重減少	0	1 (1.1%)	3 (0.6%)	4 (0.7%)
体重増加	0	0	4 (0.8%)	4 (0.7%)
肝酵素上昇	1 (1.0%)	0	3 (0.6%)	3 (0.5%)
白血球数減少	0	1 (1.1%)	2 (0.4%)	3 (0.5%)
血中アルカリホスファターゼ増加	0	0	2 (0.4%)	2 (0.3%)
血中コレステロール増加	0	0	2 (0.4%)	2 (0.3%)
血中リン減少	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
血圧上昇	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
好酸球数増加	1 (1.0%)	1 (1.1%)	1 (0.2%)	2 (0.3%)
ヘマトクリット減少	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
好中球数減少	0	2 (2.1%)	0	2 (0.3%)
好中球数増加	0	0	2 (0.4%)	2 (0.3%)
血中アルブミン減少	0	0	1 (0.2%)	1 (0.2%)
血中カルシウム減少	0	0	1 (0.2%)	1 (0.2%)
血中カルシウム増加	0	0	1 (0.2%)	1 (0.2%)
血中クロール増加	0	1 (1.1%)	0	1 (0.2%)
血中副甲状腺ホルモン増加	0	0	1 (0.2%)	1 (0.2%)
収縮期血圧上昇	0	0	1 (0.2%)	1 (0.2%)
血中ナトリウム増加	0	1 (1.1%)	0	1 (0.2%)
血中尿素増加	0	1 (1.1%)	0	1 (0.2%)
体温上昇	0	0	1 (0.2%)	1 (0.2%)
好酸球数	0	0	1 (0.2%)	1 (0.2%)
心拍数増加	0	1 (1.1%)	0	1 (0.2%)
国際標準比増加	0	0	1 (0.2%)	1 (0.2%)
リンパ球数減少	0	0	1 (0.2%)	1 (0.2%)
単球数増加	1 (1.0%)	0	1 (0.2%)	1 (0.2%)
血小板数減少	0	1 (1.1%)	0	1 (0.2%)
便ｐＨ低下	0	0	1 (0.2%)	1 (0.2%)
トランスアミナーゼ上昇	0	0	1 (0.2%)	1 (0.2%)
ツベルクリン反応陽性	0	0	1 (0.2%)	1 (0.2%)
腎超音波検査異常	0	0	1 (0.2%)	1 (0.2%)
尿中アルブミン／クレアチニン比増加	0	0	1 (0.2%)	1 (0.2%)
ビタミンＤ減少	0	0	1 (0.2%)	1 (0.2%)
白血球数増加	0	0	1 (0.2%)	1 (0.2%)
血液およびリンパ系障害	4 (4.2%)	8 (8.5%)	45 (8.6%)	53 (8.8%)
貧血	2 (2.1%)	2 (2.1%)	22 (4.2%)	24 (4.0%)
好酸球増加症	0	2 (2.1%)	8 (1.5%)	10 (1.7%)
鉄欠乏性貧血	1 (1.0%)	3 (3.2%)	3 (0.6%)	6 (1.0%)
リンパ節症	0	1 (1.1%)	4 (0.8%)	5 (0.8%)
白血球増加症	0	0	2 (0.4%)	2 (0.3%)
単球増加症	0	0	2 (0.4%)	2 (0.3%)
脾腫	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
血小板増加症	0	0	2 (0.4%)	2 (0.3%)
再生不良性貧血	0	0	1 (0.2%)	1 (0.2%)
低色素血	0	0	1 (0.2%)	1 (0.2%)
内出血発生の増加傾向	0	0	1 (0.2%)	1 (0.2%)
白血球減少症	0	0	1 (0.2%)	1 (0.2%)
リンパ節炎	0	1 (1.1%)	0	1 (0.2%)
リンパ球増加症	0	0	1 (0.2%)	1 (0.2%)

表 2.7.6.4-9 すべての有害事象（継続投与試験の投与被験者）（続き）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
好中球減少症	1 (1.0%)	0	1 (0.2%)	1 (0.2%)
血小板減少症	0	0	1 (0.2%)	1 (0.2%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2 (2.1%)	7 (7.4%)	33 (6.3%)	40 (6.7%)
皮膚乳頭腫	0	2 (2.1%)	5 (1.0%)	7 (1.2%)
脂漏性角化症	0	0	4 (0.8%)	4 (0.7%)
基底細胞癌	0	1 (1.1%)	2 (0.4%)	3 (0.5%)
大腸腺腫	0	0	3 (0.6%)	3 (0.5%)
子宮平滑筋腫	0	1 (1.1%)	2 (0.4%)	3 (0.5%)
メラノサイト性母斑	0	0	2 (0.4%)	2 (0.3%)
アクロコルドン	0	0	1 (0.2%)	1 (0.2%)
副腎腺腫	0	0	1 (0.2%)	1 (0.2%)
肛門性器疣贅	0	0	1 (0.2%)	1 (0.2%)
乳房の良性新生物	0	0	1 (0.2%)	1 (0.2%)
甲状腺の良性新生物	0	0	1 (0.2%)	1 (0.2%)
遠隔転移を伴う結腸癌	0	0	1 (0.2%)	1 (0.2%)
線維腫	0	0	1 (0.2%)	1 (0.2%)
線維性組織球腫	0	1 (1.1%)	0	1 (0.2%)
胆嚢癌	0	0	1 (0.2%)	1 (0.2%)
血管腫	0	0	1 (0.2%)	1 (0.2%)
肝臓血管腫	0	0	1 (0.2%)	1 (0.2%)
ホジキン病	0	0	1 (0.2%)	1 (0.2%)
リンパ増殖性障害	0	0	1 (0.2%)	1 (0.2%)
卵巣癌	0	0	1 (0.2%)	1 (0.2%)
卵巣上皮癌	0	1 (1.1%)	0	1 (0.2%)
前立腺癌	0	1 (1.1%)	0	1 (0.2%)
遠隔転移を伴う直腸癌	0	0	1 (0.2%)	1 (0.2%)
遠隔転移を伴う腎癌	0	0	1 (0.2%)	1 (0.2%)
扁平上皮癌	0	0	1 (0.2%)	1 (0.2%)
皮膚有棘細胞癌	0	0	1 (0.2%)	1 (0.2%)
Ｔ細胞性リンパ腫	0	0	1 (0.2%)	1 (0.2%)
甲状腺新生物	1 (1.0%)	0	1 (0.2%)	1 (0.2%)
直腸腺腫	1 (1.0%)	0	0	0
精神障害	4 (4.2%)	2 (2.1%)	37 (7.1%)	39 (6.5%)
不安	2 (2.1%)	0	13 (2.5%)	13 (2.2%)
うつ病	0	1 (1.1%)	12 (2.3%)	13 (2.2%)
不眠症	2 (2.1%)	1 (1.1%)	10 (1.9%)	11 (1.8%)
抑うつ症状	0	0	2 (0.4%)	2 (0.3%)
アルコール乱用	0	0	1 (0.2%)	1 (0.2%)
抑うつ気分	0	0	1 (0.2%)	1 (0.2%)
希死念慮を有するうつ病	0	0	1 (0.2%)	1 (0.2%)
失見当識	0	0	1 (0.2%)	1 (0.2%)
精神障害	0	0	1 (0.2%)	1 (0.2%)
精神状態変化	0	0	1 (0.2%)	1 (0.2%)
神経症	1 (1.0%)	0	1 (0.2%)	1 (0.2%)
落ち着きのなさ	0	0	1 (0.2%)	1 (0.2%)
睡眠障害	0	0	1 (0.2%)	1 (0.2%)
ストレス	0	0	1 (0.2%)	1 (0.2%)
気分変調性障害	1 (1.0%)	0	0	0
血管障害	0	5 (5.3%)	30 (5.7%)	35 (5.8%)
高血圧	0	3 (3.2%)	13 (2.5%)	16 (2.7%)
血腫	0	1 (1.1%)	2 (0.4%)	3 (0.5%)
静脈炎	0	0	3 (0.6%)	3 (0.5%)
動脈硬化症	0	0	2 (0.4%)	2 (0.3%)
深部静脈血栓症	0	0	2 (0.4%)	2 (0.3%)
低血圧	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
表在性血栓性静脈炎	0	0	2 (0.4%)	2 (0.3%)

表 2.7.6.4-9 すべての有害事象（継続投与試験の投与被験者）（続き）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
潮紅	0	0	1 (0.2%)	1 (0.2%)
ほてり	0	0	1 (0.2%)	1 (0.2%)
蒼白	0	0	1 (0.2%)	1 (0.2%)
血栓後症候群	0	0	1 (0.2%)	1 (0.2%)
レイノー現象	0	1 (1.1%)	0	1 (0.2%)
静脈瘤性潰瘍	0	0	1 (0.2%)	1 (0.2%)
静脈血栓症	0	0	1 (0.2%)	1 (0.2%)
代謝および栄養障害	4 (4.2%)	5 (5.3%)	25 (4.8%)	30 (5.0%)
高コレステロール血症	0	2 (2.1%)	5 (1.0%)	7 (1.2%)
脱水	1 (1.0%)	1 (1.1%)	3 (0.6%)	4 (0.7%)
糖尿病	0	0	3 (0.6%)	3 (0.5%)
高カリウム血症	0	0	3 (0.6%)	3 (0.5%)
痛風	1 (1.0%)	0	2 (0.4%)	2 (0.3%)
低ナトリウム血症	0	0	2 (0.4%)	2 (0.3%)
鉄欠乏	0	0	2 (0.4%)	2 (0.3%)
ビタミンD欠乏	0	0	2 (0.4%)	2 (0.3%)
悪液質	0	0	1 (0.2%)	1 (0.2%)
食欲減退	0	0	1 (0.2%)	1 (0.2%)
コントロール不良の糖尿病	1 (1.0%)	0	1 (0.2%)	1 (0.2%)
葉酸欠乏	0	0	1 (0.2%)	1 (0.2%)
耐糖能障害	0	1 (1.1%)	0	1 (0.2%)
高脂血症	1 (1.0%)	0	1 (0.2%)	1 (0.2%)
低アルブミン血症	0	0	1 (0.2%)	1 (0.2%)
低血糖症	0	1 (1.1%)	0	1 (0.2%)
ラクトース不耐性	0	0	1 (0.2%)	1 (0.2%)
２型糖尿病	0	0	1 (0.2%)	1 (0.2%)
ビタミンＢ１２欠乏	0	0	1 (0.2%)	1 (0.2%)
眼障害	0	4 (4.3%)	22 (4.2%)	26 (4.3%)
白内障	0	2 (2.1%)	5 (1.0%)	7 (1.2%)
眼乾燥	0	0	3 (0.6%)	3 (0.5%)
霧視	0	0	3 (0.6%)	3 (0.5%)
眼瞼痙攣	0	0	2 (0.4%)	2 (0.3%)
眼刺激	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
流涙増加	0	0	2 (0.4%)	2 (0.3%)
眼瞼炎	0	0	1 (0.2%)	1 (0.2%)
失明	0	0	1 (0.2%)	1 (0.2%)
結膜沈着物	0	0	1 (0.2%)	1 (0.2%)
複視	0	0	1 (0.2%)	1 (0.2%)
上強膜炎	0	0	1 (0.2%)	1 (0.2%)
眼出血	0	0	1 (0.2%)	1 (0.2%)
眼の炎症	0	1 (1.1%)	0	1 (0.2%)
眼痛	0	0	1 (0.2%)	1 (0.2%)
眼そう痒症	0	0	1 (0.2%)	1 (0.2%)
眼部腫脹	0	0	1 (0.2%)	1 (0.2%)
眼瞼浮腫	0	0	1 (0.2%)	1 (0.2%)
眼瞼発疹	0	1 (1.1%)	0	1 (0.2%)
黄斑線維症	0	0	1 (0.2%)	1 (0.2%)
近視	0	0	1 (0.2%)	1 (0.2%)
眼充血	0	0	1 (0.2%)	1 (0.2%)
網膜変性	0	0	1 (0.2%)	1 (0.2%)
網膜裂孔	0	0	1 (0.2%)	1 (0.2%)
視力低下	0	0	1 (0.2%)	1 (0.2%)
硝子体剥離	0	0	1 (0.2%)	1 (0.2%)
硝子体浮遊物	0	0	1 (0.2%)	1 (0.2%)
生殖系および乳房障害	2 (2.1%)	5 (5.3%)	21 (4.0%)	26 (4.3%)
月経過多	0	0	4 (0.8%)	4 (0.7%)
卵巣嚢胞	0	2 (2.1%)	1 (0.2%)	3 (0.5%)

表 2.7.6.4-9 すべての有害事象（継続投与試験の投与被験者）（続き）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
前立腺炎	0	1 (1.1%)	2 (0.4%)	3 (0.5%)
良性前立腺肥大症	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
乳房痛	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
子宮頚部上皮異形成	0	0	2 (0.4%)	2 (0.3%)
前立腺腫大	0	0	2 (0.4%)	2 (0.3%)
無月経	0	0	1 (0.2%)	1 (0.2%)
乳房圧痛	0	0	1 (0.2%)	1 (0.2%)
月経困難症	0	1 (1.1%)	0	1 (0.2%)
子宮内膜症	0	0	1 (0.2%)	1 (0.2%)
勃起不全	0	0	1 (0.2%)	1 (0.2%)
性器出血	0	0	1 (0.2%)	1 (0.2%)
閉経期症状	0	0	1 (0.2%)	1 (0.2%)
不正子宮出血	0	0	1 (0.2%)	1 (0.2%)
子宮頚部びらん	0	0	1 (0.2%)	1 (0.2%)
子宮脱	0	0	1 (0.2%)	1 (0.2%)
月経障害	2 (2.1%)	0	0	0
免疫系障害	0	5 (5.3%)	21 (4.0%)	25 (4.2%)
季節性アレルギー	0	3 (3.2%)	14 (2.7%)	16 (2.7%)
薬物過敏症	0	0	4 (0.8%)	4 (0.7%)
節足動物咬傷アレルギー	0	2 (2.1%)	0	2 (0.3%)
過敏症	0	0	2 (0.4%)	2 (0.3%)
食物アレルギー	0	0	1 (0.2%)	1 (0.2%)
腎および尿路障害	2 (2.1%)	4 (4.3%)	19 (3.6%)	23 (3.8%)
腎結石症	1 (1.0%)	1 (1.1%)	9 (1.7%)	10 (1.7%)
腎仙痛	0	0	4 (0.8%)	4 (0.7%)
腎嚢胞	0	1 (1.1%)	3 (0.6%)	4 (0.7%)
排尿困難	0	0	1 (0.2%)	1 (0.2%)
頻尿	0	0	1 (0.2%)	1 (0.2%)
多尿	0	0	1 (0.2%)	1 (0.2%)
蛋白尿	0	1 (1.1%)	0	1 (0.2%)
腎障害	0	0	1 (0.2%)	1 (0.2%)
急性腎不全	0	1 (1.1%)	0	1 (0.2%)
尿道障害	0	0	1 (0.2%)	1 (0.2%)
排尿躊躇	0	0	1 (0.2%)	1 (0.2%)
膀胱頚部閉塞	1 (1.0%)	0	0	0
肝胆道系障害	0	3 (3.2%)	14 (2.7%)	17 (2.8%)
肝嚢胞	0	1 (1.1%)	2 (0.4%)	3 (0.5%)
脂肪肝	0	0	3 (0.6%)	3 (0.5%)
胆石症	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
肝障害	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
非アルコール性脂肪性肝炎	0	0	2 (0.4%)	2 (0.3%)
胆道仙痛	0	1 (1.1%)	0	1 (0.2%)
慢性胆嚢炎	0	0	1 (0.2%)	1 (0.2%)
胆汁うっ滞	0	0	1 (0.2%)	1 (0.2%)
後天性肝内胆管拡張症	0	1 (1.1%)	0	1 (0.2%)
薬物性肝障害	0	0	1 (0.2%)	1 (0.2%)
肝炎	0	0	1 (0.2%)	1 (0.2%)
高ビリルビン血症	0	0	1 (0.2%)	1 (0.2%)
高トランスアミナーゼ血症	0	0	1 (0.2%)	1 (0.2%)
心臓障害	3 (3.1%)	2 (2.1%)	14 (2.7%)	16 (2.7%)
頻脈	0	2 (2.1%)	4 (0.8%)	6 (1.0%)
冠動脈疾患	0	0	2 (0.4%)	2 (0.3%)
急性心筋梗塞	0	0	1 (0.2%)	1 (0.2%)
狭心症	0	0	1 (0.2%)	1 (0.2%)
不安定狭心症	0	0	1 (0.2%)	1 (0.2%)
心房細動	0	0	1 (0.2%)	1 (0.2%)
心不全	1 (1.0%)	0	1 (0.2%)	1 (0.2%)

表 2.7.6.4-9 すべての有害事象（継続投与試験の投与被験者）（続き）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
僧帽弁逸脱	0	0	1 (0.2%)	1 (0.2%)
心筋梗塞	2 (2.1%)	0	1 (0.2%)	1 (0.2%)
心膜炎	0	0	1 (0.2%)	1 (0.2%)
心室性期外収縮	0	0	1 (0.2%)	1 (0.2%)
期外収縮	1 (1.0%)	0	0	0
耳および迷路障害	1 (1.0%)	1 (1.1%)	15 (2.9%)	16 (2.7%)
回転性めまい	1 (1.0%)	0	6 (1.1%)	6 (1.0%)
耳痛	0	0	4 (0.8%)	4 (0.7%)
耳鳴	0	1 (1.1%)	3 (0.6%)	4 (0.7%)
耳不快感	0	0	1 (0.2%)	1 (0.2%)
耳管機能障害	0	0	1 (0.2%)	1 (0.2%)
聴力低下	0	0	1 (0.2%)	1 (0.2%)
社会環境	1 (1.0%)	1 (1.1%)	6 (1.1%)	7 (1.2%)
パートナーの妊娠	0	1 (1.1%)	6 (1.1%)	7 (1.2%)
閉経	1 (1.0%)	0	0	0
妊娠、産褥および周産期の状態	1 (1.0%)	1 (1.1%)	4 (0.8%)	5 (0.8%)
妊娠	1 (1.0%)	1 (1.1%)	4 (0.8%)	5 (0.8%)
自然流産	0	0	1 (0.2%)	1 (0.2%)
内分泌障害	0	0	4 (0.8%)	4 (0.7%)
副腎腫瘤	0	0	1 (0.2%)	1 (0.2%)
自己免疫性甲状腺炎	0	0	1 (0.2%)	1 (0.2%)
クッシング様症状	0	0	1 (0.2%)	1 (0.2%)
甲状腺腫	0	0	1 (0.2%)	1 (0.2%)
先天性、家族性および遺伝性障害	0	0	2 (0.4%)	2 (0.3%)
心房中隔欠損症	0	0	1 (0.2%)	1 (0.2%)
ジルベール症候群	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.

[TSFAE01.rtf] [CNTO148\C0524T18\DBR_W228\RE_NDAJPKK\tsfae01.sas] 04FEB2016, 21:45
参照元：C0524T18 End of Study (228-Week) Clinical Study Report TSFAE01

表 2.7.6.4-10 治験薬の使用と関連性のある有害事象（継続投与試験の投与被験者）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	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 adverse events	12 (12.5%)	26 (27.7%)	166 (31.7%)	192 (32.1%)
System-organ class/preferred term				
感染症および寄生虫症	7 (7.3%)	12 (12.8%)	101 (19.3%)	113 (18.9%)
鼻咽頭炎	1 (1.0%)	3 (3.2%)	19 (3.6%)	22 (3.7%)
上気道感染	2 (2.1%)	3 (3.2%)	12 (2.3%)	15 (2.5%)
帯状疱疹	0	1 (1.1%)	12 (2.3%)	13 (2.2%)
副鼻腔炎	0	1 (1.1%)	12 (2.3%)	13 (2.2%)
口腔ヘルペス	1 (1.0%)	0	10 (1.9%)	10 (1.7%)
胃腸炎	0	0	8 (1.5%)	8 (1.3%)
気管支炎	1 (1.0%)	1 (1.1%)	5 (1.0%)	6 (1.0%)
咽頭炎	0	0	5 (1.0%)	5 (0.8%)
肺炎	1 (1.0%)	1 (1.1%)	4 (0.8%)	5 (0.8%)
扁桃炎	0	1 (1.1%)	4 (0.8%)	5 (0.8%)
麦粒腫	0	1 (1.1%)	2 (0.4%)	3 (0.5%)
インフルエンザ	0	0	3 (0.6%)	3 (0.5%)
喉頭炎	1 (1.0%)	1 (1.1%)	2 (0.4%)	3 (0.5%)
肛門膿瘍	0	0	2 (0.4%)	2 (0.3%)
クロストリジウム・ディフィシレ感染	0	0	2 (0.4%)	2 (0.3%)
感染性腸炎	0	0	2 (0.4%)	2 (0.3%)
毛包炎	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
単純ヘルペス	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
下気道感染	1 (1.0%)	0	2 (0.4%)	2 (0.3%)
ウイルス性髄膜炎	0	0	2 (0.4%)	2 (0.3%)
肺結核	0	0	2 (0.4%)	2 (0.3%)
気道感染	0	0	2 (0.4%)	2 (0.3%)
ウイルス性気道感染	0	0	2 (0.4%)	2 (0.3%)
皮膚感染	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
皮下組織膿瘍	0	0	2 (0.4%)	2 (0.3%)
股部白癬	0	0	2 (0.4%)	2 (0.3%)
癜風	0	0	2 (0.4%)	2 (0.3%)
尿路感染	0	0	2 (0.4%)	2 (0.3%)
真菌性肛門感染	0	1 (1.1%)	0	1 (0.2%)
ブラストシスティス感染	0	0	1 (0.2%)	1 (0.2%)
ボルデテラ感染	0	0	1 (0.2%)	1 (0.2%)
ボレリア感染	0	0	1 (0.2%)	1 (0.2%)
ウイルス性気管支炎	0	0	1 (0.2%)	1 (0.2%)
蜂巣炎	0	1 (1.1%)	0	1 (0.2%)
膀胱炎	0	0	1 (0.2%)	1 (0.2%)
サイトメガロウイルス感染	0	0	1 (0.2%)	1 (0.2%)
耳感染	0	0	1 (0.2%)	1 (0.2%)
細菌性耳感染	0	0	1 (0.2%)	1 (0.2%)
精巣上体炎	0	0	1 (0.2%)	1 (0.2%)
丹毒	0	0	1 (0.2%)	1 (0.2%)
大腸菌性腎盂腎炎	0	0	1 (0.2%)	1 (0.2%)
肺外結核	0	0	1 (0.2%)	1 (0.2%)
陰部ヘルペス	0	0	1 (0.2%)	1 (0.2%)
ジアルジア症	0	0	1 (0.2%)	1 (0.2%)
感染性嚢腫	0	0	1 (0.2%)	1 (0.2%)
原虫感染	0	0	1 (0.2%)	1 (0.2%)
感染性大腸炎	0	0	1 (0.2%)	1 (0.2%)
迷路炎	0	0	1 (0.2%)	1 (0.2%)
口腔カンジダ症	0	0	1 (0.2%)	1 (0.2%)
直腸周囲膿瘍	0	0	1 (0.2%)	1 (0.2%)

表 2.7.6.4-10 治験薬の使用と関連性のある有害事象（継続投与試験の投与被験者）（続き）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
細菌性咽頭炎	0	0	1 (0.2%)	1 (0.2%)
腎盂腎炎	0	0	1 (0.2%)	1 (0.2%)
膿疱性皮疹	0	0	1 (0.2%)	1 (0.2%)
鼻炎	0	0	1 (0.2%)	1 (0.2%)
敗血症	0	0	1 (0.2%)	1 (0.2%)
皮膚細菌感染	0	0	1 (0.2%)	1 (0.2%)
気管気管支炎	0	0	1 (0.2%)	1 (0.2%)
結核	0	0	1 (0.2%)	1 (0.2%)
膣膿瘍	0	0	1 (0.2%)	1 (0.2%)
前庭神経炎	0	0	1 (0.2%)	1 (0.2%)
ウイルス性上気道感染	0	0	1 (0.2%)	1 (0.2%)
外陰部膣カンジダ症	0	0	1 (0.2%)	1 (0.2%)
外陰膣真菌感染	0	0	1 (0.2%)	1 (0.2%)
創傷感染	0	0	1 (0.2%)	1 (0.2%)
胃腸障害	7 (7.3%)	6 (6.4%)	38 (7.3%)	44 (7.3%)
潰瘍性大腸炎	3 (3.1%)	3 (3.2%)	16 (3.1%)	19 (3.2%)
腹痛	2 (2.1%)	2 (2.1%)	3 (0.6%)	5 (0.8%)
悪心	0	0	5 (1.0%)	5 (0.8%)
下痢	1 (1.0%)	0	4 (0.8%)	4 (0.7%)
便秘	0	0	3 (0.6%)	3 (0.5%)
下腹部痛	0	0	2 (0.4%)	2 (0.3%)
アフタ性口内炎	0	2 (2.1%)	0	2 (0.3%)
嘔吐	0	0	2 (0.4%)	2 (0.3%)
腹部不快感	0	0	1 (0.2%)	1 (0.2%)
裂肛	0	0	1 (0.2%)	1 (0.2%)
口唇炎	0	0	1 (0.2%)	1 (0.2%)
結腸異形成	0	0	1 (0.2%)	1 (0.2%)
びらん性十二指腸炎	0	0	1 (0.2%)	1 (0.2%)
放屁	0	0	1 (0.2%)	1 (0.2%)
胃障害	0	0	1 (0.2%)	1 (0.2%)
胃炎	0	0	1 (0.2%)	1 (0.2%)
歯肉増殖	0	0	1 (0.2%)	1 (0.2%)
血便排泄	1 (1.0%)	0	1 (0.2%)	1 (0.2%)
大腸ポリープ	0	0	1 (0.2%)	1 (0.2%)
肛門周囲痛	0	0	1 (0.2%)	1 (0.2%)
偽性ポリポーシス	0	0	1 (0.2%)	1 (0.2%)
肛門直腸不快感	1 (1.0%)	0	0	0
嚥下障害	1 (1.0%)	0	0	0
直腸出血	1 (1.0%)	0	0	0
皮膚および皮下組織障害	3 (3.1%)	6 (6.4%)	30 (5.7%)	36 (6.0%)
発疹	0	1 (1.1%)	7 (1.3%)	8 (1.3%)
湿疹	0	0	4 (0.8%)	4 (0.7%)
ざ瘡	0	0	3 (0.6%)	3 (0.5%)
脱毛症	0	2 (2.1%)	1 (0.2%)	3 (0.5%)
皮膚乾燥	0	3 (3.2%)	0	3 (0.5%)
日光角化症	0	0	2 (0.4%)	2 (0.3%)
紅斑	0	0	2 (0.4%)	2 (0.3%)
寝汗	0	0	2 (0.4%)	2 (0.3%)
そう痒症	2 (2.1%)	0	2 (0.4%)	2 (0.3%)
蕁麻疹	0	0	2 (0.4%)	2 (0.3%)
水疱	0	0	1 (0.2%)	1 (0.2%)
皮膚嚢腫	0	0	1 (0.2%)	1 (0.2%)
アトピー性皮膚炎	0	0	1 (0.2%)	1 (0.2%)
乾癬様皮膚炎	0	1 (1.1%)	0	1 (0.2%)
過角化	0	0	1 (0.2%)	1 (0.2%)
丘疹	0	0	1 (0.2%)	1 (0.2%)

表 2.7.6.4-10 治験薬の使用と関連性のある有害事象（継続投与試験の投与被験者）（続き）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
粃糠疹	0	1 (1.1%)	0	1 (0.2%)
乾癬	0	0	1 (0.2%)	1 (0.2%)
丘疹性皮疹	0	0	1 (0.2%)	1 (0.2%)
そう痒性皮疹	0	0	1 (0.2%)	1 (0.2%)
皮膚亀裂	0	0	1 (0.2%)	1 (0.2%)
皮膚病変	0	0	1 (0.2%)	1 (0.2%)
神経皮膚炎	1 (1.0%)	0	0	0
一般・全身障害および投与部位の状態	3 (3.1%)	4 (4.3%)	31 (5.9%)	35 (5.8%)
発熱	0	1 (1.1%)	10 (1.9%)	11 (1.8%)
注射部位紅斑	0	1 (1.1%)	9 (1.7%)	10 (1.7%)
疲労	1 (1.0%)	2 (2.1%)	2 (0.4%)	4 (0.7%)
無力症	1 (1.0%)	0	3 (0.6%)	3 (0.5%)
注射部位疼痛	0	1 (1.1%)	2 (0.4%)	3 (0.5%)
末梢性浮腫	0	0	3 (0.6%)	3 (0.5%)
恥骨上痛	0	0	2 (0.4%)	2 (0.3%)
胸痛	0	0	1 (0.2%)	1 (0.2%)
インフルエンザ様疾患	1 (1.0%)	1 (1.1%)	0	1 (0.2%)
注射部位硬結	0	0	1 (0.2%)	1 (0.2%)
注射部位浮腫	0	0	1 (0.2%)	1 (0.2%)
注射部位そう痒感	0	0	1 (0.2%)	1 (0.2%)
注射部位発疹	0	0	1 (0.2%)	1 (0.2%)
倦怠感	0	0	1 (0.2%)	1 (0.2%)
神経系障害	2 (2.1%)	3 (3.2%)	15 (2.9%)	18 (3.0%)
頭痛	1 (1.0%)	1 (1.1%)	5 (1.0%)	6 (1.0%)
錯感覚	0	0	3 (0.6%)	3 (0.5%)
脱髄	0	0	2 (0.4%)	2 (0.3%)
浮動性めまい	0	0	2 (0.4%)	2 (0.3%)
傾眠	0	1 (1.1%)	1 (0.2%)	2 (0.3%)
無嗅覚	0	0	1 (0.2%)	1 (0.2%)
知覚過敏	0	0	1 (0.2%)	1 (0.2%)
嗜眠	0	0	1 (0.2%)	1 (0.2%)
多発性硬化症	0	0	1 (0.2%)	1 (0.2%)
一過性脳虚血発作	0	1 (1.1%)	0	1 (0.2%)
振戦	0	0	1 (0.2%)	1 (0.2%)
群発頭痛	1 (1.0%)	0	0	0
筋骨格系および結合組織障害	1 (1.0%)	3 (3.2%)	14 (2.7%)	17 (2.8%)
関節痛	1 (1.0%)	1 (1.1%)	7 (1.3%)	8 (1.3%)
背部痛	0	1 (1.1%)	2 (0.4%)	3 (0.5%)
反応性関節炎	0	1 (1.1%)	0	1 (0.2%)
筋力低下	0	0	1 (0.2%)	1 (0.2%)
筋骨格痛	0	0	1 (0.2%)	1 (0.2%)
筋肉痛	0	0	1 (0.2%)	1 (0.2%)
骨炎	0	0	1 (0.2%)	1 (0.2%)
骨粗鬆症	0	0	1 (0.2%)	1 (0.2%)
四肢痛	0	0	1 (0.2%)	1 (0.2%)
呼吸器、胸郭および縦隔障害	3 (3.1%)	2 (2.1%)	15 (2.9%)	17 (2.8%)
咳嗽	3 (3.1%)	0	10 (1.9%)	10 (1.7%)
呼吸困難	0	0	3 (0.6%)	3 (0.5%)
口腔咽頭痛	0	2 (2.1%)	1 (0.2%)	3 (0.5%)
間質性肺疾患	0	0	2 (0.4%)	2 (0.3%)
胸膜炎	0	0	2 (0.4%)	2 (0.3%)
アレルギー性咽頭炎	0	0	1 (0.2%)	1 (0.2%)
喘息	0	0	1 (0.2%)	1 (0.2%)
鼻潰瘍	0	0	1 (0.2%)	1 (0.2%)
肺臓炎	0	0	1 (0.2%)	1 (0.2%)
肺腫瘤	0	0	1 (0.2%)	1 (0.2%)

表 2.7.6.4-10 治験薬の使用と関連性のある有害事象（継続投与試験の投与被験者）（続き）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
気道うっ血	0	0	1 (0.2%)	1 (0.2%)
上気道うっ血	0	0	1 (0.2%)	1 (0.2%)
発声障害	1 (1.0%)	0	0	0
副鼻腔うっ血	1 (1.0%)	0	0	0
臨床検査	0	1 (1.1%)	10 (1.9%)	11 (1.8%)
アラニンアミノトランスフェラーゼ増加	0	1 (1.1%)	3 (0.6%)	4 (0.7%)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	2 (0.4%)	2 (0.3%)
血中アルカリホスファターゼ増加	0	0	1 (0.2%)	1 (0.2%)
血中クレアチニン増加	0	0	1 (0.2%)	1 (0.2%)
血中リン減少	0	0	1 (0.2%)	1 (0.2%)
収縮期血圧上昇	0	0	1 (0.2%)	1 (0.2%)
肝酵素上昇	0	0	1 (0.2%)	1 (0.2%)
肝機能検査異常	0	0	1 (0.2%)	1 (0.2%)
リンパ球数減少	0	0	1 (0.2%)	1 (0.2%)
白血球数増加	0	0	1 (0.2%)	1 (0.2%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	2 (2.1%)	9 (1.7%)	11 (1.8%)
皮膚乳頭腫	0	1 (1.1%)	2 (0.4%)	3 (0.5%)
基底細胞癌	0	0	2 (0.4%)	2 (0.3%)
肛門性器疣贅	0	0	1 (0.2%)	1 (0.2%)
ホジキン病	0	0	1 (0.2%)	1 (0.2%)
リンパ増殖性障害	0	0	1 (0.2%)	1 (0.2%)
卵巣上皮癌	0	1 (1.1%)	0	1 (0.2%)
遠隔転移を伴う直腸癌	0	0	1 (0.2%)	1 (0.2%)
皮膚有棘細胞癌	0	0	1 (0.2%)	1 (0.2%)
T細胞性リンパ腫	0	0	1 (0.2%)	1 (0.2%)
子宮平滑筋腫	0	0	1 (0.2%)	1 (0.2%)
血液およびリンパ系障害	0	0	6 (1.1%)	6 (1.0%)
リンパ節症	0	0	2 (0.4%)	2 (0.3%)
貧血	0	0	1 (0.2%)	1 (0.2%)
好酸球増加症	0	0	1 (0.2%)	1 (0.2%)
白血球増加症	0	0	1 (0.2%)	1 (0.2%)
リンパ球増加症	0	0	1 (0.2%)	1 (0.2%)
好中球減少症	0	0	1 (0.2%)	1 (0.2%)
眼障害	0	1 (1.1%)	4 (0.8%)	5 (0.8%)
白内障	0	0	1 (0.2%)	1 (0.2%)
上強膜炎	0	0	1 (0.2%)	1 (0.2%)
眼瞼発疹	0	1 (1.1%)	0	1 (0.2%)
霧視	0	0	1 (0.2%)	1 (0.2%)
視力低下	0	0	1 (0.2%)	1 (0.2%)
生殖系および乳房障害	0	0	4 (0.8%)	4 (0.7%)
乳房痛	0	0	1 (0.2%)	1 (0.2%)
子宮頚部上皮異形成	0	0	1 (0.2%)	1 (0.2%)
勃起不全	0	0	1 (0.2%)	1 (0.2%)
月経過多	0	0	1 (0.2%)	1 (0.2%)
血管障害	0	1 (1.1%)	3 (0.6%)	4 (0.7%)
動脈硬化症	0	0	1 (0.2%)	1 (0.2%)
深部静脈血栓症	0	0	1 (0.2%)	1 (0.2%)
レイノー現象	0	1 (1.1%)	0	1 (0.2%)
表在性血栓性静脈炎	0	0	1 (0.2%)	1 (0.2%)
耳および迷路障害	0	0	2 (0.4%)	2 (0.3%)
耳痛	0	0	1 (0.2%)	1 (0.2%)
耳鳴	0	0	1 (0.2%)	1 (0.2%)
精神障害	3 (3.1%)	0	2 (0.4%)	2 (0.3%)
不眠症	2 (2.1%)	0	1 (0.2%)	1 (0.2%)

表 2.7.6.4-10 治験薬の使用と関連性のある有害事象（継続投与試験の投与被験者）
（続き）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
精神状態変化	0	0	1 (0.2%)	1 (0.2%)
不安	1 (1.0%)	0	0	0
気分変調性障害	1 (1.0%)	0	0	0
肝胆道系障害	0	0	1 (0.2%)	1 (0.2%)
高トランスアミナーゼ血症	0	0	1 (0.2%)	1 (0.2%)
免疫系障害	0	0	1 (0.2%)	1 (0.2%)
薬物過敏症	0	0	1 (0.2%)	1 (0.2%)
傷害、中毒および処置合併症	0	0	1 (0.2%)	1 (0.2%)
挫傷	0	0	1 (0.2%)	1 (0.2%)
処置による悪心	0	0	1 (0.2%)	1 (0.2%)
代謝および栄養障害	1 (1.0%)	0	1 (0.2%)	1 (0.2%)
低ナトリウム血症	0	0	1 (0.2%)	1 (0.2%)
痛風	1 (1.0%)	0	0	0
妊娠、産褥および周産期の状態	0	0	1 (0.2%)	1 (0.2%)
自然流産	0	0	1 (0.2%)	1 (0.2%)
腎および尿路障害	0	0	1 (0.2%)	1 (0.2%)
腎結石症	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.
Note: Reasonably related AEs includes all adverse events with a relationship of possible, probable, definite, or a missing response.
Note: Adverse Events are coded using MedDRA 17.1

[TSFAE01-REL.rtf] [CNTO148\C0524T18\DBR_W228\RE_NDAJPKK\tsfae01-rel.sas] 04FEB2016, 21:45

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
Yes	Placebo	1 mg/kg IV	6404-00003	7[redacted]/F	POLAND/Caucasian			0	812	神経症	NEUROSIS	840		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								0	953	尿路感染	INFECTION OF URINARY SYSTEM	964	13	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								0	953	心筋梗塞	ANTERIOR MYOCARDIAL INFARCTION.	964	9	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
								0	953	高脂血症	HYPERLIPIDEMIA	964		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
			6705-00001	7[redacted]/F	UNITED STATES/Caucasian			0	394	尿路感染	URINARY TRACT INFECTION	411	4	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								0	617	貧血	ANEMIA	630	566	Resolved	No	Mild	Not related	None/not applicable	No /No
								0	617	尿路感染	URINARY TRACT INFECTION	640	9	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								0	704	嚥下障害	DYSPHAGIA	705	235	Resolved	No	Mild	Not related	None/not applicable	No /No
								0	752	悪心	NAUSEA	762	178	Resolved	No	Mild	Not related	None/not applicable	No /No
								0	752	嘔吐	VOMITING	762	309	Resolved	No	Mild	Not related	None/not applicable	No /No
								0	752	尿路感染	URINARY TRACT INFECTION	768	4	Resolved	No	Mild	Not related	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								0	953	一過性脳虚血発作	TRANSIENT ISCHEMIC ATTACK	981	3	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								0	1037	悪心	NAUSEA	1037		Resolved	No	Mild	Not related	None/not applicable	No /No
								0	1010	歯痛	TOOTH PAIN	1037	190	Resolved	No	Mild	Not related	None/not applicable	No /No
								0	1233	甲状腺新生物	THYROID NODULE	1245		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								0	1233	脱水	DEHYDRATION	1245	2	Resolved	No	Moderate	Not related	None/not applicable	No /No
								0	1233	靭帯捻挫	RIGHT ANKLE SPRAIN	1254	46	Resolved	No	Moderate	Not related	None/not applicable	No /No
								0	1403	貧血	ANEMIA	1410	189	Resolved	No	Mild	Not related	None/not applicable	No /No
		2 mg/kg IV	6407-00013	5[redacted]/F	POLAND/Caucasian			0	899	貧血	ANAEMIA	899	29	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								0	899	貧血	HOSPITALISATION DUE TO ANAEMIA	927	6	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
								0	933	貧血	ANAEMIA	933	14	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								0	989	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	997	49	Resolved	No	Mild	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	1067	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	1078	24	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1151	潰瘍性大腸炎	EACERBATION OF ULCERATIVE COLITIS	1164	111	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1288	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	1311	31	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1352	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	1366	80	Resolved	No	Mild	Not related	None/not applicable	No /No
		100 mg/50 mg SC	7727-00002	3[redacted]/M	UNITED STATES /Caucasian			0	361	インフルエンザ様疾患	FLU-LIKE SYMPTOMS	391	10	Resolved	No	Moderate	Possible	None/not applicable	No /No
								0	361	咳嗽	COUGH	391	6	Resolved	No	Moderate	Possible	None/not applicable	No /No
								0	361	咳嗽	WORSENING COUGH	396	5	Resolved	No	Severe	Possible	None/not applicable	No /No
								0	361	気管支炎	BRONCHITIS	398	19	Resolved	No	Moderate	Possible	None/not applicable	No /No
								0	361	喉頭炎	LARYNGITIS	398	3	Resolved	No	Moderate	Possible	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								0	427	咬傷感染	INFECTED MOSQUITO BITE	436	6	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	595	潰瘍性大腸炎	WORSENING U.C.	598	4	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
								100	595	潰瘍性大腸炎	WORSENING U.C.	602	11	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
								100	617	口腔ヘルペス	COLD SORE UPPER LIP	630	8	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	676	季節性アレルギー	SEASONAL ALLERGIES	689	20	Resolved	No	Mild	Unlikely	None/not applicable	No /No
		200 mg/100 mg SC	6705-00016	5[redacted]/M	UNITED STATES /Caucasian	100 mg	307	100	393	麦粒腫	OD STYE	413	67	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
						100 mg	307	100	393	副鼻腔うっ血	SINUS CONGESTION	413	67	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	307	100	421	背部痛	LOWER BACK PAIN	432	78	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	307	100	561	貧血	WORSENING ANEMIA	561		Not Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	307	100	617	インフルエンザ	INFLUENZA	619	8	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
						100 mg	307	100	617	頭痛	HEADACHE	650	3	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	307	100	652	頭痛	HEADACHE	652		Not Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
						100 mg	307	100	701	痔核	ANAL CANAL HEMORRHOID	701		Not Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	307	100	841	椎間板突出	HERNIATED DISC	853	2	Resolved	Yes	Severe	Not related	None/not applicable	No /No
						100 mg	307	100	841	処置による疼痛	POST OP PAIN	853	9	Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	307	100	841	筋痙縮	MUSCLE SPASM	853	101	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	307	100	841	外傷性脊椎症	TRAUMATIC CERVICAL SPONDYLOPATHY	853	2	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
						100 mg	307	100	1016	潰瘍性大腸炎	ULCERATIVE COLITIS FLAIR	1018	20	Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	307	100	1112	尿路感染	URINARY TRACT INFECTION	1145	15	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
						100 mg	307	100	1177	霧視	BLURRED VISION	1192		Not Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	307	100	1233	インフルエンザ	FLU SYMPTOMS	1264	5	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	307	100	1266	壊疽性膿皮症	PYODERMA GANGRENOSUM	1283	42	Resolved	No	Moderate	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
						100 mg	307	100	1310	壊疽性膿皮症	PYODERMA GANGRENOSUM	1325	14	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
			7001-00005	3[redacted]/M	AUSTRALIA/Other	100 mg	18	100	512	痔核	HAEMORRHOIDS REQUIRING SURGERY (HAEMORRHOIDECTOMY)	527	2	Resolved	Yes	Mild	Not related	None/not applicable	No /No
						100 mg	18	100	883	副鼻腔炎	SINUSITIS	887	35	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
						100 mg	18	100	1051	直腸出血	RECTAL BLEEDING	1079	78	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	18	100	1079	疲労	FATIGUE	1100	347	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	18	100	1212	足部白癬	ATHLETES FOOT	1245	10	Resolved	No	Mild	Not related	None/not applicable	Yes/No
						100 mg	18	100	1485	潰瘍性大腸炎	FLARE OF UC	1521	67	Resolved	No	Moderate	Not related	None/not applicable	No /No
			7213-00001	4[redacted]/F	GERMANY/Caucasian			100	594	無月経	SECONDARY AMENORRHOE			Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	673	関節痛	ARTHRALGIA ON HANDS			Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	645	関節痛	ARTHRALGIA ON KNEES			Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1065	筋痙縮	CALF CRAMPS			Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	951	脱毛症	HAIR LOSS			Resolved	No	Mild	Not related	None/not applicable	No /No
								100	391	鼻咽頭炎	COMMON COLD	395	36	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	594	注射部位紅斑	REDNESS ON INJECTION SITE (LOWER LEFT ABDOMINAL) 4CM X 2 CM	596	89	Resolved	No	Mild	Probable	None/not applicable	No /Yes
								100	616	注射部位紅斑	REDNESS ON INJEKTION SITE (LOWER RIGHT ABDOMINAL)	617	15	Resolved	No	Mild	Probable	None/not applicable	No /Yes
								100	786	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	796	3	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1091	鼻咽頭炎	COMMON COLD	1093	34	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	1175	外陰部腟カンジダ症	VAGINAL CANDIDASIS	1188	5	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	1175	鼻咽頭炎	COMMON COLD	1200	28	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	1315	貧血	ANAEMIA	1316		Not Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	1454	アレルギー性皮膚炎	ALLERGIC SKIN EXANTHEMA	1463	3	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1484	喉頭炎	LARYNGITIS	1497	9	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	1484	好酸球数	EOSINOPHILE	1524		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1484	結腸異形成	ULCERATIVE COLITIS WITH DYSPLASIA	1540	109	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								100	1484	結腸異形成	COLON-ASSOCIATED DYSPLASIA	1540	53	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
			7408-00004	2[redacted]/F	POLAND/Caucasian			0	527	潰瘍性大腸炎	ULCERATIVE COLITIS EXACERBATION.	537	2	Resolved	No	Severe	Not related	Permanent discontinuation of study agent	No /No
								0	527	潰瘍性大腸炎	UC EXACERBATION	538	94	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								0	527	痔核	HEMORRHOIDES	590	9	Resolved	No	Moderate	Not related	None/not applicable	No /No
			7456-00001	3[redacted]/M	RUSSIANFEDERATION/ Caucasian	100 mg	59	100	614	ヘモグロビン減少	DECREASE IN LEVEL OF HAEMOGLOBIN	647		Not Resolved	No	Moderate	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
						100 mg	59	100	614	血中アルブミン減少	DECREASE IN LEVEL OF ALBUMIN	647		Not Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	59	100	614	血中カルシウム減少	CA LEVEL DECLINE	647		Not Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	59	100	647	大腸腺腫	TUBULAR ADENOMA WITH A LOW DEGREE OF NEOPLASIA	653	49	Resolved	Yes	Mild	Not related	None/not applicable	No /No
						100 mg	59	100	704	排便回数増加	STOOL INCREASE FREQUENCY	727		Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	59	100	704	腹部膨満	ABDOMINAL DISTENTION	727		Resolved	No	Mild	Not related	None/not applicable	No /No
			7743-00013	4[redacted]/M	UNITED STATES /Caucasian	100 mg	32	100	473	口腔咽頭痛	SORE THROAT	500	14	Resolved	No	Mild	Not related	None/not applicable	Yes/No
						100 mg	32	100	543	上気道感染	UPPER RESPIRATORY INFECTION	561	19	Resolved	No	Moderate	Not related	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
						100 mg	32	100	759	偶発的過量投与	ACCIDENTAL NITROUS OXIDE OVERDOSE	771	1	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
		400 mg/200 mg SC	6402-00008	7[redacted]/M	POLAND/Caucasian		0		426	膀胱頚部閉塞	STRICTURE OF BLADDER NECK	441	9	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
			7026-00022	3[redacted]/F	AUSTRIA/Caucasian	100 mg	28	100	392	注射部位紅斑	ERYTHEMA AT INJECTION SITE	392	4	Resolved	No	Mild	Definite	None/not applicable	No /Yes
						100 mg	28	100	455	注射部位紅斑	ERYTHEMA AT INJECTION SITE	455	5	Resolved	No	Mild	Definite	None/not applicable	No /Yes
						100 mg	28	100	483	胃腸炎	GASTRO ENT. INFECTION	487	3	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
						100 mg	28	100	623	口腔ヘルペス	HERPES SIMPLEX LABIALIS	641	33	Resolved	No	Moderate	Probable	Temporary interruption/dose modification	Yes/No
						100 mg	28	100	703	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	710	31	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	28	100	730	口腔ヘルペス	HERPES LABIALIS	764	13	Resolved	No	Mild	Possible	None/not applicable	No /No
						100 mg	28	100	765	鼻咽頭炎	COMMON COLD	791	8	Resolved	No	Mild	Possible	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
						100 mg	28	100	800	胃腸炎	GASTROENTERITIS	807	3	Resolved	No	Severe	Unlikely	None/not applicable	Yes/No
						100 mg	28	100	800	胃腸炎	GASTROENTERITIS	809	5	Resolved	Yes	Severe	Unlikely	None/not applicable	Yes/No
						100 mg	28	100	883	インフルエンザ	INFLUENZAL INFECTION	908	47	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
						100 mg	28	100	1358	頚部痛	NECK PAIN	1368	22	Resolved	No	Mild	Not related	None/not applicable	No /No
			7207-00005	3[redacted]/F	GERMANY/Caucasian	100 mg	106	100	555	発熱	FEVER	578	3	Resolved	No	Mild	Possible	None/not applicable	No /No
						100 mg	106	100	731	嘔吐	VOMITING	743	3	Resolved	Yes	Mild	Not related	None/not applicable	No /No
						100 mg	106	100	910	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	945	6	Resolved	Yes	Moderate	Not related	Permanent discontinuation of study agent	No /No
			7413-00010	2[redacted]/M	POLAND/Caucasian	100 mg	85	100	533	腹痛	ABDOMINAL PAIN	560	1	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	85	100	1037	鼻咽頭炎	COMMOMD COLD	1057	3	Resolved	No	Mild	Not related	None/not applicable	Yes/No
						100 mg	85	100	1126	腹痛	ABDOMINAL PAIN	1146	2	Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	85	100	1126	嘔吐	VOMITTING	1146	1	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	85	100	1205	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	1211	37	Resolved	Yes	Moderate	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
						100 mg	85	100	1485	腹痛	ABDOMINAL PAIN	1557		Not Resolved	No	Mild	Not related	None/not applicable	No /No
			7502-00003	3[redacted]/F	SLOVAKIA(SlovakRepublic)/Caucasian	100 mg	283	100	618	注射部位紅斑	LOCAL SKIN ERYTHEMA IN IP INJECTION SITE	618	4	Resolved	No	Mild	Probable	None/not applicable	No /Yes
						100 mg	283	100	618	上気道感染	UPPER AIRWAYS INFECTION	646	6	Resolved	No	Mild	Possible	None/not applicable	Yes/No
						100 mg	283	100	618	下気道感染	LOWER AIRWAYS INFECTION	646	6	Resolved	No	Mild	Possible	None/not applicable	Yes/No
						100 mg	283	100	648	注射部位紅斑	LOCAL SKIN ERYTHEMA IN PI INJECTION SITE	648	3	Resolved	No	Mild	Probable	None/not applicable	No /Yes
						100 mg	283	100	673	潰瘍性大腸炎	UC FLARE	705	18	Resolved	Yes	Moderate	Unlikely	Permanent discontinuation of study agent	No /No
			7727-00009	4[redacted]/M	UNITED STATES/Caucasian	100 mg	266	100	503	坐骨神経痛	SCIATIC NERVE PAIN	517	37	Resolved	Yes	Severe	Not related	None/not applicable	No /No
						100 mg	266	100	503	悪心	NAUSEA	519	2	Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
						100 mg	266	100	1114	アラニンアミノトランスフェラーゼ増加	ELEVATED LIVER ENZYME (ALT)	1148	92	Resolved	No	Mild	Possible	None/not applicable	No /No
	Golimumab 50 mg	1 mg/kg IV	6279-00001	3[redacted]/M	ISRAEL/ Caucasian			50	774	アラニンアミノトランスフェラーゼ増加	INCREASE OF ALT	802	162	Resolved	No	Mild	Possible	None/not applicable	No /No
								50	907	パートナーの妊娠	PREGNANCY OF FEMALE PARTNER	935	58	Resolved	No	Severe	Not related	None/not applicable	No /No
								50	1100	一過性脳虚血発作	TRANSIENT CEREBRAL ISCHEMIA	1107	5	Resolved	Yes	Mild	Possible	None/not applicable	No /No
								50	1128	ウイルス感染	VIRAL INFECTION	1153	8	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								50	1128	咳嗽	COUGHING	1153	8	Resolved	No	Mild	Not related	None/not applicable	Yes/No
		2 mg/kg IV	6749-00001	7[redacted]/M	UNITED STATES /Caucasian			50	825	便秘	CONSTIPATION			Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								50	432	白内障	CATARACT SURGERY. DUE TO WORSENING OF CATARACT.	440	1	Resolved	No	Mild	Not related	None/not applicable	No /No
								50	482	結膜炎	CONJUNCTIVITIS	501	7	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								50	566	眼刺激	RIGHT EYE IRRITATED	585	6	Resolved	No	Mild	Not related	None/not applicable	No /No
								50	594	挫傷	BRUISE ON LOWER RIGHT ARM	605	46	Resolved	No	Mild	Not related	None/not applicable	No /No
								50	825	意識消失	LOSS OF CONSCIOUSNESS	846	1	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								50	825	手首関節骨折	LEFT WRIST FRACTURE	846	155	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								50	881	鼻咽頭炎	COUGH RELATED TO COLD	883	55	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	881	アレルギー性咳嗽	COUGH RELATED TO ALLERGIES	883	55	Resolved	No	Mild	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								50	881	鼻咽頭炎	COMMON COLD	883	55	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								50	972	白内障	EYE (CATERACT) SURGERY IN RIGHT EYE DUE TO WORSENING CATARACT	987	1	Resolved	No	Mild	Not related	None/not applicable	No /No
								50	1098	心拍数増加	RAPID PULSE	1098	64	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	1189	血中リン減少	LOW PHOSPHOROUS LEVEL	1203		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	1245	発熱	FEVER	1273	1	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	1350	頻脈	TACHYCARDIA	1357	15	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	1350	皮膚真菌感染	SKIN LESIONS INSIDE LEG SOCKET DUE TO FUNGAL INFECTION	1364	78	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								50	1350	皮膚病変	SKIN LESIONS - ELBOW	1364	24	Resolved	No	Mild	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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		4 mg/kg IV	6227-00003	3[redacted]/M	HUNGARY/Caucasian	100 mg	84	100	420	発熱	FEVER	434	7	Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	84	100	706	癜風	PITYRIASIS VERSICOLOR	706	24	Resolved	No	Mild	Possible	None/not applicable	Yes/No
						100 mg	84	100	813	潰瘍性大腸炎	WORSENING OF UC	813	24	Resolved	No	Moderate	Possible	None/not applicable	No /No
						100 mg	84	100	1086	腎結石症	KIDNEY STONE	1105	2	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
						100 mg	84	100	1287	潰瘍性大腸炎	WORSENING OF ULCERATIV COLITIS	1294	18	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
			6478-00003	3[redacted]/F	SERBIA/Caucasian	50 mg	115	50	394	ウイルス性気道感染	RESPIRATORY VIROSIS	418	10	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
						50 mg	115	50	394	発疹	SKIN RUSH	420	22	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						50 mg	115	50	505	ウイルス性気道感染	RESPIRATORY VIROSIS	529	6	Resolved	No	Mild	Not related	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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						50 mg	115	100	1292	多発性硬化症	CLINICALLY ISOLATED SYNDROMA POSSIBLE FIRST MANIFESTATION OF MULTIPLE SCLEROSIS	1299	8	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	No /No
						50 mg	115	100	1292	脱髄	DEMYELINATION	1299		Not Resolved	No	Moderate	Possible	Permanent discontinuation of study agent	No /No
			6716-00008	6[redacted]/M	UNITED STATES /Caucasian			50	952	毛包炎	FOLICULITIS, FACE			Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								50	451	副鼻腔炎	SINUSITIS (SINUS INFECTIONS	454	11	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								50	505	季節性アレルギー	ENVIRONMENTAL SEASONAL ALLERGIES	505		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								50	505	血便排泄	HEMATOCHEZIA	528	1	Resolved	No	Moderate	Unlikely	None/not applicable	No /No

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								50	533	排便回数増加	INCREASE FREQUENCY OF BOWEL MOVEMENTS	549	20	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								50	589	末梢性浮腫	BILATERAL LOWER LEG EDEMA	590	229	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	589	発熱	FEVER	590	1	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								50	589	口腔咽頭痛	SORE THROAT	590	1	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	589	腎結石症	LEFT RENAL PELVIC STONES	614	116	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								50	589	尿路感染	URINARY TRACT INFECTION	614	12	Resolved	Yes	Moderate	Unlikely	None/not applicable	Yes/No
								50	589	肝障害	DIFFUSELY ABNORMAL LIVER	614		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	589	後天性肝内胆管拡張症	INTRAHEPATIC BILE DUCT DILATATION	614		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	589	脾腫	SPENOMEGALY	614	299	Resolved	No	Mild	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								50	589	血中クレアチニン増加	ABNORMALLY ELEVATED CREATANINE LEVEL	614	13	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	701	皮膚刺激	SKIN IRRITATION, FACE	717	16	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								50	727	変形性関節症	WORSENING OSTEOARTHRITIS, LEFT KNEE	734	3	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								50	727	便秘	CONSTIPATION	734	2	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	762	皮膚乾燥	DRY HANDS, PALMS OF HAND, BILATERAL	762	57	Resolved	No	Mild	Possible	None/not applicable	No /No
								50	818	血便排泄	HEMATOCHEZIA	834	3	Resolved	No	Mild	Not related	None/not applicable	No /No
								50	818	大腸ポリープ	COLON POLYP	834	1	Resolved	No	Mild	Not related	None/not applicable	No /No
								50	847	肛門周囲痛	RECTAL PAIN	874	39	Resolved	No	Moderate	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								50	847	排便回数増加	INCREASE FREQUENCY OF BOWEL MOVEMENTS	874	53	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								50	847	血便排泄	HEMATOCHEZIA	874	53	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	847	ウイルス性胃腸炎	VIRAL GASTROENTERITIS	874	53	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								50	878	発声障害	HOARSENESS	891	62	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	878	嚥下痛	PAINFUL SWALLOWING	891	36	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								50	878	上腹部痛	UPPER ABDOMINAL PAIN	891	62	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								50	878	下腹部痛	LOWER ABDOMINAL PAIN	897	30	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								50	878	腹痛	ABDOMINAL CRAMPING	897	30	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	878	体重減少	WEIGHT LOSS	912	15	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								50	878	低血圧	HYPOTENSION	912	15	Resolved	No	Moderate	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								50	878	血中尿素増加	ELEVATED BUN	912	14	Resolved	No	Moderate	Unlikely	Temporary interruption/dose modification	No /No
								50	878	血中クレアチニン増加	ELEVATED CREATANINE LEVEL	912	14	Resolved	No	Moderate	Unlikely	Temporary interruption/dose modification	No /No
								50	878	脱水	DEHYDRATION	912	15	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								50	878	肺腫瘤	5 MM RIGHT MIDDLE LOBE PULMONARY NODULE	912		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	878	リンパ節症	SMALL LYMPH NODES MESENTERIC FAT ADJACENT TO ASCENDING COLON	912		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	878	鼠径ヘルニア	LEFT INGUINAL HERNIA	912		Not Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								50	878	腹部ヘルニア	RIGHT ABDOMINAL WALL HERNIA	912		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								50	878	腎結石症	SCATTERED CALCIFIED DENSITIES LEFT KIDNEY	912		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	878	十二指腸潰瘍	DUODENAL ULCERATIONS	913	152	Resolved	No	Moderate	Unlikely	Temporary interruption/dose modification	No /No
								50	926	鉄欠乏性貧血	IRON DEFICIENCY ANEMIA	926		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								50	926	単純ヘルペス	HERPES SIMPLEX, FACE AND LIPS	948	47	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								50	952	下痢	INCREASE IN LOOSENESS OF STOOLS	968	97	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								50	1014	骨挫傷	LEFT RIB CONTUSION	1019	46	Resolved	No	Moderate	Not related	None/not applicable	No /No
								50	1064	咽頭炎	THROAT INFECTION	1070	11	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								50	1127	関節痛	BILATERAL SHOULDER ARTHRITIC PAIN	1144	2	Resolved	No	Moderate	Not related	None/not applicable	No /No
								50	1127	上腹部痛	UPPER ABDOMINAL PAIN	1146	6	Resolved	No	Moderate	Not related	None/not applicable	No /No
								50	1239	関節痛	ARTHRITIS PAIN, LEFT HIP	1239		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
								50	1239	ヘマトクリット減少	LOW HEMATOCRIT	1239	7	Resolved	No	Mild	Not related	None/not applicable	No /No
								50	1239	滑液包炎	LEFT GREATER TROCHANTERIC BURSITIS	1245		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
								50	1239	鼠径部膿瘍	GROIN ABSCESS	1249	48	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								50	1267	鼻出血	EPISTAXIS	1299	1	Resolved	No	Moderate	Not related	None/not applicable	No /No
								50	1301	腎結石症	KIDNEY STONES	1316	24	Resolved	No	Mild	Not related	None/not applicable	No /No
								50	1330	前立腺癌	PROSTATE CANCER	1339		Not Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								50	1330	腱付着部症	ANKLE AND TARSUS ENTHESOPATHY	1350		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								50	1330	リンパ節症	ENLARGED RETROCURUAL LYMPH NODE,	1380		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								50	1330	毛包炎	FOLLICULTIS	1421		Not Resolved	No	Mild	Not related	None/not applicable	Yes/No
		100 mg/50 mg SC	7408-00002	5[redacted]/F	POLAND/Caucasian			50	567	硬化性苔癬	LICHEN ATROPHICUS WITH A LARGE CORNIFICATION OF THE LARGE PUDENDAL LIP			Resolved	Yes	Mild	Unlikely	None/not applicable	No /No
								50	426	背部痛	PAIN OF LUMBAL AND SACRAL REGION	451	74	Resolved	No	Moderate	Possible	None/not applicable	No /No
								50	510	乾癬様皮膚炎	PSOROID DERMATITIS	534	34	Resolved	No	Moderate	Possible	None/not applicable	No /No
								50	740	鉄欠乏性貧血	IDIOPATHIC SIDEROPENIC ANEMIA	746	12	Resolved	Yes	Moderate	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								50	853	歯周炎	PARADENTITIS	873	6	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								50	1434	坐骨神経痛	SCIATICA	1460	31	Resolved	No	Mild	Unlikely	None/not applicable	No /No
		200 mg/100 mg SC	6404-00021	6[redacted]/F	POLAND/Caucasian	50 mg	184	50	804	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	819	36	Resolved	No	Mild	Not related	None/not applicable	No /No
						50 mg	184	50	1101	潰瘍性大腸炎	ULCERATIVE COLITIS EXACERBATION	1122	99	Resolved	Yes	Severe	Unlikely	Temporary interruption/dose modification	No /No
						50 mg	184	50	1101	急性腎不全	ACUTE OF RENAL INSUFICIENCY	1136	57	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
						50 mg	184	50	1101	貧血	SECOUNDARY ANEMIA RELATED TO EXACERBATION OF UC	1136	57	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
						50 mg	184	100	1304	消化不良	HEARTBURN	1325	15	Resolved	No	Mild	Not related	None/not applicable	No /No
			6726-00024	4[redacted]/M	UNITED STATES/Caucasian	100 mg	57	100	549	乳房痛	LEFT BREAST PAIN			Not Resolved	No	Mild	Possible	None/not applicable	No /No
						100 mg	57	100	392	ウイルス性胃腸炎	STOMACH VIRUS	415	6	Resolved	No	Moderate	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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						100 mg	57	100	392	上気道感染	UPPER RESPIRATORY INFECTION	418	6	Resolved	No	Mild	Possible	None/not applicable	Yes/No
						100 mg	57	100	421	肝機能検査異常	ELEVATED LIVER FUNCTION	444	42	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	57	100	421	頻脈	TACHACARDIA	444	106	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	57	100	444	副鼻腔炎に伴う頭痛	SINUS PAIN	458	6	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	57	100	864	結腸異形成	HIGH GRADE DISPLASIA IN THE AREA OF THE SPLENIC FLEXURE	878	39	Resolved	Yes	Severe	Possible	Permanent discontinuation of study agent	No /No
			7228-00001	4[redacted]/F	HUNGARY/Caucasian			50	422	インフルエンザ	FLU	450	8	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								50	450	肺炎	PNEUMONIA	463	29	Resolved	Yes	Moderate	Not related	None/not applicable	Yes/No
			7278-00004	5[redacted]/F	ISRAEL/Caucasian	100 mg	169	100	429	皮膚乳頭腫	VIAL WARTS			Resolved	No	Moderate	Not related	None/not applicable	Yes/No
						100 mg	169	100	539	潰瘍性大腸炎	EXACERBATION OF UC	547	8	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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						100 mg	169	100	602	腹痛	ABDOMINAL PAIN	620		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	169	100	623	潰瘍性大腸炎	EXACERBATION OF UC	647	5	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
		400 mg/200 mg SC	6751-00018	3[redacted]/F	UNITED STATES /Black	50 mg	88	50	480	関節痛	JOINT PAIN	498		Not Resolved	No	Mild	Not related	None/not applicable	No /No
						50 mg	88	50	703	腹痛	ABDOMINAL CRAMPING	719	73	Resolved	No	Moderate	Not related	None/not applicable	No /No
						50 mg	88	50	703	卵巣嚢胞	CYSTIC MASS IN RIGHT OVARY	725	67	Resolved	No	Moderate	Not related	None/not applicable	No /No
						50 mg	88	50	788	卵巣上皮癌	OVARIAN INVASIVE MUCINOUS ADENOCARCINOMA	791	79	Resolved	Yes	Severe	Possible	Permanent discontinuation of study agent	No /No
						50 mg	88	50	788	潰瘍性大腸炎	ULCERATIVE COLITIS FLARE	825	82	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
						50 mg	88	50	788	関節痛	JOINT PAIN	825		Not Resolved	No	Mild	Not related	None/not applicable	No /No
						50 mg	88	50	788	骨痛	BONE PAIN	825		Not Resolved	No	Mild	Not related	None/not applicable	No /No
						50 mg	88	50	788	毛巣嚢胞	PILONIDAL CYST	833		Not Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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			7007-00003	5[redacted]/F	AUSTRALIA/Caucasian			50	868	鼻閉	NASAL CONGESTION			Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	420	発疹	SKIN RASH TO SCALP	436	443	Resolved	No	Mild	Not related	None/not applicable	No /No
								50	476	脱毛症	LOSS OF SCALP HAIR	503	376	Resolved	No	Moderate	Possible	None/not applicable	No /No
								50	504	鼻閉	NASAL CONGESTION	527	186	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	504	処置による疼痛	PAIN RELATED TO SURGERY	542	3	Resolved	No	Moderate	Not related	None/not applicable	No /No
								50	504	処置による悪心	NAUSEA RELATED TO SURGERY	542	1	Resolved	No	Moderate	Not related	None/not applicable	No /No
								50	504	発疹	SKIN RASH TO UNDERARMS	560	44	Resolved	No	Moderate	Possible	None/not applicable	No /No
								50	616	皮膚感染	SCALP INFECTION	634	25	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								50	728	インフルエンザ	INFLUENZA SYMPTOMS	731	6	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								50	728	下気道感染	CHEST INFECTION	738	7	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No

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								50	784	発疹	LEFT PALM RASH	805	44	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								50	812	皮膚感染	NASAL SKIN INFECTION	827	42	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								50	926	眼感染	EYE INFECTION	932	10	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								50	926	発疹	SKIN RASH TO NECK AND SHOULDERS	937	247	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	987	眼感染	RIGHT EYE INFECTION	1007	15	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								50	1008	副鼻腔炎	SINUSITIS	1036	24	Resolved	Yes	Moderate	Not related	Temporary interruption/dose modification	No /No
								50	1008	中耳炎	OTITIS MEDIA	1058	12	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								50	1008	耳感染	EAR INFECTION	1070	20	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								50	1071	発疹	RASH AROUND THE EARS	1085	362	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	1071	発疹	RASH ON HANDS	1086		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No

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								50	1071	発疹	SCALP RASH	1087	35	Resolved	No	Mild	Possible	None/not applicable	No /No
								50	1071	皮膚感染	NASAL SKIN INFECTION	1088	359	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								50	1148	鼻炎	NASAL INFECTION	1161	14	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								50	1148	発疹	RIGHT EAR LODE RASH	1161	8	Resolved	No	Mild	Possible	None/not applicable	No /No
								50	1176	鼻閉	NASAL CONGESTION	1183	264	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	1204	蜂巣炎	CELLULITIS RIGHT FOOT	1210	17	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								50	1288	節足動物咬傷アレルギー	REACTION TO SPIDER BITE ON LEFT ARM AND NECK	1298	12	Resolved	No	Mild	Not related	None/not applicable	No /No
								50	1344	結膜炎	CONJUNCTIVITIS LEFT EYE	1350	8	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								50	1372	眼の炎症	INFLAMATION LEFT EYE	1392	16	Resolved	No	Mild	Unlikely	None/not applicable	No /No

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								50	1477	皮膚腫瘤	2 REDDENED LUMPS ON FRONT OF LOWERE LEFT LEG	1479		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	1477	鼻炎	NASAL INFECTION	1512		Not Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
			7026-00014	3[redacted]/F	AUSTRIA/Caucasian			50	365	うつ病	DEPRESSION			Not Resolved	No	Severe	Unlikely	None/not applicable	No /No
								50	491	皮膚腫瘤	SUBCUTANEOUS NODULES			Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	470	関節痛	JOINT PAIN	480		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								50	491	リンパ節炎	LYMPHADENITIS COLLI	511		Resolved	No	Moderate	Unlikely	Temporary interruption/dose modification	Yes/No
								50	491	うつ病	WORSENING OF DEPRESSION	520	8	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								50	550	咳嗽	INTERMITTENT COUGH	551		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	571	胸痛	THORACIC PAIN	587	172	Resolved	No	Mild	Not related	None/not applicable	No /No
								50	646	鼻咽頭炎	COMMON COLD	648	8	Resolved	No	Moderate	Possible	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								50	674	扁桃炎	PURULENT TOSILLITIS	690	9	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								50	701	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	726		Not Resolved	No	Severe	Not related	Permanent discontinuation of study agent	No /No
			7456-00004	3[redacted]/F	RUSSIA NFEDERATION/ Caucasian			50	864	痔核	HEMORRHOID	867	67	Resolved	No	Mild	Not related	None/not applicable	No /No
								50	864	裂肛	ACUTE ANAL FISSURE	867	67	Resolved	No	Mild	Not related	None/not applicable	No /No
								50	1310	子宮平滑筋腫	UTERINE LEIOMYOMA WITH INTRALIGAMENTOUS BIG SIZE NODE LOCATION	1339	30	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								50	1310	子宮平滑筋腫	UTERINE LEIOMYOMA (MYOMECTOMY)	1339	38	Resolved	Yes	Severe	Unlikely	Temporary interruption/dose modification	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
			7584-00004	5[redacted]/F	UKRAINE/Caucasian			50	365	大葉性肺炎	RIGHT SIDE LOWER LOBE PNEUMONIA	391	16	Resolved	Yes	Moderate	Not related	None/not applicable	Yes/No
	Golimumab 100 mg	1 mg/kg IV	6257-00005	2[redacted]/F	INDIA/Asian			100	587	自然流産	SPONTANEOUS ABORTION			Resolved	Yes	Mild	Possible	None/not applicable	No /No
								100	587	妊娠	PREGNANCY	623		Resolved	No	Mild	Not related	Permanent discontinuation of study agent	No /No
			6716-00006	2[redacted]/M	UNITED STATES/Other			100	439	腹痛	ABDOMINAL CRAMPING	461		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	439	排便回数増加	INCREASE FREQUENCY OF BM'S	471	32	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	439	血便排泄	HEMATOCHEZIA	471	32	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	487	好中球数増加	ELEVATED NEUTROPHIL COUNT	502	78	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	593	うつ病	SEVERE DEPRESSION	597	2	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	593	アルコール乱用	ALCOHOL ABUSE	597	2	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	593	うつ病	DEPRESSION	598	334	Resolved	No	Mild	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	607	下痢	LOOSE STOOLS	673	61	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	800	副鼻腔うっ血	SINUS CONGESTION	830	9	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	800	咳嗽	COUGH	830	9	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	873	希死念慮を有するうつ病	SUICIDAL DEPRESSION	931	4	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	873	うつ病	DEPRESSION	934		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1010	レジオネラ菌性肺炎	BILATERAL LEGIONELLA PNEUMONIA	1045	38	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	Yes/No
								100	1010	胸水	LEFT LARGE PARAPNEUMONIC EFFUSION	1045	6	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
								100	1010	呼吸不全	RESPITORY FAILURE	1045	11	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	Yes/No
								100	1010	血小板増加症	THROMBOCYTOSIS	1045	38	Resolved	Yes	Moderate	Unlikely	Permanent discontinuation of study agent	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	1010	肝炎	LEGIONELLA HEPATITIS	1045	18	Resolved	Yes	Moderate	Not related	Permanent discontinuation of study agent	Yes/No
								100	1010	低ナトリウム血症	HYPONATREMIA	1048	7	Resolved	Yes	Mild	Not related	Permanent discontinuation of study agent	No /No
								100	1010	肺塞栓症	PULMONARY EMBOLIZATION	1050		Not Resolved	Yes	Moderate	Unlikely	Permanent discontinuation of study agent	No /No
								100	1010	細菌性敗血症	BACTERIAL SEPSIS	1050		Not Resolved	Yes	Moderate	Unlikely	Permanent discontinuation of study agent	Yes/No
		2 mg/kg IV	6027-00002	3[redacted]/F	AUSTRIA/Caucasian			100	1470	紅斑	ERYTHEMA			Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	372	インフルエンザ	COMMON FLU	395	8	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	477	頭痛	HEADACHE	500	31	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	477	上腹部痛	STOMACH ACHE	500	31	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	477	回転性めまい	VERTIGO	500	31	Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	531	ダニ媒介ウイルス脳炎	VIRAL MENINGOENCEPHALITIS DUE TO TICK-BONE ENCEPHALITIS	561	14	Resolved	Yes	Moderate	Unlikely	Temporary interruption/dose modification	Yes/No
								100	617	鼻咽頭炎	COMMON COLD	639	34	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	728	胃腸炎	GASTROENTERITIS	749	6	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	728	頭痛	HEADACHE	749	6	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	784	頭痛	INTERMITTING HEADACHE	784	29	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	812	口腔ヘルペス	HERPES LABIALIS	812	29	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	1008	末梢性浮腫	EDEMA LEGS	1019	18	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1008	胸痛	RETROSTERNAL PAIN	1022	15	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1092	鼻咽頭炎	COMMON COLD	1096	18	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	1232	口腔ヘルペス	HERPES LABIALIS	1247	41	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	1288	脱毛症	HAIR LOSS	1315	29	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1498	静脈炎	PHLEBITIS	1563		Resolved	No	Mild	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
			6402-00002	3[redacted]/M	POLAND/Caucasian			100	448	上気道感染	UPPER RESPIRATORY TRACT INFECTION	462	8	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	952	咳嗽	COUGH	973	65	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	952	ボルデテラ感染	BRODATELLA PERTUSSIS INFECTION	973	65	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	1037	腹痛	SEVERE ABDOMINAL PAIN	1051	109	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
								100	1037	胆汁うっ滞	CHOLESTASIS	1059	101	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
								100	1037	貧血	ANAEMIA	1059	101	Resolved	No	Severe	Unlikely	Permanent discontinuation of study agent	No /No
								100	1037	胆嚢癌	GALLBLADDER CARCINOMA	1063	97	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
			6730-00001	2[redacted]/F	UNITED STATES /Caucasian	200 mg (100 mg)	100 (643)	200	401	潰瘍性大腸炎	WORSENING ULCERATIVE COLITIS	405	7	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						200 mg (100 mg)	100 (643)	200	482	注射部位紅斑	INJECTION SITE ERYTHEMA	482	1	Resolved	No	Mild	Probable	None/not applicable	No /Yes
						200 mg (100 mg)	100 (643)	200	482	ウイルス性上気道感染	VIRAL UPPER RESPIRATORY INFECTION	495	6	Resolved	No	Mild	Not related	None/not applicable	Yes/No
						200 mg (100 mg)	100 (643)	200	539	注射部位浮腫	INJECTION SITE EDEMA	539	1	Resolved	No	Mild	Probable	None/not applicable	No /Yes
						200 mg (100 mg)	100 (643)	200	594	注射部位浮腫	INJECTION SITE EDEMA	594	1	Resolved	No	Mild	Probable	None/not applicable	No /Yes
						200 mg (100 mg)	100 (643)	200	594	靭帯捻挫	RIGHT FOOT SPRAIN	612	47	Resolved	No	Moderate	Not related	None/not applicable	No /No
						200 mg (100 mg)	100 (643)	200	615	ウイルス性胃腸炎	VIRAL GASTROENTERITIS	642	2	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
						200 mg (100 mg)	100 (643)	100	643	靭帯捻挫	RIGHT FOOT SPRAIN	658	32	Resolved	No	Mild	Not related	None/not applicable	No /No
						200 mg (100 mg)	100 (643)	100	701	季節性アレルギー	WORSENING SEASONAL ALLERGIES	724	10	Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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						200 mg (100 mg)	100 (643)	100	755	ウイルス性上気道感染	VIRAL UPPER RESPIRATORY INFECTION	775	11	Resolved	No	Mild	Not related	None/not applicable	Yes/No
						200 mg (100 mg)	100 (643)	100	755	放屁	INCREASED GASTROINTESTINAL GAS	781	37	Resolved	No	Moderate	Not related	None/not applicable	No /No
						200 mg (100 mg)	100 (643)	100	811	末梢性浮腫	EDEMA IN LOWER EXTREMITIES	815	13	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						200 mg (100 mg)	100 (643)	100	811	ウイルス性上気道感染	VIRAL UPPER RESPIRATORY INFECTION	836	16	Resolved	No	Mild	Not related	None/not applicable	Yes/No
						200 mg (100 mg)	100 (643)	100	846	潰瘍性大腸炎	WORSENING ULCERATIVE COLITIS	865	13	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						200 mg (100 mg)	100 (643)	100	868	筋痙縮	MUSCLE CRAMPS IN LOWER EXTREMITIES	869	1	Resolved	No	Severe	Unlikely	None/not applicable	No /No
						200 mg (100 mg)	100 (643)	100	868	知覚過敏	HYPERASTHESIA OF THROAT	875	57	Resolved	No	Moderate	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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						200 mg (100 mg)	100 (643)	100	868	潰瘍性大腸炎	WORSENING ULCERATIVE COLITIS	891	30	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						200 mg (100 mg)	100 (643)	100	868	消化不良	OCCASIONAL HEARTBURN	897	24	Resolved	No	Mild	Not related	None/not applicable	No /No
						200 mg (100 mg)	100 (643)	100	868	クロストリジウム・ディフィシレ感染	CLOSTRIDIUM DIFFICILE INFECTION NOT CONFIRMED	901	29	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
						200 mg (100 mg)	100 (643)	100	922	貧血	WORSENED ANEMIA	922	37	Resolved	No	Moderate	Not related	None/not applicable	No /No
						200 mg (100 mg)	100 (643)	100	922	上気道感染	UPPER RESPIRATORY INFECTION	929	33	Resolved	No	Mild	Not related	None/not applicable	Yes/No
						200 mg (100 mg)	100 (643)	100	922	潰瘍性大腸炎	WORSENING ULCERATIVE COLITIS	947	8	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						200 mg (100 mg)	100 (643)	100	952	クロストリジウム・ディフィシレ感染	CLOSTRIDIUM DIFFICILE INFECTION	983	31	Resolved	No	Moderate	Not related	None/not applicable	Yes/No

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						200 mg (100 mg)	100 (643)	100	1002	クロストリジウム・ディフィシレ感染	CLOSTRIDIUM DIFFICILE INFECTION	1013	4	Resolved	Yes	Severe	Not related	None/not applicable	Yes/No
						200 mg (100 mg)	100 (643)	100	1002	悪心	NAUSEA	1013	10	Resolved	No	Severe	Not related	None/not applicable	No /No
						200 mg (100 mg)	100 (643)	100	1002	クロストリジウム・ディフィシレ感染	CLOSTRIDIUM DIFFICILE INFECTION	1016	12	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
						200 mg (100 mg)	100 (643)	100	1002	静脈炎	LEFT ANTECUBITAL PHLEBITIS	1019	12	Resolved	No	Moderate	Not related	None/not applicable	No /No
						200 mg (100 mg)	100 (643)	100	1030	末梢性浮腫	EDEMA IN LOWER EXTREMITIES	1030	18	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						200 mg (100 mg)	100 (643)	100	1030	潰瘍性大腸炎	WORSENING ULCERATIVE COLITIS	1038	84	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						200 mg (100 mg)	100 (643)	100	1030	筋痙縮	CRAMPING OF BILATERAL CALF MUSCLES	1043	10	Resolved	No	Severe	Unlikely	None/not applicable	No /No
						200 mg (100 mg)	100 (643)	100	1030	好酸球増加症	TOXIC EOSINOPHILIA	1051	2	Resolved	No	Mild	Not related	None/not applicable	No /No

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						200 mg (100 mg)	100 (643)	100	1058	貧血	WORSENED ANEMIA	1058	9	Resolved	No	Moderate	Not related	None/not applicable	No /No
						200 mg (100 mg)	100 (643)	100	1058	末梢性浮腫	EDEMA IN LOWER EXTREMITIES	1061	16	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						200 mg (100 mg)	100 (643)	100	1058	各種物質毒性	PREDNISONE TOXICITY	1071	57	Resolved	No	Moderate	Not related	None/not applicable	No /No
		4 mg/kg IV	6231-00014	3[redacted]/M	HUNGARY/Caucasian			100	785	パートナーの妊娠	PARTNER PREGNANCY			Resolved	No		Not related	None/not applicable	No /No
								100	1178	腎障害	RENAL COMPLAINTS			Resolved	No	Mild	Not related	None/not applicable	No /No
								100	534	肺炎	PNEUMONIA	543	14	Resolved	Yes	Moderate	Not related	None/not applicable	Yes/No
								100	983	裂傷	CUT OF THUMB ON RIGHT HAND	994	3	Resolved	No	Mild	Not related	None/not applicable	No /No
			6281-00007	4[redacted]/M	ISRAEL/Caucasian	100 mg	52	100	445	白内障	MILD CATARACT LEFT EYE	452		Not Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	52	100	575	浮動性めまい	DIZZINESS NOS	588	3	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	52	100	1114	湿疹	ECZEMA ON BOTH ARMS	1135	34	Resolved	No	Mild	Not related	None/not applicable	No /No

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						100 mg	52	100	1166	湿疹	ECZEMA ON ARMS AND LEGS	1169	32	Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	52	100	1194	乾癬	PSORIASIS	1201		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	52	100	1215	発疹	RASH OF UNKNOWN ORIGIN	1221	8	Resolved	Yes	Severe	Possible	Permanent discontinuation of study agent	No /No
						100 mg	52	100	1215	爪囲炎	PARONYCHIA, RIGHT THUMB	1222	10	Resolved	No	Mild	Not related	None/not applicable	Yes/No
		200 mg/100 mg SC	7203-00006	7[redacted]/M	GERMANY/Caucasian	100 mg	248	100	400	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	400	29	Resolved	No	Severe	Not related	None/not applicable	No /No
						100 mg	248	100	913	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	913	27	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	248	100	1394	日光角化症	AKTINIC KERATOSSIS OF THE HEAD	1431	1	Resolved	No	Mild	Possible	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
						100 mg	248	100	1394	過角化	KERATOSIS OF THE UPPER ARM ON THE RIGHT SIDE	1431	1	Resolved	No	Mild	Possible	None/not applicable	No /No
						100 mg	248	100	1520	冠動脈疾患	CORONARY ARTERY DISEASE	1564	78	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
						100 mg	248	100	1520	頚動脈狭窄	CAROTIS DESOBLITERATION BY STENOSIS OF 80%	1638	4	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
			7258-00004	1[redacted]/M	INDIA/Asian			100	1152	発熱	FEVER	1167	14	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	1271	肺結核	PULMONARY TUBERCLOSIS	1303	301	Resolved	Yes	Mild	Probable	Permanent discontinuation of study agent	Yes/No
			7460-00005	4[redacted]/F	RUSSIANFEDERATION/Caucasian	100 mg	118	100	506	肺炎	BILATERAL PNEUMONIA	536	11	Resolved	Yes	Severe	Unlikely	Temporary interruption/dose modification	Yes/No
			7727-00004	5[redacted]/M	UNITED STATES/Black			100	448	頭痛	HEADACHE	463	1	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	504	肺炎	PNEUMONIA	520	17	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	651	節足動物刺傷	INSECT STING	665	4	Resolved	No	Moderate	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	932	背部痛	BACK PAIN	958	22	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	1071	血中コレステロール増加	HIGH CHOLESTEROL	1092		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	1099	胸痛	CHEST PAIN	1104	8	Resolved	No	Severe	Unlikely	None/not applicable	No /No
								100	1099	胃食道逆流性疾患	GASTRO ESOPHAGEAL REFLUX DISEASE	1111		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1099	肺塞栓症	BILATERAL PULMONARY EMBOLI	1111	388	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	1099	深部静脈血栓症	LEFT LOWER EXTREMITY DVT	1111	388	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	1099	不安	ANXIETY	1112	1	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1211	肝酵素上昇	ELEVATED LIVER ENZYMES	1238	86	Resolved	No	Mild	Possible	None/not applicable	No /No
			7743-00009	4[redacted]/M	UNITED STATES /Caucasian			100	394	悪心	NAUSEA	394	4	Resolved	No	Moderate	Probable	None/not applicable	No /No
								100	459	胃腸炎	GASTROENTERITIS	482	6	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	704	上気道感染	UPPER RESPIRATORY INFECTION	732	4	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	863	副鼻腔炎	SINUSITIS	876	5	Resolved	No	Moderate	Probable	None/not applicable	Yes/No
								100	863	肺炎	PNEUMONIA	882	55	Resolved	Yes	Severe	Probable	Temporary interruption/dose modification	Yes/No
		400 mg/200 mg SC	6177-00016	4[redacted]/M	FRANCE/Caucasian			100	483	鼻咽頭炎	COLD			Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	483	無力症	ASTHENIA			Resolved	No	Mild	Not related	None/not applicable	No /No
								100	448	筋肉痛	MUSCULAR PAIN (RIGHT ARM)			Resolved	No	Mild	Not related	None/not applicable	No /No
								100	504	気管支炎	BRONCHIAL SUPERINFECTION			Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	420	過敏性血管炎	LEUKOCYTOCLASTIC VASCULITIS			Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
								100	504	血栓後症候群	WORSENING OF POST THROMBOTIC SYNDROME			Resolved	No	Moderate	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	588	直腸出血	PROCTORRAGIA			Resolved	No	Mild	Not related	None/not applicable	No /No
								100	588	不眠症	INSOMNIA			Resolved	No	Mild	Not related	None/not applicable	No /No
								100	588	寝汗	NIGHT SWEATS			Resolved	No	Mild	Not related	None/not applicable	No /No
								100	588	潰瘍性大腸炎	FLARE UP OF UC			Resolved	No	Mild	Not related	None/not applicable	No /No
								100	385	紅斑	SKIN REDNESS	385	1	Resolved	No	Mild	Definite	None/not applicable	No /Yes
								100	420	丘疹	PAPULE	420	2	Resolved	No	Mild	Definite	None/not applicable	No /Yes
								100	448	紅斑	SKIN REDNESS	448	2	Resolved	No	Mild	Definite	None/not applicable	No /Yes
								100	483	丘疹	PAPULE	483	1	Resolved	No	Mild	Definite	None/not applicable	No /Yes
								100	504	丘疹	PAPULE	504	1	Resolved	No	Mild	Definite	None/not applicable	No /Yes
								100	504	潰瘍性大腸炎	FLARE UP OF UC	505		Resolved	No	Mild	Not related	None/not applicable	No /No
								100	539	丘疹	PAPULE	539	1	Resolved	No	Mild	Definite	None/not applicable	No /Yes
								100	539	うつ病	DEPRESSION	557		Resolved	No	Mild	Not related	None/not applicable	No /No
								100	567	丘疹	PAPULE	567	1	Resolved	No	Mild	Definite	None/not applicable	No /Yes
			6404-00017	6[redacted]/F	POLAND/Caucasian			100	393	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	417	26	Resolved	No	Moderate	Not related	Temporary interruption/dose modification	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	813	大腸狭窄	SEVERE SIGMOID COLON STENOSIS	815	69	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
								100	813	大腸狭窄	SIGMOID COLON STENOSIS	883		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
			6404-00026	5[redacted]/F	POLAND/Caucasian	100 mg	44	100	709	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS.	731	151	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	44	100	791	静脈炎	PHLEBITIS OF LEFT POPLITEAL VEIN.	802	47	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	44	100	791	貧血	ANEMIA	802	103	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	44	100	988	腎超音波検査異常	HYPOECHOGENIC AREA IN THE UPPER POLE OF LEFT KIDNEJ.	1008	15	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	44	100	1016	脂肪肝	FATTY DEGENERATION OF THE LIVER.	1022		Not Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	44	100	1016	子宮平滑筋腫	UTERINE MYOMA.	1022	305	Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
						100 mg	44	100	1071	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS.	1096	56	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	44	100	1100	腎嚢胞	RIGHT RENAL CYSTS.	1107	220	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	44	100	1151	紅斑	ERYTHEMA OF THE LEFT LOWER LEG.	1159	8	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	44	100	1259	インフルエンザ	INFLUENZA	1268	9	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
						100 mg	44	100	1287	発熱	FEVER	1313	22	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
						100 mg	44	100	1287	回転性めまい	VERTIGO	1326		Not Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	44	100	1287	尿路感染	INFECTION OF URINARY SYSTEM	1326	6	Resolved	No	Mild	Not related	None/not applicable	Yes/No
						100 mg	44	100	1287	関節痛	ARTHRALGIA	1327	19	Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	44	100	1287	発熱	FEVER	1335	11	Resolved	Yes	Moderate	Not related	None/not applicable	Yes/No
						100 mg	44	100	1287	貧血	ANEMIA	1335	19	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	44	100	1287	発熱	FEVER	1346	34	Resolved	No	Mild	Not related	Permanent discontinuation of study agent	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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						100 mg	44	100	1287	関節痛	ARTHRALGIA	1379	15	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
						100 mg	44	100	1287	鼻炎	RHINITIS	1379	15	Resolved	No	Mild	Not related	None/not applicable	Yes/No
			7008-00004	5[redacted]/F	AUSTRALIA/Caucasian			100	1093	靭帯捻挫	SPRAINED LEFT ANKLE			Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	393	咳嗽	COUGH	393	4	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	421	潰瘍性大腸炎	WORSENING OF UC SYMPTOMS	438	222	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	421	口腔咽頭痛	SORE THROAT	449	9	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	456	口腔ヘルペス	COLD SORE	456	8	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	456	恥骨上痛	SUPRAPUBIC PAIN	476	186	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	638	胃食道逆流性疾患	REFLUX (GORD)	638	73	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	729	咳嗽	MILD DRY COUGH	736	30	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	729	胃食道逆流性疾患	REFLUX (GORD)	737		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	785	上気道感染	UPPER RESPIRATORY TRACT INFECTION	800	13	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	834	胃腸炎	INFECTIOUS GASTROENTERITIS	841	4	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
								100	834	うつ病	DEPRESSION	841		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	918	そう痒症	ITCH (HANDS)	920	152	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	918	上気道感染	UPPER RESPIRATORY TRACT INFECTION	928	22	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	918	背部痛	BACK PAIN	951	465	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1037	尿路感染	URINARY TRACT INFECTION	1068	21	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	1072	腎感染	KIDNEY INFECTION	1072	8	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	1093	尿路感染	URINARY TRACT INFECTION	1099	10	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	1093	筋骨格痛	MUSCULOSKELETAL PAIN	1100	316	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1177	呼吸困難	WORSENING DYSPNOEA	1184	113	Resolved	No	Moderate	Possible	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	1177	肺腫瘤	PULMONARY NODULES	1196		Not Resolved	No	Mild	Possible	None/not applicable	No /No
								100	1177	湿性咳嗽	PRODUCTIVE COUGH	1205	14	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1261	尿路感染	URINARY TRACT INFECTION	1280	8	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	1261	知覚過敏	INCREASED FACIAL SENSITIVITY RIGHT SIDE	1288	5	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	1324	歯肉痛	SORE GUMS	1345	3	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1352	ラ音	FINE CRACKLING LEFT BASE OF LUNG	1352	29	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1352	口腔ヘルペス	COLD SORE (TOP LIP)	1378	22	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	1380	外陰部腟カンジダ症	VAGINAL CANDIDIASIS	1393	16	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	1415	疲労	FATIGUE	1416	70	Resolved	No	Mild	Unlikely	None/not applicable	No /No

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								100	1429	口唇炎	ANGULAR STOMATITIS	1443	43	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1485	高血圧	HYPERTENSION	1507		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1485	不安	ANXIETY	1507		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1485	上気道感染	UPPER RESPIRATORY TRACT INFECTION	1507	8	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1485	扁平上皮癌	SQUAMOUS CELL CARCINOMA SKIN LESION - LEFT HAND (FULLY EXCISED)	1549	1	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1485	発疹	RASH - NECK AND TRUNK	1612	11	Resolved	No	Moderate	Not related	None/not applicable	No /No
			7212-00001	5[redacted]/F	GERMANY/Caucasian			100	364	鼻咽頭炎	COMMON COLD	382	11	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	392	歩行障害	GAIT DISTURBANCE	412	1	Resolved	No	Mild	Not related	None/not applicable	No /No

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								100	511	頚腕症候群	SHOULDER-ARM-SYNDROME	512	31	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	651	鼻咽頭炎	COMMON COLD	665	47	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	791	上気道うっ血	UPPER RESPIRATORY CONGESTION	809	11	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	931	上気道うっ血	UPPER RESPIRATORY CONGESTION	957	3	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1015	ライム病	BORRELIOSIS	1027	21	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	1043	インフルエンザ	FLUE	1048	23	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	1043	嘔吐	VOMOTING	1071	2	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1099	嘔吐	VOMOTING	1099	2	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	1099	無力症	WEAKNESS NOS	1099	11	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	1099	四肢痛	LIMB PAIN	1099	11	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	1162	卵巣嚢胞	OVARIAN CYST	1162		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1183	腹痛	ABDOMINAL PAIN	1193	54	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1211	下痢	DIARRHOE	1241	28	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1316	下痢	DIARRHOE	1340	7	Resolved	No	Mild	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	1343	下腹部痛	HYPOGASTRIUM PAIN	1343	170	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1343	変形性関節症	SUSPICION OF COXARTHROSIS LEFT SIDE	1343	85	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1343	鼠径ヘルニア	INGUINAL HERNIA	1343		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1343	下痢	DIARRHOE	1373	16	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1400	下痢	DIARRHOE	1412	20	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	1427	肛門の炎症	ANITIS	1427	30	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1456	インフルエンザ	INFLUENZA INFECTION	1469	44	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	1456	口腔ヘルペス	HERPES LOWER LIP	1469	44	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	1456	うつ病	DEPRESSION	1469	44	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1483	急性心筋梗塞	ACUTE MYOCARD INFARCTION	1576	21	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	1483	潰瘍性大腸炎	WORSENING OF ULCERATION COLLITIS	1626	49	Resolved	Yes	Moderate	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
			7414-00019	2[redacted]/M	POLAND/Caucasian	100 mg	358	100	358	肛門膿瘍	PERIANAL ABSCESS	377	17	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
						100 mg	358	100	666	肛門膿瘍	PERIANAL ABSCESS	701	8	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
						100 mg	358	100	869	過敏性腸症候群	IBS-LIKE (IRRITABLE BOWEL SYNDROME) SYMPTOMS	911	318	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	358	100	1107	潰瘍性大腸炎	CLINICAL FLARE OF ULCERATIVE COLITIS	1130	6	Resolved	Yes	Severe	Not related	Temporary interruption/dose modification	No /No
						100 mg	358	100	1170	潰瘍性大腸炎	ULCERATIVE COLITIS PROGRESSION.	1227	13	Resolved	Yes	Severe	Possible	None/not applicable	No /No
						100 mg	358	100	1170	リンパ増殖性障害	LYMPHOPROLIFERATIVE DISORDER IN COLON (HISTPATOLOGY RESULT)	1228		Not Resolved	No	Severe	Possible	None/not applicable	No /No
						100 mg	358	100	1170	ホジキン病	HODGKIN'S LYMPHOMA	1364		Not Resolved	Yes	Severe	Possible	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
			7783-00005	3[redacted]/M	UNITED STATES /Caucasian			100	484	痔核	EXTERNAL HEMORRHOIDS	485		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	484	頭痛	HEADACHE	511	2	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	553	非心臓性胸痛	CHEST PAIN NON CARDIAC	566	4	Resolved	Yes	Mild	Unlikely	None/not applicable	No /No
			7814-00002	5[redacted]/F	JAPAN/ Asian			100	518	悪心	NAUSEA			Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	812	痔核	INTERNAL HEMORRHOIDS			Resolved	No	Mild	Not related	None/not applicable	No /No
								100	399	白内障	WORSENING OF CATARACT	404	7	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								100	434	関節痛	KNEE PAIN	434	239	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	455	注射部位紅斑	INJECTION SITE REACTION(REDNESS)	455	1	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	455	注射部位そう痒感	INJECTION SITE REACTION. (ITCHING)	455	1	Resolved	No	Mild	Possible	None/not applicable	No /Yes

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	455	皮膚嚢腫	WORSENING OF SKIN ATHEROMA	470	126	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	455	口腔ヘルペス	HERPES LABIALIS	484	7	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	455	頭痛	HEADACHE	484		Not Resolved	No	Mild	Possible	None/not applicable	No /No
								100	490	注射部位紅斑	INJECTION SITE REACTION(REDNESS)	490	1	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	490	注射部位そう痒感	INJECTION SITE REACTION. (ITCHING)	490	1	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	518	口腔ヘルペス	HERPES LABIALIS	545	15	Resolved	No	Mild	Probable	None/not applicable	Yes/No
								100	546	副鼻腔炎	SINUSITIS	566	368	Resolved	No	Mild	Possible	Temporary interruption/dose modification	Yes/No
								100	595	末梢性浮腫	HAND EDEMA	613	88	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	672	収縮期血圧上昇	BLOOD PRESSURE SYSTOLIC HIGH	672	337	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	672	便秘	CONSTIPATION	692	9	Resolved	No	Mild	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	700	悪心	NAUSEA	715	44	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	700	便秘	CONSTIPATION	746	81	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	763	注射部位紅斑	INJECTION SITE REACTION. (REDNESS)	763	3	Resolved	No	Mild	Probable	None/not applicable	No /Yes
								100	763	注射部位そう痒感	INJECTION SITE REACTION. (ITCHING)	763	3	Resolved	No	Mild	Probable	None/not applicable	No /Yes
								100	763	注射部位硬結	INJECTION SITE REACTION. (INDURATION)	763	3	Resolved	No	Mild	Probable	None/not applicable	No /Yes
								100	763	回転性めまい	DIZZINESS(FEELS LIKE FLOATING)	763	7	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	812	注射部位硬結	INJECTION SITE REACTION. (INDURATION)	812	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	812	注射部位そう痒感	INJECTION SITE REACTION. (ITCHING)	812	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	812	注射部位紅斑	INJECTION SITE REACTION. (REDNESS)	812	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	812	真菌性耳感染	LEFT EAR CANAL MYCOSIS	814	120	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	840	注射部位硬結	INJECTION SITE REACTION. (INDURATION)	840	4	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	840	注射部位そう痒感	INJECTION SITE REACTION. (ITCHING)	840	4	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	840	注射部位紅斑	INJECTION SITE REACTION. (REDNESS)	840	4	Resolved	No	Mild	Possible	None/not applicable	No /Yes

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	889	注射部位そう痒感	INJECTION SITE REACTION. (ITCHING)	889	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	889	注射部位紅斑	INJECTION SITE REACTION. (REDNESS)	889	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	889	注射部位硬結	INJECTION SITE REACTION. (INDURATION)	889	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	924	注射部位そう痒感	INJECTION SITE REACTION. (ITCHING)	924	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	924	注射部位紅斑	INJECTION SITE REACTION. (REDNESS)	924	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	924	注射部位硬結	INJECTION SITE REACTION. (INDURATION)	924	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	924	口腔ヘルペス	HERPES LABIALIS	949	15	Resolved	No	Mild	Probable	None/not applicable	Yes/No
								100	952	注射部位そう痒感	INJECTION SITE REACTION. (ITCHING)	952	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	952	注射部位紅斑	INJECTION SITE REACTION. (REDNESS)	952	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	952	注射部位硬結	INJECTION SITE REACTION. (INDURATION)	952	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	980	注射部位そう痒感	INJECTION SITE REACTION. (ITCHING)	980	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	980	注射部位紅斑	INJECTION SITE REACTION. (REDNESS)	980	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	980	注射部位硬結	INJECTION SITE REACTION. (INDURATION)	980	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1008	注射部位硬結	INJECTION SITE REACTION. (INDURATION)	1008	4	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1008	注射部位そう痒感	INJECTION SITE REACTION. (ITCHING)	1008	4	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1008	注射部位紅斑	INJECTION SITE REACTION. (REDNESS)	1008	4	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1048	注射部位そう痒感	INJECTION SITE REACTION. (ITCHING)	1048	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1048	注射部位紅斑	INJECTION SITE REACTION. (REDNESS)	1048	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	1048	注射部位硬結	INJECTION SITE REACTION. (INDURATION)	1048	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1071	注射部位そう痒感	INJECTION SITE REACTION. (ITCHING)	1071	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1071	注射部位紅斑	INJECTION SITE REACTION. (REDNESS)	1071	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1071	注射部位硬結	INJECTION SITE REACTION. (INDURATION)	1071	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1092	注射部位そう痒感	INJECTION SITE REACTION. (ITCHING)	1092	5	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1092	注射部位紅斑	INJECTION SITE REACTION. (REDNESS)	1092	5	Resolved	No	Mild	Possible	None/not applicable	No /Yes

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	1092	注射部位硬結	INJECTION SITE REACTION.(INDURATION)	1092	5	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1120	注射部位紅斑	INJECTION SITE REACTION.(REDNESS)	1120	6	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1120	注射部位硬結	INJECTION SITE REACTION.(INDURATION)	1120	6	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1120	注射部位そう痒感	INJECTION SITE REACTION.(ITCHING)	1120	6	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1120	口内炎	STOMATITIS	1142	6	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1120	口腔ヘルペス	HERPES LABIALIS.	1148	7	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	1155	注射部位紅斑	INJECTION SITE REACTION.(REDNESS)	1155	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1155	注射部位硬結	INJECTION SITE REACTION.(INDURATION)	1155	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	1155	注射部位そう痒感	INJECTION SITE REACTION.(ITCHING)	1155	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1155	口腔ヘルペス	HERPES LABIALIS	1156	7	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	1176	注射部位そう痒感	INJECTION SITE REACTION.(ITCHING)	1176	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1176	注射部位硬結	INJECTION SITE REACTION.(INDURATION)	1176	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1176	注射部位紅斑	INJECTION SITE REACTION.(REDNESS)	1176	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1176	口腔ヘルペス	HERPES LABIALIS	1195	5	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	1204	注射部位そう痒感	INJECTION SITE REACTION.(ITCHING)	1204	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1204	注射部位紅斑	INJECTION SITE REACTION.(REDNESS)	1204	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	1204	注射部位硬結	INJECTION SITE REACTION.(INDURATION)	1204	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1204	口内炎	STOMATITIS	1210	5	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1204	口内炎	STOMATITIS	1223	37	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1225	注射部位硬結	INJECTION SITE REACTION.(INDURATION)	1225	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1225	注射部位紅斑	INJECTION SITE REACTION.(REDNESS)	1225	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1225	注射部位そう痒感	INJECTION SITE REACTION.(ITCHING)	1225	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1253	注射部位そう痒感	INJECTION SITE REACTION.(ITCHING)	1253	4	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1253	注射部位紅斑	INJECTION SITE REACTION.(REDNESS)	1253	4	Resolved	No	Mild	Possible	None/not applicable	No /Yes

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	1253	注射部位硬結	INJECTION SITE REACTION.(INDURATION)	1253	4	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1288	注射部位紅斑	INJECTION SITE REACTION(REDNESS)	1288	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1288	注射部位硬結	INJECTION SITE REACTION(INDURATION)	1288	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1288	注射部位そう痒感	INJECTION SITE REACTION(ITCHING)	1288	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1316	注射部位そう痒感	INJECTION SITE REACTION(ITCHING)	1316	5	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1316	注射部位紅斑	INJECTION SITE REACTION(REDNESS)	1316	5	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1316	注射部位硬結	INJECTION SITE REACTION(INDUTATION)	1316	5	Resolved	No	Mild	Possible	None/not applicable	No /Yes

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	1351	注射部位硬結	INJECTION SITE REACTION(INDUTATION)	1351	2	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1351	注射部位紅斑	INJECTION SITE REACTION(REDNESS)	1351	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1351	注射部位そう痒感	INJECTION SITE REACTION.(ITCHING)	1351	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1380	注射部位紅斑	INJECTION SITE REACTION(REDNESS)	1380	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1380	注射部位硬結	INJECTION SITE REACTION(INDUTATION)	1380	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1380	注射部位そう痒感	INJECTION SITE REACTION.(ITCHING)	1380	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1407	注射部位紅斑	INJECTION SITE REACTION(REDNESS)	1407	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	1407	注射部位硬結	INJECTION SITE REACTION(INDUTATION)	1407	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1407	注射部位そう痒感	INJECTION SITE REACTION.(ITCHING)	1407	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1435	注射部位紅斑	INJECTION SITE REACTION.(REDNESS)	1435	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1435	注射部位硬結	INJECTION SITE REACTION(INDUTATION)	1435	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1435	注射部位そう痒感	INJECTION SITE REACTION(ITCHING)	1435	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1470	注射部位そう痒感	INJECTION SITE REACTION.(ITCHING)	1470	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1470	注射部位紅斑	INJECTION SITE REACTION.(REDNESS)	1470	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	1470	注射部位硬結	INJECTION SITE REACTION(INDUTATION)	1470	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1498	注射部位そう痒感	INJECTION SITE REACTION(ITCHING)	1498	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1498	注射部位硬結	INJECTION SITE REACTION(INDURATION)	1498	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1498	注射部位紅斑	INJECTION SITE REACTION(REDNESS)	1498	3	Resolved	No	Mild	Possible	None/not applicable	No /Yes
								100	1498	浮動性めまい	DIZZINESS NOS	1499	14	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1498	嘔吐	VOMITING	1499	37	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1498	口内炎	STOMATITIS	1516	74	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1498	上腹部痛	EPIGASTRALGIA	1529	7	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1498	胃炎	GASTRITIS	1534		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1498	そう痒症	ITCHING	1554	15	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1498	くしゃみ	SNEEZING	1554		Not Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
No	Placebo (PBO induction Responder)	Placebo IV	6101-00001	5[redacted]/F	CANADA/Caucasian	100 mg	113	100	563	インフルエンザ	INFLUENZA	577	7	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
						100 mg	113	100	598	歯の障害	BAD TOOTH.	602	1	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	113	100	598	膀胱炎	BLADDER INFECTION.	624	22	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
						100 mg	113	100	626	上気道うっ血	UPPER RESPIRATORY CONGESTION	638	5	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	113	100	727	歯の障害	DENTAL WORK - TOOTH IMPLANTATION DUE TO BAD TOOTH.	736	1	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	113	100	899	卵巣癌	RIGHT OVARY PT1A CLEAR CELL CARCINOMA.	902	3	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
			6227-00004	4[redacted]/M	HUNGARY/Caucasian	100 mg	147	100	671	潰瘍性大腸炎	WORSENING OF UC	678	10	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
						100 mg	147	100	785	インフルエンザ	FLU	805	7	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
						100 mg	147	100	785	発熱	FEVER	805	3	Resolved	No	Mild	Not related	None/not applicable	Yes/No
						100 mg	147	100	785	聴力低下	HYPACUSIS	805	15	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	147	100	785	耳鳴	TINITUS	805	15	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
						100 mg	147	100	902	四肢痛	PAIN OF RIGHT LEG	908	17	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	147	100	902	末梢性浮腫	OEDEMA OF RIGHT LEG	908	17	Resolved	No	Mild	Unlikely	None/not applicable	No /No
		Placebo SC	6177-00009	5[redacted]/M	FRANCE/Caucasian			100	442	気管支炎	BRONCHITIS	458	15	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	490	サイトメガロウイルス感染	NIGHT SWEATS (DUE TO PRIMARY CMV INFECTION)	513		Resolved	No	Moderate	Possible	Temporary interruption/dose modification	Yes/No
								100	490	頭痛	HEADACHE	513		Resolved	No	Moderate	Possible	Temporary interruption/dose modification	No /No
								100	490	咳嗽	COUGH	513		Resolved	No	Moderate	Possible	Temporary interruption/dose modification	Yes/No
								100	490	関節痛	ARTHRALGIA	513		Resolved	No	Moderate	Possible	Temporary interruption/dose modification	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	490	サイトメガロウイルス感染	PRIMARY CMV INFECTION	527		Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	Yes/No
			7006-00002	3[redacted]/M	AUSTRALIA/Caucasian			0	424	直腸出血	RECTAL BLEEDING	427		Resolved	No	Mild	Probable	None/not applicable	No /No
								0	507	咳嗽	DRY COUGH	521	29	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								0	645	直腸腺腫	SESSILE SERRATED ADENOMA IN RECTUM	646	1	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								0	645	群発頭痛	WORSENING OF CLUSTER HEADACHES	649	320	Resolved	No	Moderate	Possible	None/not applicable	No /No
								0	701	下気道感染	CHEST INFECTION	714	14	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								0	788	靭帯捻挫	TWISTED LEFT RING FINGER	813	61	Resolved	No	Mild	Not related	None/not applicable	No /No
								0	815	下気道感染	LOWER RESPIRATORY TRACT INFECTION	817	51	Resolved	No	Mild	Possible	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								0	851	肛門直腸不快感	ANAL SPHINCTER DISCOMFORT	868	124	Resolved	No	Mild	Possible	None/not applicable	No /No
								0	851	気分変調性障害	DYSTHYMIC	868	472	Resolved	No	Mild	Possible	None/not applicable	No /No
								0	915	潰瘍性大腸炎	ULCERATIVE COLITIS EXACERBATION	926	14	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	1088	湿疹	BILATERAL ELBOW ECZEMA	1111	324	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1114	帯状疱疹	LOCALISED SHINGLES LEFT FLANK TO LEFT CHEST	1127	32	Resolved	Yes	Moderate	Possible	Temporary interruption/dose modification	Yes/No
								100	1165	副鼻腔炎	SINUSITIS	1176	137	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	1359	便秘	CONSTIPATION	1370	1	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1478	胃腸炎	GASTROENTERITIS	1514	8	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	1478	副鼻腔炎	SINUSITIS	1567		Not Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
			7079-00004	3[redacted]/F	BULGARIA/Caucasian			100	1044	肺結核	PULMONARY TUBERCULOSIS	1062	117	Resolved	Yes	Moderate	Not related	Permanent discontinuation of study agent	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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			7180-00005	5[redacted]/F	FRANCE/Caucasian			100	680	無力症	ASTHENIA			Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1104	筋痙縮	CRAMPS			Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1160	無力症	ASTHENIA			Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1503	無力症	ASTHENIA			Not Resolved	No	Mild	Not related	None/not applicable	No /No
								0	366	腱断裂	SEVERED TENDON ON FOOT	395	24	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								0	481	コントロール不良の糖尿病	IMBALANCE DIABETES	485	60	Resolved	No	Mild	Not related	None/not applicable	No /No
								0	569	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	569	112	Resolved	No	Moderate	Possible	Temporary interruption/dose modification	No /No
								100	624	気管支炎	BRONCHITIS	639	67	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	761	コントロール不良の糖尿病	IMBALANCE DIABET	761	490	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	761	湿疹	ECZEMA	786	32	Resolved	No	Moderate	Probable	None/not applicable	No /No
								100	874	頭痛	HEADACHE	893	20	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	908	頭痛	HEADACHE	923		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	932	頚部痛	CERVICAL PAIN	942	24	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	965	外骨腫	CALCANEAL THORN	965	161	Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	965	関節痛	KNEE PAIN	975	11	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	965	気管支炎	BRONCHITIS	976	17	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	992	胃腸炎	GASTROENTERITIS	1000	5	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	1020	高コレステロール血症	HYPERCHOLESTEROLEMIA	1041	116	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1192	胃食道逆流性疾患	GASTROOESOPHAGEAL REFLUX DISEASE	1192		Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1248	糖尿病	WORSENING OF IMBALANCED DIABETES	1251	5	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								100	1300	背部痛	LOMBALGIA	1322		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1300	腱炎	TENDINITIS - RIGHT FOOT	1322		Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1300	咳嗽	COUGHING ON MORNING	1322	11	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	1356	筋肉痛	MUSCULAR PAIN IN RIGHT ARM	1366		Not Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	1356	直腸炎	PROCTITIS	1366	68	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1402	頭痛	WORSENING OH HEADACHE	1403	31	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1433	気管支炎	BRONCHITIS	1454	5	Resolved	No	Mild	Not related	None/not applicable	Yes/No
			7213-00003	2[redacted]/F	GERMANY/Caucasian			100	639	脱毛症	HAIRLOSS DUE TO SITE EFFECTS OF PREDNISOLON			Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								0	596	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS			Resolved	No	Moderate	Not related	Temporary interruption/dose modification	No /No
								100	756	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	781		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	812	アラニンアミノトランスフェラーゼ増加	HIGH ALT RESULT	812	71	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	786	アスパラギン酸アミノトランスフェラーゼ増加	HIGH AST RESULT	812	71	Resolved	No	Moderate	Unlikely	None/not applicable	No /No

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								100	840	潰瘍性大腸炎	UC FLARE	844	17	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
								100	840	蒼白	PALLOR	844		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	840	悪液質	CACHEXIA	844		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	840	胃腸音異常	VIVID ABDOMINAL SOUNDS	844	17	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	840	腹部圧痛	DIFFUSE TENDERNESS ON ABDOMINAL PALPATION	844	17	Resolved	No	Moderate	Not related	None/not applicable	No /No
			7401-00006	3[redacted]/M	POLAND/Caucasian			0	757	胸椎骨折	THORACIC VERTEBRAL FRACTURE	785		Not Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
			7407-00010	5[redacted]/M	POLAND/Caucasian			0	729	心筋梗塞	CARDIAC INFARCT	731	8	Resolved	Yes	Moderate	Not related	Permanent discontinuation of study agent	No /No
								0	729	肺炎	PNEUMONIA	743	5	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								0	729	心不全	HEART FAILURE	743	5	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
			7414-00005	5[redacted]/F	POLAND/Caucasian	100 mg	22	100	729	貧血	ANAEMIA	731	202	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	22	100	729	表在性血栓性静脈炎	SUPERFICIAL THROMBOPHLEBITIS (LEFT LEG)	732	26	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
						100 mg	22	100	932	潰瘍性大腸炎	LEUCOCYTOSIS (CONNECTED TO UC FLARE AND STEROIDS)	960	29	Resolved	No	Mild	Unlikely	None/not applicable	No /No
			7451-00003	4[redacted]/F	RUSSIANFEDERATION/ Caucasian	100 mg	171	100	487	月経過多	MENORRHAGIA	488	5	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	171	100	570	発熱	FEVER	588	41	Resolved	No	Moderate	Possible	Temporary interruption/dose modification	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
						100 mg	171	100	570	自己免疫性甲状腺炎	SUBACUTE AUTOIMMUNE THYROIDITIS.	604	25	Resolved	Yes	Moderate	Not related	Temporary interruption/dose modification	No /No
						100 mg	171	100	570	甲状腺新生物	THYROID NODULES	604		Not Resolved	No	Mild	Not related	None/not applicable	No /No
			7732-00005	4[redacted]/F	UNITED STATES /Caucasian	100 mg	185	100	420	背部痛	BACK PAIN	442	77	Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	185	100	513	発熱	FEVER	518	8	Resolved	No	Mild	Possible	None/not applicable	Yes/No
						100 mg	185	100	513	副鼻腔炎	SINUS INFECTION	518	8	Resolved	No	Mild	Possible	None/not applicable	Yes/No
						100 mg	185	100	569	深部静脈血栓症	RIGHT LOWER EXTREMITY DEEP VENOUS THROMBOSIS	569	1	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	185	100	569	咳嗽	NON-PRODUCTIVE COUGH	569		Not Resolved	No	Moderate	Possible	None/not applicable	Yes/No
						100 mg	185	100	569	胸膜炎	COUGH WITH PLEURITIC CHEST PAIN	581	387	Resolved	No	Moderate	Possible	Permanent discontinuation of study agent	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
						100 mg	185	100	569	肺炎	MULTIFOCAL CAVITARY PNEUMONIA	581	389	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	Yes/No
			7771-00003	5[redacted]/F	UNITED STATES /Asian	100 mg	203	100	589	胆石症	GALL STONES			Not Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	203	100	820	乾癬	PSORIASIS			Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	203	100	1151	精神障害	EXACERBATION OF ALTERED MENTAL STATUS			Not Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
						100 mg	203	100	388	潰瘍性大腸炎	WORSENING OF UC (POSSIBLE STRESS RELATED)	388	104	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	203	100	561	頭痛	HEADACHE	586	3	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	203	100	762	粘液便	MUCOUS IN STOOL	781	40	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	203	100	785	大腸腺腫	ADENOMATOUS POLYP DISTAL TRANSVERSE COLON	804	1	Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
						100 mg	203	100	785	下痢	DIARRHEA	813	45	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	203	100	820	白癬感染	RING WORM	830	82	Resolved	No	Mild	Not related	None/not applicable	Yes/No
						100 mg	203	100	862	粘液便	MUCOUS IN STOOL	892	20	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	203	100	946	湿疹	ECZEMA	948		Not Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	203	100	946	血便排泄	LIGHT BLOOD IN STOOL	950	123	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	203	100	974	不安	ANXIETY	974		Not Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	203	100	1072	高カリウム血症	HYPERKALEMIA	1072	31	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	203	100	1102	白癬感染	RING WORM RIGHT ANKLE	1124		Not Resolved	No	Mild	Not related	None/not applicable	Yes/No
						100 mg	203	100	1151	低ナトリウム血症	HYPONATREMIA	1151	11	Resolved	No	Moderate	Possible	None/not applicable	No /No
						100 mg	203	100	1151	精神状態変化	ALTERED MENTAL STATUS	1151	208	Resolved	No	Moderate	Possible	Permanent discontinuation of study agent	No /No
						100 mg	203	100	1151	脳炎	LIMBIC ENCEPHALITIS	1431		Not Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
			7805-00001	3[redacted]/M	JAPAN/ Asian	100 mg	148	100	428	潰瘍性大腸炎	WORSENING OF UC	450	28	Resolved	Yes	Severe	Not related	None/not applicable	No /No
						100 mg	148	100	428	口腔咽頭痛	PHARYNGEAL PAIN	455	4	Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
						100 mg	148	100	428	口内炎	STOMATITIS	455	4	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	148	100	428	関節痛	LEFT HIP PAIN	470	4	Resolved	No	Mild	Not related	None/not applicable	No /No
	Golimumab 100 mg (PBO induction nonresponder)	Placebo IV	6078-00002	4[redacted]/M	BULGARIA/Caucasian			100	576	ウイルス感染	VIRAL INFECTION	604	18	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	992	A型肝炎	ACUTE HEPATITIS A.	994	13	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	Yes/No
			6281-00001	6[redacted]/M	ISRAEL/Caucasian			100	456	裂肛	MILD ANAL FISSURE	477		Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	485	上腹部痛	STOMACHACHE	491		Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1018	血便排泄	BLOODY STOOLS	1023	234	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1044	咽頭炎	THROAT INFECTION	1074	18	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	1329	不安定狭心症	UNSTABLE ANGINA PECTORIS	1339	7	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1329	冠動脈疾患	SINGLE ARTERY DISEASE	1346	2	Resolved	Yes	Severe	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
			6716-00009	5[redacted]/M	UNITED STATES /Caucasian			100	365	細菌感染	FINGER INFECTION (BACTERIAL)	399	7	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	400	排便回数増加	INCREASE FREQUENCY OF BOWEL MOVEMENTS	418	10	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	425	副鼻腔炎	SINUSITIS (INFECTION)	431	6	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	425	外傷性関節炎	POST-TRAUMATIC RIGHT ANKLE ARTHRITIS	437	405	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	425	潰瘍性大腸炎	WORSENING SYMPTOMS OF ULCERATIVE COLITIS	445	24	Resolved	No	Severe	Unlikely	None/not applicable	No /No
								100	453	副鼻腔炎	RIGHT MAXILLARY SINUSITIS	473	33	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	453	気管支炎	BRONCHITIS	473	33	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	453	悪心	NAUSEA	482	4	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	453	頭痛	HEADACHES	482	4	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	453	疼痛	OVERALL BODY ACHES	482	24	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	453	季節性アレルギー	SEASONAL ENVIRONMENTAL ALLERGIES	484	22	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	485	皮膚病変	SKIN LESION OF LEFT ARM	497	9	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	572	毛包炎	FOLLICULITIS	572	120	Resolved	No	Moderate	Possible	Temporary interruption/dose modification	Yes/No
								100	572	リンパ節症	CERVICAL LYMPHADENOPATHY	572		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	537	脂漏性角化症	INFLAMED SEBORRHEIC KERATOSIS	572	1	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	572	股部白癬	TINEA CRURIS	635	50	Resolved	No	Moderate	Possible	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	572	狭窄性腱鞘炎	LEFT THUMB/ WRIST PAIN (DE QUERVAIN'S TENOSYNOVITIS)	640	65	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	572	口唇炎	PERLECHE (CORNER OF MOUTH INFECTION)	649	36	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	572	日光角化症	ACTINIC KERATOSIS	649	1	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	572	下痢	INCREASE LOOSENESS OF STOOLS	689	41	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	572	排便回数増加	INCREASE FREQUENCY OF STOOLS	689	41	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	572	腹痛	ABDOMINAL CRAMPING	689	41	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	572	血便排泄	HEMATOCHEZIA	695	8	Resolved	No	Moderate	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	703	椎間板変性症	CERVICAL DEGENRATIVE DISC DISEASE	725		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	729	副鼻腔炎	SINUS INFECTION	738	30	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	754	副鼻腔炎	SINUS INFECTION	782	12	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	841	関節痛	RIGHT ANKLE PAIN	841		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	862	鼻部不快感	RIGHT NOSTRIL IRRITATION RIGHT NOSTRIL IRRITATION	876	16	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	862	鼻閉	NASAL CONGESTION	891	10	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	862	失明	VISION LOSS	899	2	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	862	胸痛	CHEST PAIN	899	3	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	862	心房中隔欠損症	PATENT FORAMEN OVALE	900		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	862	高血圧	WORSENING HYPERTENSION	900	1	Resolved	No	Mild	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	862	前兆を伴う片頭痛	MIGRAINE HEADACHE WITH AURA	900	1	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	908	血管偽動脈瘤	EXTRADURAL PETROUS LEFT INTERNAL CAROTID ARTERY PSEUDOANEURYSM	915	251	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
								100	926	毛包炎	FOLLICULTIIS	929	102	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	926	下痢	INCREASE LOOSE STOLOLS	935	26	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	926	血便排泄	HEMATOCHEZIA	935	26	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	967	関節痛	LEFT KNEE PAIN	1001	82	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1030	裂傷	FACIAL LACERATION	1074	1	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1030	半月板損傷	TORN MEDIAL MENISCUS LEFT KNEE	1082	1	Resolved	No	Moderate	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	1030	関節損傷	ARTICULAR SURFACE DAMAGE OF THE PATELLOFERMORAL AREA	1082	1	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1101	耳管機能障害	EUSTACHAIN TUBE DYSFUNCTION	1118		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1128	眼瞼炎	BLEPHARITIS	1146		Not Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	1181	毛包炎	FOLLICULITIS	1202	8	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	1181	血腫	SCALP HEMATOMA OVER THE RIGHT FRONTAL REGION	1204	1	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1181	硝子体浮遊物	VITREOUS FLOATERS	1204		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1181	硝子体剥離	VITREOUS DETACHMENT	1216		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1229	副鼻腔炎	SINUSITIS	1254	14	Resolved	No	Moderate	Not related	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	1229	毛包炎	FOLLICULTIIS	1254	106	Resolved	No	Moderate	Possible	Permanent discontinuation of study agent	Yes/No
								100	1229	光線過敏性反応	PHOTOTOXIC DERMATITIS	1254	9	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1299	足骨折	RIGHT 5TH TOE FRACTURE	1412	8	Resolved	No	Mild	Not related	None/not applicable	No /No
		Placebo SC	6106-00008	3[redacted]/F	CANADA/Caucasian			100	483	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	510	22	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	510	鼻咽頭炎	COMMON HEAD COLD	512	23	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	895	鼻咽頭炎	COMMON HEAD COLD	915	5	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	951	鼻咽頭炎	COMMON HEAD CLOD	959	29	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	1036	嘔吐	VOMITTING	1064	3	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1092	クローン病	CROHN'S DISEASE	1103	9	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
								100	1092	クローン病	CROHN'S DISEASE	1112		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
			7003-00003	3[redacted]/F	AUSTRALIA/Caucasian			100	467	血性下痢	DIARRHOEA BLEEDING	481	2	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	519	潰瘍性大腸炎	WORSENING UC	525	136	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	711	気管支炎	BRONCHITIS	725	15	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	757	上気道感染	URTI	773	8	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	842	皮下組織膿瘍	ABSCESS LEFT BUTTOCK	844	37	Resolved	Yes	Severe	Possible	None/not applicable	Yes/No
								100	922	ざ瘡	SMALL 'PIMPLE' - REDDENED AREAON ABDO	950	38	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	1066	口腔咽頭痛	SORE THROAT	1084	7	Resolved	No	Mild	Not related	None/not applicable	Yes/No
			7008-00007	2[redacted]/F	AUSTRALIA/Caucasian			100	342	皮膚細菌感染	SKIN INFECTION (DORSUM LEFT FOOT) - BACTERIAL	367	4	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	377	背部痛	BACK PAIN	401	55	Resolved	No	Mild	Possible	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	406	上気道感染	UPPER RESPIRATORY TRACT INFECTION	420	16	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	440	口腔咽頭痛	SORE THROAT	450	12	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	440	副鼻腔炎	SINUSITIS	452	10	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	440	気管支炎	BRONCHITIS	462	27	Resolved	No	Moderate	Possible	Temporary interruption/dose modification	Yes/No
								100	517	湿疹	ECZEMA	541	14	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	517	上気道感染	UPPER RESPIRATORY TRACT INFECTION	543	9	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	517	発疹	RASH ON TOP OF FEET	546	126	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	552	上気道感染	UPPER RESPIRATORY TRACT INFECTION	557	75	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	601	食欲減退	ANOREXIA	602		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	601	副鼻腔炎	SINUSITIS	614	18	Resolved	No	Mild	Possible	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	685	潰瘍性大腸炎	REFRACTORY ULCERATIVE COLITIS	756	30	Resolved	Yes	Severe	Not related	None/not applicable	No /No
			7077-00007	6[redacted]/M	BULGARIA/Caucasian			100	406	咳嗽	COUGH	424	29	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	406	発熱	FEVER	425	7	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	406	肺炎	BILATERAL PNEUMONIA	427	9	Resolved	Yes	Moderate	Not related	None/not applicable	Yes/No
			7126-00014	4[redacted]/M	DENMARK/Caucasian			100	785	疲労	FATIQUE			Resolved	No	Mild	Not related	None/not applicable	No /No
								100	453	鼻咽頭炎	COMMON COLD	475	6	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	477	頭痛	HEADACHE	484	49	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	621	高血圧	HYPERTENSION	621		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	785	頭痛	HEADACHE	816	15	Resolved	No	Severe	Not related	None/not applicable	No /No
								100	820	ウイルス性髄膜炎	VIRAL MENINGITIS	820	11	Resolved	Yes	Severe	Possible	Temporary interruption/dose modification	Yes/No
								100	820	頭痛	HEADACHE	830	52	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	953	インフルエンザ	INFLUENZA	966	24	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	1013	胃腸炎	GASTROENTERITIS	1035	3	Resolved	No	Mild	Not related	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	1233	腱鞘炎	LEFT HAND TENDOVAGINITIS	1257	8	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1261	筋骨格痛	LEFT SHOULDER PAIN	1276		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1457	頭痛	HEADACHE	1468	45	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1489	鼻咽頭炎	COMMON COLD	1588		Not Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
			7205-00005	4[redacted]/M	GERMANY/Caucasian			100	504	潰瘍性大腸炎	WORSENING ULCERATIVE COLITIS	504	365	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	532	遠隔転移を伴う直腸癌	ADVANCED RECTAL CANCER WITH LIVER METASTASIS	854	402	Resolved	Yes	Moderate	Possible	None/not applicable	No /No
			7378-00004	3[redacted]/M	NEWZEALAND/Caucasian			100	398	ウイルス感染	VIRAL ILLNESS	418	3	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	476	靭帯捻挫	LEFT ANKLE SPRAIN	492	47	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	476	胃腸炎	GASTROENTERITIS	503	7	Resolved	No	Mild	Not related	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	538	膿痂疹	IMPETIGO N LEFT CHEEK,LIP AND LEFT MANDIBULAR AREA	545	93	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	558	ウイルス性胃腸炎	VIRAL GASTROENTERITIS	560	3	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	558	尿道障害	URETHRAL DYSSYNERIA	575		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	589	靭帯捻挫	RIGHT ANKLE SPRAIN	604	71	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	617	鼻潰瘍	ULCER IN RIGHT NOSTRIL	633	5	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	677	悪心	NAUSEA	692	4	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	677	胸痛	CHEST PAIN	695	68	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	821	齲歯	DENTAL CARIES REQUIRING REMOVAL OF TEETH	831	1	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	874	毛包炎	FOLICULITIS	880		Not Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	874	鼻咽頭炎	HEADCOLD	897	35	Resolved	No	Mild	Not related	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	930	うつ病	DEPRESSIVE EPISODE	938		Not Resolved	No	Severe	Not related	None/not applicable	No /No
								100	930	企図的過量投与	INTENTIONAL OVERDOSE	958	1	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								100	1015	潰瘍性大腸炎	SAE OF WORSENING ULCERATIVE COLITIS	1043	18	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
			7378-00010	4[redacted]/F	NEWZEALAND/ Caucasian			100	443	大腸菌性腎盂腎炎	E-COLI PYELONEPHRITIS	463	21	Resolved	Yes	Severe	Possible	Permanent discontinuation of study agent	Yes/No
								100	443	潰瘍性大腸炎	FLARE OF ULCERATIVE COLITIS	492		Not Resolved	No	Severe	Not related	None/not applicable	No /No
			7407-00012	4[redacted]/F	POLAND/Caucasian			100	365	下痢	DIARRHEA	392	10	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	394	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	414	14	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	449	急性副鼻腔炎	ACUTE SINUSITIS	474	13	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	589	胸痛	CHEST PAIN	603	4	Resolved	Yes	Mild	Not related	None/not applicable	No /No
								100	672	背部痛	BACKACHE	676	364	Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	1157	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	1173	36	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1187	口腔ヘルペス	LABIAL HERPES	1194	31	Resolved	No	Mild	Not related	None/not applicable	Yes/No
			7427-00003	5[redacted]/M	ROMANIA/Caucasian			100	1098	心筋梗塞	MIOCARDIAL INFARCTION	1111	1	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
			7734-00011	2[redacted]/F	UNITED STATES/Caucasian			100	427	痔核	EXTERNAL HEMORRHOIDS	455	56	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	427	関節損傷	INJURED ANKLE	456	14	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	460	副鼻腔炎	SINUS INFECTION	462	32	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	573	処置による悪心	NAUSEA AFTER INJECTION	573	14	Resolved	No	Moderate	Probable	None/not applicable	No /No
								100	601	処置による悪心	NASUEA AFTER INJECTION	601	2	Resolved	No	Mild	Probable	None/not applicable	No /No
								100	601	副鼻腔炎	ACUTE SINUS INFECTION	623	89	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	601	気道出血	SINUS BLEEDING	623	87	Resolved	No	Mild	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	630	処置による悪心	NAUSEA AFTER INJECTION	630	2	Resolved	No	Mild	Probable	None/not applicable	No /No
								100	630	寝汗	NIGHT SWEATS	652	60	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	630	挫傷	BRUISE ON LEG	652	60	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	630	不眠症	INSOMNIA	652	69	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	630	挫傷	BRUISE ON LOWER ARM	652	60	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	630	疲労	GENERALIZED FATIGUE	658		Resolved	No	Mild	Possible	None/not applicable	No /No
								100	630	浮動性めまい	LIGHTHEADEDNESS	663	49	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	630	悪心	NAUSEA	663	49	Resolved	No	Mild	Probable	None/not applicable	No /No
								100	630	下腹部痛	INTERMITTENT LOWER LEFT ABDOMINAL PAIN	663	49	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	665	耳痛	BILATERAL EAR PAIN	678		Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	665	頭痛	DAILY HEADACHES	678		Resolved	No	Moderate	Possible	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	806	痔核	EXTERNAL HEMORRHOIDS	827		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	841	頭痛	HEADACHE	844	7	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	876	鼻咽頭炎	HEAD CONGESTION	906	3	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	911	鼻咽頭炎	HEAD CONGESTION	935	8	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	938	副鼻腔炎	SINUSITIS	943	14	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	938	気管支炎	BRONCHITIS	943	18	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	938	リンパ節感染	LYMPH NODE/S INFECTION	965	4	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	938	体重減少	WEIGHT LOSS	968	7	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	938	悪心	NAUSEA	968	27	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	938	腹痛	ABDOMINAL PAIN	974	5	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	938	背部痛	BACK PAIN	974	7	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	938	ウイルス性上気道感染	VIRAL SINUS CONGESTION	974	20	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	938	腹痛	ABDOMINAL PAIN	979	2	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No

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								100	938	副腎腫瘤	RIGHT ADRENAL GLAND MASS	979	75	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	938	副腎腺腫	RIGHT ADRENAL CORTICAL ADENOMA	1054	2	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	938	処置による疼痛	POST SURGERY PAIN	1054		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	938	尿路感染	URINE TRACT INFECTION	1066	11	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
			7738-00017	4[redacted]/F	UNITED STATES /Caucasian			100	390	うつ病	DEPRESSION			Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	478	消化不良	HEARTBURN			Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	448	月経過多	MENORRHAGIA	451	43	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	448	節足動物咬傷	MULTIPLE INSECT BITES ON NECK	475	72	Resolved	No	Moderate	Not related	None/not applicable	No /No

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								100	645	季節性アレルギー	WORSENING OF SEASONAL ALLERGIES	658	76	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	730	アトピー性皮膚炎	RASH FACE (ATOPIC DERMATITIS)	733		Not Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	924	処置後出血	POST-PROCEDURAL RECTAL BLEEDING (BLEEDING FROM POLYP EXCISION)	945	8	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	924	直腸ポリープ	RECTAL INFLAMMATORY POLYP (BENIGN)	945	1	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	924	大腸ポリープ	8MM INFLAMMATORY POLYP SIGMOID (BENIGN)	945	1	Resolved	No	Moderate	Not related	None/not applicable	No /No

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								100	924	偽性ポリポーシス	THREE PSEUDO POLYPS (COLONIC)	945		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1213	上気道感染	UPPER RESPIRATORY INFECTION	1235	20	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	1373	鼻咽頭炎	HEAD COLD	1385	30	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1492	頚部痛	NECK PAIN	1545		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1492	副鼻腔うっ血	SINUS CONGESTION	1560	46	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1492	呼吸困難	DIFFICULTY BREATHING	1560	40	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1492	肺感染	LUNG INFECTION	1565	6	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	1492	肺炎	PNEUMONIA (LEFT LUNG)	1570	30	Resolved	Yes	Mild	Not related	None/not applicable	Yes/No
			7808-00006	4[redacted]/M	JAPAN/ Asian			100	367	ざ瘡	ACNE VULGARIS	376	1177	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	367	脂漏性皮膚炎	SEBORRHEIC DERMATITIS	376	1177	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	452	鼻咽頭炎	COLD	452	17	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	535	感染性腸炎	ENTERITIS INFECTIOUS	550	49	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	647	口腔咽頭痛	SORE THROAT	672	33	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	739	鼻咽頭炎	COLD	739	133	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	794	関節周囲炎	PERIATHRITIS SCAPULOHUMERALIS	795		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	843	インフルエンザ	INFLUENZA VIRAL INFECTIONS	853	1	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	871	鼻咽頭炎	COMMON COLD	878	83	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1120	鼻咽頭炎	COMMON COLD	1120	8	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1148	鼻咽頭炎	COMMON COLD	1148	8	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1284	鼻咽頭炎	COMMON COLD	1311	7	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1341	皮膚亀裂	SKIN FISSURE	1341	148	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1390	鼻咽頭炎	COMMON COLD	1390	8	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1418	鼻咽頭炎	COMMON COLD	1442	5	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1488	潰瘍性大腸炎	ULCERATIVE COLITIS	1505	64	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								100	1488	頭痛	HEADACHE	1506	3	Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	1488	肛門周囲痛	ANAL PAIN	1551		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1488	鼻咽頭炎	COMMON COLD	1562	9	Resolved	No	Mild	Not related	None/not applicable	No /No
			7816-00003	4[redacted]/F	JAPAN/ Asian			100	596	再生不良性貧血	APLASTIC ANAEMIA	617		Not Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
								100	596	偽膜性大腸炎	ENTERITIS PSEUDOMEMBRANOUS	625	30	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	596	不眠症	INSOMNIA	634	6	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	596	上気道の炎症	ACUTE UPPER RESPIRATORY INFLAMMATION	672	3	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	596	頭痛	HEADACHES	679	1	Resolved	No	Mild	Not related	None/not applicable	No /No
			7821-00002	5[redacted]/F	JAPAN/ Asian			100	393	爪真菌症	WORSENING OF NAIL TINEA	405		Not Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	477	蜂巣炎	CELLULITIS	492	98	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	477	結膜沈着物	CONJUNCTIVAL CONCRETION (LEFT)	496		Not Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	505	黄斑線維症	PRERETINAL FIBROSIS(R) AGGRAVATED	511	23	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								100	505	白内障	CATARACT(R)	511	23	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								100	505	網膜裂孔	RETINAL BREAKS	512	1	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	505	網膜変性	LATTICE DEGENNERATION	512	1	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	505	筋骨格痛	PAIN(SHOULDER)	513	1	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	560	毛包炎	FOLLICULITIS	560	30	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	673	閉経期症状	MENOPAUSAL SYNDROME	673		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	673	大腸菌性胃腸炎	ENTEROPATHIC E.COLI O74	680	21	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	673	口内炎	STOMATITIS	680	105	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	673	関節炎	ARTHRITIS	680		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	673	注射部位紅斑	INJECTION SITE REACTIOUS(ERYTHEMA)	680	3	Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	673	体重増加	BODY WEIGHT INCREASED	784		Not Resolved	No	Mild	Not related	None/not applicable	No /No
	Golimumab 100 mg (Golimumab induction nonresponder)	1 mg/kg IV	6051-00002	7[redacted]/M	BELGIUM/Caucasian			100	366	そう痒症	ITCHING			Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	478	筋骨格痛	PAIN LEFT SHOULDER			Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	450	皮膚有棘細胞癌	INVASIVE SPINOCELLULAR CARCINOMA ON EAR			Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	450	基底細胞癌	BASOCELLULAR CARCINOMA ON EAR			Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	1234	薬疹	RASH ON LOWER ARMSS DUE TO EFFUDIX OINTMENT			Resolved	No	Moderate	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	1318	呼吸困難	DYSPNEA			Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	478	鼻咽頭炎	COMMON COLD	504	6	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	540	上気道感染	UPPER RESPIRATORY TRACT INFECTION	554	6	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	562	鼻咽頭炎	COMMON COLD	585	9	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	618	上気道感染	UPPER RESPIRATORY TRACT INFECTION	625	5	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	786	創傷	FALL WITH WOUND ON LEFT LEG	810		Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	842	基底細胞癌	INFILTRATED BASOCELLULAR CARCINOMA PRE AURICULAR ON RIGHT SIDE	842	37	Resolved	No	Moderate	Possible	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	842	基底細胞癌	NODULAR BASOCELLULAR CARCINOMA RETROAURICULAR LEFT SIDE	842	27	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	842	気管支炎	BRONCHITIS	854	84	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	842	咽頭の炎症	THROAT INFLAMMATION	854		Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	1010	骨挫傷	BRUISED RIBS DUE TO FALL	1019		Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1290	咳嗽	COUGH	1309	107	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	1346	悪心	NAUSEA	1370		Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	1346	胃炎	MILD ACTIVE MILD CHRONIC PANGASTRITIS	1372		Not Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	1374	胃障害	GASTROPATHY	1374		Not Resolved	No	Moderate	Possible	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	1374	びらん性十二指腸炎	DUODENOPATHY: EROSIONS IN SECOND PART OF THE DUODENUM	1374		Not Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	1402	間質性肺疾患	INTERSTITIAL LUNG DISEASE	1416	196	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	No /No
								100	1402	呼吸困難	INCREASED DYSPNEA	1423	2	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	1402	間質性肺疾患	ACUTE FLARE OF INTERSTITIAL LUNG DISEASE	1425	19	Resolved	Yes	Severe	Possible	None/not applicable	No /No
								100	1402	心不全	SECONDARY CARDIAC FAILURE	1425	19	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1402	間質性肺疾患	ACUTE FLARE INTERSTITIAL LUNGDISEAE	1451	10	Resolved	Yes	Severe	Possible	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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			6179-00003	4[redacted]/F	FRANCE/Caucasian			100	407	そう痒症	PRURITUS			Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	547	視力低下	DECREASE IN VISUAL ACUITY			Resolved	No	Mild	Possible	None/not applicable	No /No
								100	360	耳感染	OTITIS	383	10	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	407	耳感染	OTITIS	436	22	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	442	喉頭炎	LARYNGITIS	455	7	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	471	関節痛	INTERMITTENT ARTHRALGIA ON HANDS	471	77	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	471	そう痒症	PRURITUS	497	4	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	520	耳感染	SUPERINFECTED OTITIS	540	1	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	547	腹痛	ABDOMINAL PAIN	554	22	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	547	放屁	FLATULENCE	554	22	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	547	便秘	CONSTIPATION	571	3	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	596	胃腸炎	GASTROENTERITIS	604	11	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	596	錯感覚	TINGLING ON THE RIGHT LEG	605	1	Resolved	No	Mild	Possible	None/not applicable	No /No

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								100	617	錯感覚	TINGLING ON THE LOWER AND THE UPPER LIMB	635		Not Resolved	No	Mild	Possible	None/not applicable	No /No
								100	709	扁桃炎	TONSILITIS	721	6	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	730	アレルギー性咽頭炎	ALLERGIC PHARYNGITIS	749	4	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	758	穿刺部位疼痛	LUMBAR PAIN AFTER LUMBAR PONCTURE	772	15	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	882	脱髄	DEMYELINIISATION	884	442	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	No /No
			6407-00004	3[redacted]/M	POLAND/Caucasian			100	617	潰瘍性大腸炎	AGGRAVATION OF ULCERATIVE COLITIS	617	144	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	729	潰瘍性大腸炎	PROGRESSION OF ULCERATIVE COLITIS	760	6	Resolved	Yes	Moderate	Unlikely	Permanent discontinuation of study agent	No /No

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			6502-00008	3[redacted]/F	SLOVAKIA(SlovakRepublic)/Caucasian			100	757	喉頭炎	LARYNGITIS CHRONICA HYPERPLASTICA	772		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	792	肺結核	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	561	多尿	DIURESIS - INCREASED URINATION	574	9	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	561	発熱	FEVER - INCREASED TEMPERATURE BETWEEN 38 - 39 GRAD	577	3	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	561	疲労	FATIGUE	579	4	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	589	発熱	FEVER - INCREASED TEMPERATURE 37,8	590	6	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	589	敗血症	SEPSIS	639	1	Resolved	Yes	Severe	Possible	None/not applicable	Yes/No

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			6112-00001	5[redacted]/M	CANADA/Caucasian			100	477	帯状疱疹	SHINGLES, LOWER BACK, DIFFUSE	481	9	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	806	消化不良	INTERMITTENT INDIGESTION	821		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	939	発疹	RASH, BACK AND HEAD	952	24	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	982	心膜炎	PERICARDITIS	990	42	Resolved	Yes	Moderate	Unlikely	None/not applicable	Yes/No
								100	1044	発疹	RASH, SCALP	1046	114	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	1156	ウイルス性上気道感染	COLD VIRUS	1183	24	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	1212	皮膚乳頭腫	PLANTAR WART	1221	38	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	1212	処置後感染	INFECTION AT SITE OF PLANTAR WART EXCISION	1224	21	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	1296	背部痛	LEFT SIDED BACK PAIN	1322	118	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
			6477-00005	5[redacted]/F	SERBIA/Caucasian			100	1149	子宮脱	UTERINE PROLAPSE	1154	14	Resolved	Yes	Mild	Not related	None/not applicable	No /No

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			6478-00011	4[redacted]/F	SERBIA/Caucasian			100	561	ウイルス感染	VIROSIS	584	3	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	841	基底細胞癌	BASAL CELL CARCINOMA	848	15	Resolved	Yes	Mild	Possible	None/not applicable	No /No
								100	953	咳嗽	DRY COUGH	977	11	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1069	痔核	NODULI HEMORRHOIDALES	1083		Not Resolved	No	Mild	Not related	None/not applicable	No /No
		100 mg/50 mg SC	7210-00001	4[redacted]/F	GERMANY/Caucasian			100	456	大腸炎	PANCOLITIS	476	7	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								100	456	悪心	NAUSEA	476	7	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								100	456	腹痛	PAIN LEFT ABDOMINAL	476	7	Resolved	No	Moderate	Not related	None/not applicable	No /No
			7354-00003	2[redacted]/F	NETHERLANDS/Caucasian			100	422	鼻炎	RHINITIS	451	13	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	562	上気道感染	UPPER RESPIRATORY INFECTION	565	7	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	618	膿疱性皮疹	PUSTULAS UNDER RIGHT FOOT	641	39	Resolved	No	Mild	Possible	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	702	上気道感染	UPPER RESPIRATORY INFECTION	702	11	Resolved	No	Mild	Probable	None/not applicable	Yes/No
								100	729	上気道感染	UPPER RESPIRATORY INFECTION	751	9	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	781	副鼻腔炎	SINUSITIS	794	17	Resolved	No	Moderate	Probable	None/not applicable	Yes/No
								100	814	帯状疱疹	HERPES ZOSTER	833	62	Resolved	No	Mild	Probable	None/not applicable	Yes/No
								100	842	抑うつ症状	DEPRESSIVE SYMPTOMS	852	44	Resolved	Yes	Mild	Not related	None/not applicable	No /No
								100	897	上気道感染	UPPER RESPIRATORY INFECTION	921	7	Resolved	No	Mild	Probable	None/not applicable	Yes/No
								100	1066	悪心	NAUSEA	1087	4	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	1066	頭痛	HEADACHE	1087	4	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	1094	上気道感染	UPPER RESPIRATORY INFECTION	1105	6	Resolved	No	Mild	Probable	None/not applicable	Yes/No
								100	1206	上気道感染	UPPER RESPIRATORY INFECTION	1231	3	Resolved	No	Mild	Probable	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	1262	上気道感染	UPPER RESPIRATORY INFECTION	1263	15	Resolved	No	Mild	Probable	None/not applicable	Yes/No
								100	1430	細菌性耳感染	BACTERIAL INFECTION BOTH EARLOBES	1452	30	Resolved	No	Mild	Probable	None/not applicable	Yes/No
								100	1454	上気道感染	UPPER RESPIRATORY INFECTION	1468	26	Resolved	No	Mild	Probable	None/not applicable	Yes/No
								100	1486	上気道感染	UPPER RESPIRATORY INFECTION	1596		Not Resolved	No	Mild	Possible	None/not applicable	Yes/No
			7376-00002	4[redacted]/M	NEWZEALAND/ Other			100	617	発疹	RASH BOTH FOREARMS	619	8	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	876	肛門膿瘍	PERIANAL ABCESS	886		Not Resolved	Yes	Severe	Possible	None/not applicable	Yes/No
								100	997	上気道感染	URTI	1035		Not Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
			7413-00001	4[redacted]/F	POLAND/Caucasian			100	393	頭痛	HEADACHE	401	2	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	393	膣感染	COLPITIS	403	15	Resolved	No	Moderate	Not related	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	393	子宮頚部びらん	EROSION CERVIX UTERI	404	14	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	701	鼻咽頭炎	COLD	714	8	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	841	紅斑	ERYTHEMA CRURIS	867	31	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	897	潰瘍性大腸炎	ULCERATIVE COLITIS WORSENING	905	37	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	1009	アレルギー性皮膚炎	DERMATITIS ALLERGIC	1037	27	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1205	咽頭炎	PHARYNGITIS	1228	5	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	1345	腎仙痛	RENAL COLIC ON THE LEFT	1358	3	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
			7728-00002	4[redacted]/F	UNITED STATES /Caucasian			100	771	潰瘍性大腸炎	UC FLARE	777		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	863	脊椎炎	LAMINECTOMY C6-C7 BILATERAL KEYHOLE FORAMINOTOMY C6-C7 POSTERIOR FUSION DUE TO CERVICAL SPONDYLITIS	880	3	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	863	漿液腫	SEROMA	902	2	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
			7761-00003	5[redacted]/M	UNITED STATES /Caucasian			100	535	変形性関節症	ADVANCED LEFT HIP OSTEOARTHRITIS			Resolved	No	Severe	Not related	None/not applicable	No /No
								100	400	インフルエンザ	FLU SYMPTOMS	422	13	Resolved	No	Moderate	Not related	Temporary interruption/dose modification	Yes/No
								100	400	排便回数増加	INCREASED FREQUENCY OF STOOLS	432	13	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	619	骨粗鬆症	OSTEOPOROSIS	624		Not Resolved	No	Moderate	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	876	変形性関節症	LEFT HIP REPLACEMENT D/T LEFT HIP OSTEOARTHRITIS	912	3	Resolved	Yes	Moderate	Not related	Temporary interruption/dose modification	No /No
								100	933	直腸出血	RECTAL BLEEDING	934		Resolved	No	Mild	Not related	None/not applicable	No /No
								100	960	蕁麻疹	ITCHING / HIVES	1040	7	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1044	頻脈	TACHYCARDIA	1067	38	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1108	頻脈	TACHYCARDIA	1109	6	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1108	潰瘍性大腸炎	U/C FLARE	1125	41	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1200	偽性ポリポーシス	PSUEDOPOLYPS IN MID SIGMOID AND DISTAL TRANSVERSE COLON AND CECUM.	1212	1	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1200	歯痛	TOOTH PAIN	1213	4	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1348	頻脈	TACHYCARDIA	1372	83	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1348	潰瘍性大腸炎	U/C FLARE	1377	27	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1404	鼻咽頭炎	COLD	1424	31	Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	1404	下痢	DIARRHEA	1429	2	Resolved	No	Mild	Not related	None/not applicable	No /No
		200 mg/100 mg SC	6404-00010	2[redacted]/F	POLAND/Caucasian			100	394	胃腸炎	GASTROENTERITIS	420	6	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	448	大腸ポリープ	POLYPUS OF COLON.	450	2	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								100	730	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS.	744	90	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	815	クッシング様症状	MOON FACE	819	127	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	815	紅斑	ERYTHEMA FACE	819	127	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	926	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS.	953	85	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1009	クッシング様症状	MOON FACE	1011	139	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1065	紅斑	ERYTHEMA FACE	1079	41	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1205	腹痛	ABDOMINAL PAIN.	1211	1	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1205	嘔吐	VOMITUS.	1211	1	Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	1317	苔癬様角化症	LICHENOID LESIONS ON A DORSUM RIGHT FEET.	1318	35	Resolved	No	Mild	Not related	None/not applicable	No /No
			7116-00008	5[redacted]/M	CANADA/Caucasian			100	454	肺炎	COMMUNITY ACQUIRED PNEUMONIA	468	9	Resolved	No	Moderate	Probable	None/not applicable	Yes/No
								100	701	鼻炎	NASAL INFECTION	718	75	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	813	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	832	8	Resolved	Yes	Severe	Possible	None/not applicable	No /No
								100	1058	鼻咽頭炎	COMMON COLD	1091	27	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	1121	副鼻腔炎	SINUSITIS	1127		Not Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	1121	鼻出血	EPISTAXIS	1131	65	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
			7207-00015	3[redacted]/M	GERMANY/Caucasian			100	385	呼吸困難	SHORTNESS OF BREATH			Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	843	鼻咽頭炎	COMMON COLD			Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	616	扁桃炎	TONSILITIS	631	7	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	728	副鼻腔炎	SINUSITIS	733	20	Resolved	No	Moderate	Possible	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	953	帯状疱疹	VARIZELLA ZOSTER LOCALIZED TO LOWER RIGHT ABDOMEN	955	9	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	953	副鼻腔炎	SINUSITIS	970	40	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	1067	副鼻腔炎	SINUSITIS	1093	8	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	1184	大腸ポリープ	SIGMOID POLYP	1190	80	Resolved	Yes	Mild	Not related	None/not applicable	No /No
			7230-00018	4[redacted]/F	HUNGARY/Caucasian			100	533	虫垂炎	ACUT APPENDICITIS	546	20	Resolved	Yes	Severe	Not related	Temporary interruption/dose modification	Yes/No
			7263-00007	3[redacted]/F	INDIA/Asian			100	965	咳嗽	COUGH	990	13	Resolved	No	Mild	Possible	Permanent discontinuation of study agent	Yes/No
								100	965	発熱	FEVER	990	13	Resolved	No	Mild	Possible	Permanent discontinuation of study agent	Yes/No
								100	992	肺外結核	EXTRA PULMONARY TUBERCULOSIS	1002	18	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	Yes/No

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								100	992	肺外結核	EXTRA PULMONARY TUBERCULOSIS	1019		Not Resolved	No	Mild	Possible	None/not applicable	Yes/No
			7741-00005	6[redacted]/F	UNITED STATES /Caucasian			100	372	無気肺	ATLECTASIS	408	13	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	410	椎間板突出	STENOSIS D/T DISC HERNIATION C5 & C6	410		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	410	口腔咽頭痛	SORE THROAT	426	3	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	410	頭痛	HEAD ACHE	426	3	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	410	鼻漏	CLEAR IN COLOR NASAL DRAINAGE	426	3	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	410	湿性咳嗽	COUGH WITH MILD PHLEM	426	38	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	458	咳嗽	COUGH, WITH DEEP BREATHS ONLY	464	118	Resolved	No	Mild	Not related	None/not applicable	No /No

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								100	564	咳嗽	INCREASED FREQUENCY OF DRY COUGH	581	41	Resolved	No	Moderate	Possible	Temporary interruption/dose modification	No /No
								100	564	呼吸困難	SHORTNESS OF BREATH	581	46	Resolved	No	Mild	Possible	Temporary interruption/dose modification	No /No
								100	564	呼吸困難	TIRED FEELING R/T INCREASED SOB	583	41	Resolved	No	Moderate	Possible	Temporary interruption/dose modification	No /No
								100	564	咳嗽	CHEST TIGHTENING R/T INCREASED COUGH FREQUENCY	583	41	Resolved	No	Mild	Possible	Temporary interruption/dose modification	No /No
								100	564	咳嗽	HEAD ACHES DUE TO INCREASED COUGHING	584	37	Resolved	No	Mild	Possible	Temporary interruption/dose modification	No /No
								100	564	高血圧	MILD HYPERTENSION	597		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	564	肺気腫	EMPHYSEMA	599		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No

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								100	564	間質性肺疾患	INTERSTITIAL LUNG DISEASE	618	43	Resolved	Yes	Moderate	Probable	Permanent discontinuation of study agent	No /No
								100	564	肺臓炎	PNEUMONITIS	618	128	Resolved	Yes	Moderate	Probable	Permanent discontinuation of study agent	No /No
								100	564	筋痙縮	CRAMPING OF FINGERS	648	6	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	564	筋痙縮	CRAMPING OF TOES	648	6	Resolved	No	Mild	Not related	None/not applicable	No /No
			7746-00005	4[redacted]/M	UNITED STATES /Caucasian			100	447	副鼻腔炎	SINUS INFECTION	476	7	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	622	上気道感染	UPPER RESPIRATORY INFECTION	643	4	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	651	副鼻腔うっ血	SINUS CONGESTION	676	8	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	842	血便排泄	BLOOD IN STOOL	870	6	Resolved	No	Moderate	Not related	None/not applicable	No /No

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								100	1316	潰瘍性大腸炎	CHRONIC ULCERATIVE COLITIS AT INCREASED RISK FOR DYSPLASIA	1344	337	Resolved	No	Moderate	Not related	Permanent discontinuation of study agent	No /No
								100	1316	骨盤内敗血症	PELVIC SEPSIS	1421	4	Resolved	Yes	Severe	Not related	None/not applicable	Yes/No
			7753-00004	5[redacted]/M	UNITED STATES /Black			100	573	浮動性めまい	LIGHTHEADED			Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	454	嚢胞	REMOVAL OF CYST ON BACK OF NECK	476	2	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	505	鼻咽頭炎	HEAD COLD	536	6	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	627	インフルエンザ	INFLUENZA	638	10	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	788	気管支炎	BRONCHITIS	821	119	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	853	白血球数増加	ELEVATED WHITE BLOOD CELL COUNT	881		Not Resolved	No	Mild	Possible	None/not applicable	No /No
								100	909	振戦	TREMORS	929		Not Resolved	No	Mild	Possible	None/not applicable	No /No
								100	963	副鼻腔炎	SINUS INFECTION	975	10	Resolved	No	Mild	Possible	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	999	T細胞性リンパ腫	T CELL LYMPHOMA	1028		Not Resolved	Yes	Mild	Possible	Permanent discontinuation of study agent	No /No
								100	999	気管支炎	BRONCHITIS	1042	15	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	999	痔核	HEMORRHOIDS	1059		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	999	誤嚥	MASSIVE ASPIRATION	1145	1	Resolved	Yes	Severe	Not related	None/not applicable	No /No
			7776-00005	4[redacted]/F	UNITED STATES /Caucasian			100	422	上気道感染	UPPER RESPIRATORY INFECTION	428	21	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	449	ウイルス性上気道感染	POST VIRAL COUGH	451	55	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	533	潰瘍性大腸炎	WORSENING ULCERATIVE COLITIS	560	58	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	813	上気道感染	UPPER RESPIRATORY TRACT INFECTION	833	37	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	953	カンジダ感染	CANDIDIASIS OF INNER THIGHS	961	15	Resolved	No	Mild	Not related	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	953	睡眠時無呼吸症候群	OBSTRUCTIVE SLEEP APNEA	967		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1063	潰瘍性大腸炎	WORSENING ULCERATIVE COLITIS	1065	29	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1093	上腹部痛	RIGHT UPPER QUADRANT PAIN	1100	50	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1121	消化不良	HEARTBURN	1121	92	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1121	遠隔転移を伴う腎癌	METASTIC CARCINOMA OF THE RIGHT KIDNEY	1123	31	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
								100	1121	貧血	ANEMIA	1149	1	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1121	体重減少	WEIGHT LOSS	1149	64	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1121	疲労	FATIGUE	1149	64	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1121	低血圧	HYPOTENSION	1192	21	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1121	末梢性浮腫	EDEMA, BILATERAL ANKLES	1201	12	Resolved	No	Moderate	Not related	None/not applicable	No /No
			7808-00001	5[redacted]/F	JAPAN/ Asian			100	393	大腸ポリープ	COLONIC POLYP	419	5	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								100	587	不眠症	INSOMNIA	588	110	Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	842	不眠症	INSOMNIA	842		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	926	感覚障害	SENSORY ADERRATIONS	937		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1010	関節周囲炎	PERIARTHRITIS SCAPULOHUMERALIS	1017		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1010	舌炎	TOUGUE IRRITATION	1017		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1010	不安	FEELING ANXIOUS	1017		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1073	裂肛	ANAL FISSURE	1090	58	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1147	鼻咽頭炎	COMMON COLD	1149	6	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1178	頭痛	HEAD ACHE	1179	12	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1290	頭痛	HEAD ACHE	1291	335	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1458	大腸ポリープ	COLON POLYP	1478		Not Resolved	No	Mild	Probable	None/not applicable	No /No
								100	1483	感染性皮膚嚢腫	PYOGENIC ATHEROMA	1483		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1483	脂漏性角化症	SEBORRHEIC KERATOSIS	1483		Not Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
			7809-00001	2[redacted]/M	JAPAN/ Asian			100	406	消化管感染	ACUTE INTESTINAL INFECTION	421	2	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	424	消化管感染	ACUTE INTESTINAL INFECTION	457	28	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	484	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	492	19	Resolved	Yes	Severe	Not related	None/not applicable	No /No
			7822-00001	2[redacted]/M	JAPAN/ Asian			100	387	鼻咽頭炎	COMMON COLD	413	31	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	674	口内炎	STOMATITIS	674	64	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1178	肛門膿瘍	PERIANAL ABSCESS	1188	355	Resolved	No	Moderate	Probable	Permanent discontinuation of study agent	Yes/No
								100	1178	肛門膿瘍	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	450	咳嗽	COUGH	461	45	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	482	下痢	DIARRHOEA	492	5	Resolved	Yes	Mild	Not related	None/not applicable	No /No
								100	482	腎盂腎炎	PYELONEPHRITIS	500	3	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	505	咳嗽	COUGH	512	92	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	533	口腔咽頭痛	SORE THROAT	557	16	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	561	上気道感染	UPPER RESPIRATORY INFECTION	588	22	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	589	悪心	NAUSEA	608	16	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	617	耳不快感	BLOCKED RIGHT EAR CANAL	632	8	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	785	筋骨格痛	RIGHT SHOULDER PAIN	807		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	811	関節炎	OLIGOARTHRITIS OF LEFT KNEE	845		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	846	関節痛	RIGHT ELBOW PAIN	868	72	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1176	胃腸炎	INFECTIOUS GASTROENTERITIS	1213	18	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	1323	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	1330	32	Resolved	No	Mild	Unlikely	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	1323	インフルエンザ	FLU	1343	7	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	1482	上気道感染	URTI	1583	6	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
			7077-00006	4[redacted]/M	BULGARIA/Caucasian			100	364	好酸球増加症	EOSINOPHILIA	406	76	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	406	咳嗽	COUGHT	424		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	406	発熱	HIGH TEMPERATURE	425	5	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	481	毛巣嚢胞	PILONIDAL ABSCESS	516	9	Resolved	Yes	Severe	Not related	None/not applicable	Yes/No
								100	481	肛門膿瘍	PUNCTION OF PERIANAL ABSCESS	517	8	Resolved	Yes	Moderate	Not related	None/not applicable	Yes/No
								100	481	発熱	FEVER - 37,6 C	517	2	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	519	肛門周囲痛	PAIN IN THE ANAL AREA	525	63	Resolved	No	Mild	Not related	None/not applicable	Yes/No
			7079-00010	3[redacted]/M	BULGARIA/Caucasian			100	363	血小板増加症	THROMBOCITOSIS	391	108	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	447	無力症	WEAKNESS /ASTHENIA/	468	31	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	447	貧血	ANAEMIA	475	9	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	475	低アルブミン血症	HYPOALBUMINEMIA	483	16	Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

Randomized at Week 0 of the Maintenance Study	Maintenance Treatment Group	Actual Treatment Group in Induction	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	Verbatim Term	Study Day of AE	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Infection/ Injection-site Reaction
								100	475	貧血	WORSENING OF ANAEMIA	483	16	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								100	531	貧血	ANAEMIA	559	113	Resolved	No	Mild	Not related	None/not applicable	No /No
			7203-00005	2[redacted]/M	GERMANY/Caucasian			100	796	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS			Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	451	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	474	34	Resolved	No	Severe	Not related	None/not applicable	No /No
								100	655	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	655	30	Resolved	No	Severe	Not related	None/not applicable	No /No
								100	796	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	810		Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	907	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	907	7	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
			7207-00012	2[redacted]/M	GERMANY/Caucasian			100	456	ウイルス性髄膜炎	VIRAL MENINGITIS	477	16	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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			7213-00008	2[redacted]/M	GERMANY/Caucasian			100	475	細菌の過剰増殖	BACTERIAL OVERGROWTH SYNDROM			Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	562	潰瘍性大腸炎	WORSENING OF UC	585	6	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
								100	562	遠隔転移を伴う結腸癌	METASTATIC ADENOCARCINOMA OF THE COLON	585	978	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								100	562	腎嚢胞	PARAPELVIC RENAL CYSTE UPPER LEFT POLE	590		Not Resolved	No	Mild	Not related	None/not applicable	No /No
			7413-00003	3[redacted]/M	POLAND/Caucasian			100	395	血小板減少症	THROMBOCYTOPENIA	395	84	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	507	潰瘍性大腸炎	ULCERATIVE COLITIS WORSENING	526	66	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	619	頻脈	TACHYCARDIA	619	280	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	814	耳感染	OTITIS RIGHT	826	7	Resolved	No	Moderate	Not related	None/not applicable	Yes/No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	871	帯状疱疹	ZOSTER ON THE LEFT SIDE OF THE TRUNK	883	7	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
			7791-00001	2[redacted]/F	UNITED STATES /Black			100	406	歯痛	TOOTH PAIN	417	1	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	420	上腹部痛	STOMACH CRAMPING	420	4	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	504	嘔吐	VOMITING	534	3	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	536	腹痛	ABDOMINAL PAIN	556	14	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	536	下痢	DIARRHEA	556	14	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	536	直腸出血	RECTAL BLEEDING	556	14	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	536	慢性胆嚢炎	CHRONIC CHOLECYSTITIS WITH CHOLELITHIASIS	563	7	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	536	悪心	NAUSEA	563	7	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	536	貧血	ANEMIA	569		Not Resolved	No	Mild	Not related	None/not applicable	No /No

表 2.7.6.4-11 重篤な有害事象を発現した症例の一覧（継続投与試験の投与被験者）（続き）

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								100	641	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITITS	662	3	Resolved	Yes	Mild	Not related	None/not applicable	No /No
								100	842	腹痛	ABDOMINAL PAIN	843	4	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	842	尿路感染	URINARY TRACT INFECTION	843	4	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	897	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	933		Not Resolved	Yes	Mild	Not related	Permanent discontinuation of study agent	No /No
								100	897	膣感染	VAGINITIS	933	3	Resolved	No	Mild	Not related	None/not applicable	Yes/No
			7819-00001	3[redacted]/F	JAPAN/ Asian			100	544	鼻咽頭炎	COMMON COLD	557	16	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	544	子宮頚部上皮異形成	HIGH GRADE CERVICAL DYSPLASIA	575	68	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	No /No

[a] Study day is the number of days from Week 0 of the maintenance study
[b] Infection as assessed by the investigator
Note: Adverse Events are coded using MedDRA 17.1

以下に，継続投与試験でゴリムマブの投与開始後に死亡及び重篤な有害事象を発現した症例のうち，重篤な有害事象により治験薬投与を中止した症例及び治験担当医師により重篤な有害事象が感染症と判断された症例の詳細を示す。

(1) ゴリムマブの使用と関連性のある死亡の叙述

被験者識別コード：7205-00005

■ REASON FOR NARRATIVE SELECTION

Death

SAE

■ Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
09FEB2012 (854)	遠隔転移を伴う直腸癌 (ADVANCED RECTAL CANCER WITH LIVER METASTASIS)	Yes	Moderate/ Possible	No/ NA	None/not applicable	16MAR2013 (1255)

■ Other Adverse Events

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
24FEB2011 (504)	潰瘍性大腸炎 (WORSENING ULCERATIVE COLITIS)	Moderate/ Not related	No/ NA	None/not applicable	23FEB2012 (868)

■ Demographics and Baseline Characteristics

□ Race: Caucasian
□ Age (yrs): 4[redacted]
□ Sex: Male
□ Date of birth: 01APR[redacted]
□ Height (cm): 176
□ Weight (kg): 77.5
□ Date of UC diagnosis: -----1995
□ UC disease duration (years): 13.7
□ Relevant medical history at baseline: 喫煙（過去/現在）

■ Treatment Groups

□ Induction study: C0524T17

□ Treatment group in induction: Placebo SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to placebo induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ Treatment Received

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	28OCT2010	385	1	Placebo	0 mg
Week 56 - EXT	28OCT2010	385	1	Golimumab	100 mg
Week 60 - EXT	25NOV2010	413	2	Golimumab	100 mg
Week 60 - EXT	25NOV2010	413	2	Placebo	0 mg
Week 64 - EXT	22DEC2010	440	3	Golimumab	100 mg
Week 64 - EXT	22DEC2010	440	3	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 68 - EXT	31JAN2011	480	4	Placebo	0 mg
Week 68 - EXT	31JAN2011	480	4	Golimumab	100 mg
Week 72 - EXT	24FEB2011	504	5	Golimumab	100 mg
Week 72 - EXT	24FEB2011	504	5	Placebo	0 mg
Week 76 - EXT	24MAR2011	532	6	Golimumab	100 mg
Week 76 - EXT	24MAR2011	532	6	Placebo	0 mg

■ **NARRATIVE TEXT**

本被験者は，2009 年 8 月 28 日に寛解導入試験（T17 試験）でプラセボを初回皮下投与された。プラセボ寛解導入 non-responder であり，2009 年 10 月 9 日から寛解維持試験でゴリムマブ 100 mg を 4 週ごとに投与された。2010 年 10 月 28 日（Day 385）から継続投与試験でゴリムマブ 100 mg を 4 週ごとに継続投与された。

CIOMS で報告されている併用薬には，prednisone，pantoprazole（2009 年 8 月 14 日から継続），metamizole sodium（Novalgin®，2009 年 8 月 14 日から継続），zinc DL-aspartate（Unizink®，2009 年 10 月 10 日から継続）があった。継続投与試験中に使用された併用薬を，以下の表に示した。

死亡／重篤な有害事象：遠隔転移を伴う直腸癌（Day 854）

2011 年 4 月 20 日（Day 559），本被験者は効果不十分により治験薬投与を中止し，治験薬の最終投与は 3 月 24 日（Day 532）であった。

CIOMS の報告では，2012 年 2 月 9 日の腹部 CT スキャンで，既知の UC によるリンパ転移形成を伴う壊死性の直腸癌に一致し局所リンパ節への関与が明らかであるエビデンスのある左側の遠位直腸に 7×5 cm の腫瘤，S 状結腸及び上行結腸に長い分節状の壁厚，左胃間膜部に腸重積症の疑い及び腸管膜血管の陥入を伴う環状の空腸ループ，右葉及び左葉に最大 3.5 cm の複数の低密度の肝病巣，下胸部では右下葉に 5 mm 未満の肺腫瘤が認められた。

2 月 9 日の腫瘍マーカーは次のとおりであった：CA19-9 2893.00 U/mL［基準値（以下 NR）<27］，CEA 5.2 ng/mL（NR <5.0）。2 月 9 日（Day 854）に，肝転移を伴う進行直腸癌（重篤な有害事象）と診断され，本被験者は入院した。

2 月 9 日の臨床検査値は次のとおりであった：CRP 19.80 mg/L（NR <5.0 mg/L），γ-グルタミルトランスフェラーゼ（以下 GGT）81 U/L（NR 10-71），ヘマトクリット 42.0%（NR 43.0%-49.0%），乳酸脱水素酵素（以下 LDH）319 U/L（NR 135-225 U/L），平均赤血球容積（以下 MCV）83.7 fL（NR 85.0-95.0 fL）及び白血球数 9870/μL（NR 4600-9500/μL）。2 月 14 日の臨床検査値は次のとおりであった：CRP 19.70 mg/L，MCV 81.7 fL 及び白血球数 10960/μL）。

2 月 14 日の大腸内視鏡検査で，肛門から 3～4 cm から 16 cm の範囲に広範な半円形の潰瘍性直腸癌，癌の反対側で肛門から 3～4 cm の遠位部に 15 mm の鮮明なポリープ 1 つのほかに 10 mm の扁平性ポリープ 1 つ（左側），さらに，S 状結腸の肛門から 17 cm 及び 21 cm の部位に小さな癌の疑い，S 状結腸に複数のポリープ状病変が認められた。また，画像では，左弯曲部から直腸にかけて右結腸の UC 又はポリープ状病変を伴う左弯曲部から直腸の burned out UC も認められた。

2 月 15 日の大腸内視鏡検査で，隣接組織（外周の約 3 分の 2）に及ぶ広範な直腸癌，肛門から約 5 cm の遠位切離端の腫瘍境界，深達度 4 cm 超の大きな中心性壊死が認められた。内視鏡検査の結果から，T4N1 が疑われた。回腸終末部及び結腸から切除した検体に関する 2 月 15 日の病理

報告で，UC による軽度活動性（Riley に基づく Grade I）を伴う直腸癌が認められ，病変 3 カ所に臨床的な疑いが確認された。15 cm の部位の突起は肉芽組織ポリープであった。17 cm 及び 21 cm の部位の腫瘍は Grade 3（high grade），直腸癌は Grade 3（high grade），L0 V0 で，高リスクと分類された。

2 月 17 日の胸部 CT スキャンで，左上葉基底部に瘢痕が認められ，既知のびまん性肝転移の形成が目視で確認可能であった。2 月 22 日の臨床検査異常値は次のとおりであった：CRP 20.50 mg/L，GGT 101 U/L，ヘマトクリット 41.2%及び MCV 82.7 fL。

2 月 23 日の臨床検査値は次のとおりであった：塩基過剰 0.7 mmol/L（NR 不明），ヘマトクリット 33.2%，ヘモグロビン 11.4 g/dL（NR 14.0-18.0 g/dL），乳酸 0.7 mmol/L，MCV 81.0 fL，赤血球数 4.10×10^6/μL（NR 4.60-6.20$\times10^6$/μL）及び WBC 10150/μL。2 月 24 日の臨床検査値は次のとおりであった：塩基過剰 3.9 mmol/L 及び乳酸 0.9 mmol/L（NR 及び単位不明）。

2 月 23 日（Day 868）に，結腸亜全摘術及び胆嚢摘出術が行われた。2 月 27 日の病理報告で，S 状結腸及び直腸に肝転移を伴う UC による 4 つの腺癌が確認された。既知の UC は軽度活動性（Riley に基づく Grade I）であった。腫瘍分類（TNM 2010）は Grade 3（高リスク）で，pT3d (4), pN2b (8/43) pM1a (HEP) L1 V1 Pn0，UICC TNM 分類でステージ IV A Local R0 wide，CRM 陰性，全体的に R2（肝転移）であった。

2 月 28 日（Day 873）に，オキサリプラチン，葉酸，5-FU，5FU-Ci がボーラス投与された。腫瘍のステージ分類から疾患進行が認められた。3 月 2 日の KRAS 変異解析で，KRAS 野生型の直腸低分化腺癌であることが確認された。治験担当医師は，一次治療の 3 カ月後に癌が両肺及びリンパ節に転移したことを確認した。

3 月 9 日（Day 883）に本被験者は退院し，7 月 11 日（Day 1007）に二次治療を開始した。2013 年 3 月 16 日（Day 1255）に，本被験者は遠隔転移を伴う進行直腸癌により死亡した。剖検実施の有無は報告されていない。治験担当医師は，遠隔転移を伴う直腸癌の重症度は中等度で，治験薬との関連性を「可能性大」と判断した。

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
MESALAZINE,Rectal	20APR2011	14JUN2011
BUDESONIDE,Rectal	20APR2011	17MAY2011
PREDNISOLONE,Oral	20APR2011	28JUL2011

被験者識別コード：6076-00002

■ **REASON FOR NARRATIVE SELECTION**

Death

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
19OCT2010 (639)	敗血症 (SEPSIS)	Yes	Severe/ Possible	Yes/ Yes	None/not applicable	19OCT2010 (639)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
15AUG2010 (574)	多尿 (DIURESIS - INCREASED URINATION)	Moderate/ Not related	No/ NA	None/not applicable	23AUG2010 (582)
18AUG2010 (577)	発熱 (FEVER - INCREASED TEMPERATURE BETWEEN 38 - 39 GRAD)	Moderate/ Possible	Yes/ Yes	None/not applicable	20AUG2010 (579)
20AUG2010 (579)	疲労 (FATIGUE)	Moderate/ Unlikely	Yes/ Yes	None/not applicable	23AUG2010 (582)
31AUG2010 (590)	発熱 (FEVER - INCREASED TEMPERATURE 37.8)	Mild/ Not related	Yes/ Yes	None/not applicable	05SEP2010 (595)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 4[redacted]
□ Sex: Female
□ Date of birth: 10MAR[redacted]
□ Height (cm): 158
□ Weight (kg): 83.0
□ Date of UC diagnosis: 01OCT2004
□ UC disease duration (years): 4.2
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T16

□ Treatment group in induction: 2 mg/kg IV

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE:

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	22FEB2010	400	1	Placebo	0 mg
Week 56 - EXT	22FEB2010	400	1	Golimumab	100 mg
Week 56 - EXT	22FEB2010	400	1	Placebo	0 mg
Week 60 - EXT	15MAR2010	421	2	Placebo	0 mg
Week 60 - EXT	15MAR2010	421	2	Golimumab	100 mg
Week 64 - EXT	12APR2010	449	3	Placebo	0 mg
Week 64 - EXT	12APR2010	449	3	Golimumab	100 mg
Week 68 - EXT	11MAY2010	478	4	Golimumab	100 mg
Week 68 - EXT	11MAY2010	478	4	Placebo	0 mg
Week 72 - EXT	07JUN2010	505	5	Golimumab	100 mg
Week 72 - EXT	07JUN2010	505	5	Placebo	0 mg
Week 76 - EXT	05JUL2010	533	6	Golimumab	100 mg
Week 76 - EXT	05JUL2010	533	6	Placebo	0 mg
Week 80 - EXT	02AUG2010	561	7	Golimumab	100 mg
Week 80 - EXT	02AUG2010	561	7	Placebo	0 mg
Week 84 - EXT	30AUG2010	589	8	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 84 - EXT	30AUG2010	589	8	Golimumab	100 mg

■ **NARRATIVE TEXT**

本被験者は，2008 年 12 月 8 日に寛解導入試験（T16 試験）でゴリムマブ 2 mg/kg を初回静脈内投与された。ゴリムマブ寛解導入 non-responder であり，2009 年 1 月 19 日からゴリムマブ寛解維持試験で 100 mg を 4 週ごとに投与された。54 週までの寛解維持試験を完了し，2010 年 2 月 22 日（Day 400）から継続投与試験でゴリムマブ 100 mg を 4 週ごとに継続投与された。

CIOMS で報告されている併用薬には，UC に対するメサラジン（Salofalk®），高血圧に対するビソプロロールフマル酸塩（Concor®）があった。継続投与試験中に使用された併用薬を，以下の表に示した。

死亡／重篤な有害事象／重篤な感染症：敗血症（Day 639）

寛解維持試験の 54 週までに有害事象は報告されなかった。

54 週までの総括報告書作成時点で入手可能であった CIOMS の報告では，本被験者は休暇中の 2010 年 7 月（正確な日付不明）に山羊の生乳を経口摂取し，その後，利尿／排尿増加［8 月 15 日（Day 574）から 8 月 23 日（Day 582）まで］，発熱［8 月 18 日（Day 577）から 8 月 20 日（Day 579）まで 38°C～39°C，8 月 31 日（Day 590）から 9 月 5 日（Day 595）まで 37.8°C］，疲労［8 月 20 日（Day 579）から 8 月 23 日（Day 582）まで］を発現した。8 月 18 日から 8 月 28 日までシプロフロキサシン 500 mg を 1 日 2 回，8 月 31 日から 9 月 5 日までレボフロキサシン 500 mg を投与された。関連する検査結果又は臨床検査値は報告されなかった。

CIOMS の報告では，本被験者は 8 月 30 日（Day 589）に治験薬を最終投与され，9 月 21 日（Day 611）に詳細不明の有害事象により同意を撤回した。同意撤回の数日後に神経性症状を発現し，9 月 26 日に入院した。脱髄と暫定的に診断されたが，撤回された。本被験者は 10 月 19 日に死亡した。主な死因は敗血症と確認され，山羊の生乳の摂取による脳炎が原因である可能性が高かった。剖検は実施されなかった。

治験担当医師は，重篤な有害事象である敗血症（死亡）の発現日を 10 月 19 日と報告し，敗血症と盲検下での治験薬との関連性を「可能性大」と判断した。治験担当医師は，重症度を高度，感染症（抗生剤の経口投与により治療）との関連性があり，試験手順との関連性はないと判断した。

■ **Treatment and Study Status**

□ Date of study discontinuation: 21SEP2010

□ Reason for noncompletion: Withdrawal of consent

□ Other reason for noncompletion/details: -

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
CIPROFLOXACIN,Intravenous	20AUG2010	30AUG2010
DESMOPRESSIN,Intranasal	23AUG2010	29AUG2010
LEVOFLOXACIN,Oral	31AUG2010	05SEP2010

(2) ゴリムマブの使用と関連性がないと判断された死亡及びその他の重篤な有害事象の叙述

1) 寛解維持試験の 0 週にランダム割付けされた被験者

a) プラセボ群

被験者識別コード：6705-00016

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
18SEP2012 (853)	椎間板突出 (HERNIATED DISC)	Yes	Severe/ Not related	No/ NA	None/not applicable	19SEP2012 (854)
18SEP2012 (853)	外傷性脊椎症 (TRAUMATIC CERVICAL SPONDYLOPATHY)	Yes	Moderate/ Not related	No/ NA	None/not applicable	19SEP2012 (854)
03JAN2014 (1325)	壊疽性膿皮症 (PYODERMA GANGRENOSUM)	Yes	Severe/ Not related	No/ NA	Permanent discontinuation of study agent	16JAN2014 (1338)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
06JUL2011 (413)	麦粒腫 (OD STYE)	Mild/ Unlikely	Yes/ No	None/not applicable	10SEP2011 (479)
06JUL2011 (413)	副鼻腔うっ血 (SINUS CONGESTION)	Mild/ Unlikely	No/ NA	None/not applicable	10SEP2011 (479)
25JUL2011 (432)	背部痛 (LOWER BACK PAIN)	Mild/ Not related	No/ NA	None/not applicable	10OCT2011 (509)
01DEC2011 (561)	貧血 (WORSENING ANEMIA)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
28JAN2012 (619)	インフルエンザ (INFLUENZA)	Moderate/ Not related	Yes/ No	None/not applicable	04FEB2012 (626)
28FEB2012 (650)	頭痛 (HEADACHE)	Moderate/ Unlikely	No/ NA	None/not applicable	01MAR2012 (652)
01MAR2012 (652)	頭痛 (HEADACHE)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
19APR2012 (701)	痔核 (ANAL CANAL HEMORRHOID)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
18SEP2012 (853)	筋痙縮 (MUSCLE SPASM)	Mild/ Not related	No/ NA	None/not applicable	27DEC2012 (953)
18SEP2012 (853)	処置による疼痛 (POST OP PAIN)	Moderate/ Not related	No/ NA	None/not applicable	26SEP2012 (861)
02MAR2013 (1018)	潰瘍性大腸炎 (ULCERATIVE COLITIS FLAIR)	Moderate/ Not related	No/ NA	None/not applicable	21MAR2013 (1037)
07JUL2013 (1145)	尿路感染 (URINARY TRACT INFECTION)	Moderate/ Not related	Yes/ Yes	None/not applicable	21JUL2013 (1159)

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
23AUG2013 (1192)	霧視 (BLURRED VISION)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
03NOV2013 (1264)	インフルエンザ (FLU SYMPTOMS)	Mild/ Not related	No/ NA	None/not applicable	07NOV2013 (1268)
22NOV2013 (1283)	壊疽性膿皮症 (PYODERMA GANGRENOSUM)	Moderate/ Not related	No/ NA	None/not applicable	02JAN2014 (1324)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 5[redacted]
□ Sex: Male
□ Date of birth: 14OCT[redacted]
□ Height (cm): 178
□ Weight (kg): 85.0
□ Date of UC diagnosis: --JUN1983
□ UC disease duration (years): 26.8
□ Relevant medical history at baseline: 喫煙（過去/現在），アフタ性口内炎，関節炎

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 200mg -> 100mg SC

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/placebo in maintenance

□ Dose adjusted?: Yes

□ Adjusted treatment group: Golimumab 100 mg

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	16JUN2011	393	1	Placebo	0 mg
Week 56 - EXT	16JUN2011	393	1	Golimumab	100 mg
Week 60 - EXT	14JUL2011	421	2	Golimumab	100 mg
Week 60 - EXT	14JUL2011	421	2	Placebo	0 mg
Week 64 - EXT	10AUG2011	448	3	Placebo	0 mg
Week 64 - EXT	10AUG2011	448	3	Golimumab	100 mg
Week 68 - EXT	06SEP2011	475	4	Placebo	0 mg
Week 68 - EXT	06SEP2011	475	4	Golimumab	100 mg
Week 72 - EXT	06OCT2011	505	5	Placebo	0 mg
Week 72 - EXT	06OCT2011	505	5	Golimumab	100 mg
Week 76 - EXT	01NOV2011	531	6	Golimumab	100 mg
Week 76 - EXT	01NOV2011	531	6	Placebo	0 mg
Week 80 - EXT	01DEC2011	561	7	Placebo	0 mg
Week 80 - EXT	01DEC2011	561	7	Golimumab	100 mg
Week 84 - EXT	29DEC2011	589	8	Golimumab	100 mg
Week 88 - EXT	26JAN2012	617	9	Golimumab	100 mg
Week 92 - EXT	01MAR2012	652	10	Golimumab	100 mg
Week 96 - EXT	29MAR2012	680	11	Golimumab	100 mg
Week 100 - EXT	19APR2012	701	12	Golimumab	100 mg
Week 104 - EXT	17MAY2012	729	13	Golimumab	100 mg
Week 108 - EXT	14JUN2012	757	14	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 112 - EXT	12JUL2012	785	15	Golimumab	100 mg
Week 116 - EXT	16AUG2012	820	16	Golimumab	100 mg
Week 120 - EXT	06SEP2012	841	17	Golimumab	100 mg
Week 124 - EXT	04OCT2012	869	18	Golimumab	100 mg
Week 128 - EXT	01NOV2012	897	19	Golimumab	100 mg
Week 132 - EXT	29NOV2012	925	20	Golimumab	100 mg
Week 136 - EXT	26DEC2012	952	21	Golimumab	100 mg
Week 140 - EXT	24JAN2013	981	22	Golimumab	100 mg
Week 144 - EXT	28FEB2013	1016	23	Golimumab	100 mg
Week 148 - EXT	21MAR2013	1037	24	Golimumab	100 mg
Week 152 - EXT	11APR2013	1058	25	Golimumab	100 mg
Week 156 - EXT	09MAY2013	1086	26	Golimumab	100 mg
Week 160 - EXT	04JUN2013	1112	27	Golimumab	100 mg
Week 164 - EXT	11JUL2013	1149	28	Golimumab	100 mg
Week 168 - EXT	08AUG2013	1177	29	Golimumab	100 mg
Week 172 - EXT	06SEP2013	1206	30	Golimumab	100 mg
Week 176 - EXT	03OCT2013	1233	31	Golimumab	100 mg
Week 180 - EXT	05NOV2013	1266	32	Golimumab	100 mg
Week 184 - EXT	26NOV2013	1287	33	Golimumab	100 mg
Week 188 - EXT	19DEC2013	1310	34	Golimumab	100 mg

■ **Treatment and Study Status**

□ Date of study discontinuation: 23JAN2014

□ Reason for noncompletion: Other

□ Other reason for noncompletion/details: Patient refused to come in for final safety visit

□ Date of disposition status: 23Jan2014

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
HYDROCORTISONE,Intraarticular	27JUN2011	27JUN2011
HYDROCORTISONE,Intraarticular	25JUL2011	25JUL2011
HYDROCORTISONE,Intraarticular	06SEP2011	06SEP2011
BUPRENORPHINE,Transdermal	20APR2012	18SEP2012
HYDROCORTISONE,Intraarticular	21APR2012	21APR2012
FOLIC ACID,Oral	13JUL2012	30APR2013
IRON,Oral	13JUL2012	28FEB2013
FENTANYL,Intravenous	18SEP2012	18SEP2012
CEFAZOLIN,Intravenous	18SEP2012	18SEP2012
FENTANYL,Transdermal	18SEP2012	26SEP2012
HYDROMORPHONE,Intravenous	18SEP2012	18SEP2012
METHOCARBAMOL,Oral	18SEP2012	27DEC2012
LIDOCAINE,Intradermal	18SEP2012	18SEP2012
MORPHINE,Intravenous	18SEP2012	18SEP2012
PANTOPRAZOLE,Oral	18SEP2012	19SEP2012
DIPHENHYDRAMINE,Oral	19SEP2012	19SEP2012
PNEUMOCOCCAL VACCINE,Intramuscular	19SEP2012	19SEP2012
DIAZEPAM,Oral	01NOV2012	01NOV2012
VICODIN,Oral	01NOV2012	01NOV2012

Prior/Concomitant Therapy, Route	Start Date	End Date
DICYCLOVERINE,Oral	30NOV2012	27DEC2012
IRON,Oral	01MAR2013	Ongoing
PREDNISONE,Oral	06MAR2013	02JUN2013
CIPROFLOXACIN,Oral	07JUL2013	21JUL2013
PREDNISONE,Oral	27NOV2013	04DEC2013
PARACETAMOL,Oral	19DEC2013	Ongoing
HYDROCODONE,Oral	19DEC2013	Ongoing
PREDNISONE,Oral	19DEC2013	02JAN2014
VANCOMYCIN,Oral	03JAN2014	Ongoing
SULFADIAZINE,Topical	03JAN2014	Ongoing
PIP/TAZO,Oral	03JAN2014	Ongoing
FENTANYL,Intravenous	06JAN2014	06JAN2014
HYDROMORPHONE,Intravenous	06JAN2014	06JAN2014
ANESTHETICS, GENERAL,Intravenous	06JAN2014	06JAN2014
AUGMENTIN /00756801/,Oral	18JAN2014	27JAN2014
CIPROFLOXACIN,Oral	18JAN2014	27JAN2014
AMOXICILLIN,Oral	23JAN2014	02FEB2014
PREDNISONE,Oral	23JAN2014	Ongoing

被験者識別コード：7743-00013

■ **REASON FOR NARRATIVE SELECTION**

Death

SAE

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
28AUG2012 (771)	偶発的過量投与 (ACCIDENTAL NITROUS OXIDE OVERDOSE)	Yes	Severe/ Not related	No/ NA	Permanent discontinuation of study agent	28AUG2012 (771)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
01DEC2011 (500)	口腔咽頭痛 (SORE THROAT)	Mild/ Not related	Yes/ No	None/not applicable	14DEC2011 (513)
31JAN2012 (561)	上気道感染 (UPPER RESPIRATORY INFECTION)	Moderate/ Not related	Yes/ Yes	None/not applicable	18FEB2012 (579)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 4[redacted]
□ Sex: Male
□ Date of birth: 05DEC[redacted]
□ Height (cm): 193
□ Weight (kg): 99.2
□ Date of UC diagnosis: 05JAN2009
□ UC disease duration (years): 1.4
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 200mg -> 100mg SC

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/placebo in maintenance

□ Dose adjusted?: Yes

□ Adjusted treatment group: Golimumab 100 mg

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	19AUG2011	396	1	Placebo	0 mg
Week 56 - EXT	19AUG2011	396	1	Golimumab	100 mg
Week 60 - EXT	16SEP2011	424	2	Golimumab	100 mg
Week 60 - EXT	16SEP2011	424	2	Placebo	0 mg
Week 64 - EXT	21OCT2011	459	3	Placebo	0 mg
Week 64 - EXT	21OCT2011	459	3	Golimumab	100 mg
Week 68 - EXT	04NOV2011	473	4	Golimumab	100 mg
Week 68 - EXT	04NOV2011	473	4	Placebo	0 mg
Week 72 - EXT	09DEC2011	508	5	Golimumab	100 mg
Week 72 - EXT	09DEC2011	508	5	Placebo	0 mg
Week 76 - EXT	13JAN2012	543	6	Golimumab	100 mg
Week 80 - EXT	10FEB2012	571	7	Golimumab	100 mg
Week 84 - EXT	02MAR2012	592	8	Golimumab	100 mg
Week 88 - EXT	30MAR2012	620	9	Golimumab	100 mg
Week 92 - EXT	27APR2012	648	10	Golimumab	100 mg
Week 96 - EXT	24MAY2012	675	11	Golimumab	100 mg
Week 100 - EXT	22JUN2012	704	12	Golimumab	100 mg
Week 104 - EXT	20JUL2012	732	13	Golimumab	100 mg
Week 108 - EXT	16AUG2012	759	14	Golimumab	100 mg

■ **Treatment and Study Status**

□ Date of study discontinuation: 28Aug2012

□ Reason for noncompletion: Death

□ Other reason for noncompletion/details: -

□ Date of disposition status: 28Aug2012

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
CEFDINIR,Oral	03FEB2012	18FEB2012
CYANOCOBALAMIN,Subcutaneous	11APR2012	Ongoing

被験者識別コード：7026-00022

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
02DEC2011 (809)	胃腸炎 (GASTROENTERITIS)	Yes	Severe/ Unlikely	Yes/ Yes	None/not applicable	06DEC2011 (813)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
11OCT2010 (392)	注射部位紅斑 (ERYTHEMA AT INJECTION SITE)	Mild/ Definite	No/ NA	None/not applicable	14OCT2010 (395)
13DEC2010 (455)	注射部位紅斑 (ERYTHEMA AT INJECTION SITE)	Mild/ Definite	No/ NA	None/not applicable	17DEC2010 (459)
14JAN2011 (487)	胃腸炎 (GASTROENT. INFECTION)	Moderate/ Possible	Yes/ No	None/not applicable	16JAN2011 (489)
17JUN2011 (641)	口腔ヘルペス (HERPES SIMPLEX LABIALIS)	Moderate/ Probable	Yes/ Yes	Temporary interruption/dose modification	19JUL2011 (673)
25AUG2011 (710)	潰瘍性大腸炎 (WORSENING OF ULCERATIVE COLITIS)	Moderate/ Unlikely	No/ NA	None/not applicable	24SEP2011 (740)
18OCT2011 (764)	口腔ヘルペス (HERPES LABIALIS)	Mild/ Possible	No/ NA	None/not applicable	30OCT2011 (776)
14NOV2011 (791)	鼻咽頭炎 (COMMON COLD)	Mild/ Possible	Yes/ No	None/not applicable	21NOV2011 (798)
30NOV2011 (807)	胃腸炎 (GASTROENTERITIS)	Severe/ Unlikely	Yes/ Yes	None/not applicable	02DEC2011 (809)
10MAR2012 (908)	インフルエンザ (INFLUENZAL INFECTION)	Moderate/ Unlikely	Yes/ No	None/not applicable	25APR2012 (954)
13JUN2013 (1368)	頚部痛 (NECK PAIN)	Mild/ Not related	No/ NA	None/not applicable	04JUL2013 (1389)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian □ Date of birth: 23SEP[redacted] □ Date of UC diagnosis: --JAN1999
□ Age (yrs): 3[redacted] □ Height (cm): 163 □ UC disease duration (years): 10.5
□ Sex: Female □ Weight (kg): 53.3 □ Relevant medical history at baseline: 喫煙（過去/現在）

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 400mg -> 200mg SC

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/placebo in maintenance

□ Dose adjusted?: Yes

□ Adjusted treatment group: Golimumab 100 mg

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	11OCT2010	392	1	Placebo	0 mg
Week 56 - EXT	11OCT2010	392	1	Golimumab	100 mg
Week 60 - EXT	11NOV2010	423	2	Golimumab	100 mg
Week 60 - EXT	11NOV2010	423	2	Placebo	0 mg
Week 64 - EXT	13DEC2010	455	3	Golimumab	100 mg
Week 64 - EXT	13DEC2010	455	3	Placebo	0 mg
Week 68 - EXT	10JAN2011	483	4	Golimumab	100 mg
Week 68 - EXT	10JAN2011	483	4	Placebo	0 mg
Week 72 - EXT	07FEB2011	511	5	Golimumab	100 mg
Week 72 - EXT	07FEB2011	511	5	Placebo	0 mg
Week 76 - EXT	03MAR2011	535	6	Golimumab	100 mg
Week 76 - EXT	03MAR2011	535	6	Placebo	0 mg
Week 80 - EXT	04APR2011	567	7	Placebo	0 mg
Week 80 - EXT	04APR2011	567	7	Golimumab	100 mg
Week 84 - EXT	28APR2011	591	8	Placebo	0 mg
Week 84 - EXT	28APR2011	591	8	Golimumab	100 mg
Week 88 - EXT	30MAY2011	623	9	Placebo	0 mg
Week 88 - EXT	30MAY2011	623	9	Golimumab	100 mg
Week 92 - EXT	30JUN2011	654	10	Placebo	0 mg
Week 92 - EXT	30JUN2011	654	10	Golimumab	100 mg
Week 96 - EXT	21JUL2011	675	11	Golimumab	100 mg
Week 96 - EXT	21JUL2011	675	11	Placebo	0 mg
Week 100 - EXT	18AUG2011	703	12	Placebo	0 mg
Week 100 - EXT	18AUG2011	703	12	Golimumab	100 mg
Week 104 - EXT	14SEP2011	730	13	Placebo	0 mg
Week 104 - EXT	14SEP2011	730	13	Golimumab	100 mg
Week 108 - EXT	19OCT2011	765	14	Golimumab	100 mg
Week 108 - EXT	19OCT2011	765	14	Placebo	0 mg
Week 112 - EXT	23NOV2011	800	15	Golimumab	100 mg
Week 112 - EXT	23NOV2011	800	15	Placebo	0 mg
Week 116 - EXT	19DEC2011	826	16	Golimumab	100 mg
Week 116 - EXT	19DEC2011	826	16	Placebo	0 mg
Week 120 - EXT	16JAN2012	854	17	Golimumab	100 mg
Week 124 - EXT	14FEB2012	883	18	Golimumab	100 mg
Week 128 - EXT	19MAR2012	917	19	Golimumab	100 mg
Week 132 - EXT	12APR2012	941	20	Golimumab	100 mg
Week 136 - EXT	02MAY2012	961	21	Golimumab	100 mg
Week 140 - EXT	30MAY2012	989	22	Golimumab	100 mg
Week 144 - EXT	20JUN2012	1010	23	Golimumab	100 mg
Week 148 - EXT	19JUL2012	1039	24	Golimumab	100 mg
Week 152 - EXT	20AUG2012	1071	25	Golimumab	100 mg
Week 156 - EXT	24SEP2012	1106	26	Golimumab	100 mg
Week 160 - EXT	24OCT2012	1136	27	Golimumab	100 mg
Week 164 - EXT	14NOV2012	1157	28	Golimumab	100 mg
Week 168 - EXT	12DEC2012	1185	29	Golimumab	100 mg
Week 172 - EXT	09JAN2013	1213	30	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 176 - EXT	05FEB2013	1240	31	Golimumab	100 mg
Week 180 - EXT	11MAR2013	1274	32	Golimumab	100 mg
Week 184 - EXT	08APR2013	1302	33	Golimumab	100 mg
Week 188 - EXT	06MAY2013	1330	34	Golimumab	100 mg
Week 192 - EXT	03JUN2013	1358	35	Golimumab	100 mg
Week 196 - EXT	28JUN2013	1383	36	Golimumab	100 mg
Week 200 - EXT	22JUL2013	1407	37	Golimumab	100 mg
Week 204 - EXT	26AUG2013	1442	38	Golimumab	100 mg
Week 208 - EXT	23SEP2013	1470	39	Golimumab	100 mg
Week 212 - EXT	15OCT2013	1492	40	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
SACCHAROMYCES BOULARDII,Oral	07FEB2011	17FEB2011
VALACICLOVIR,Oral	20JUN2011	05JUL2011
MESALAZINE,Rectal	14SEP2011	20SEP2011
MESALAZINE,Rectal	14SEP2011	27SEP2011
PARACETAMOL,Oral	30NOV2011	30NOV2011
PANTOPRAZOLE,Oral	02DEC2011	07DEC2011
CIPROFLOXACIN,Intravenous	02DEC2011	06DEC2011
METRONIDAZOLE,Intravenous	02DEC2011	06DEC2011
SUCRALFATE,Oral	02DEC2011	07DEC2011
CIPROFLOXACIN,Oral	06DEC2011	12DEC2011
METRONIDAZOLE,Oral	06DEC2011	12DEC2011
THYMUS VULGARIS,Oral	14MAR2012	05APR2012
AMBROXOL,Oral	14MAR2012	05APR2012
HYOSCINE,Oral	15MAR2012	15MAR2012
BOTULINUM TOXIN TYPE A,Intramuscular	21MAR2013	21MAR2013
BOTULINUM TOXIN TYPE A,Intramuscular	13JUN2013	13JUN2013
NEUROBION FORTE /06411001/,Oral	22JUL2013	--NOV2013
GOLIMUMAB,Subcutaneous	11NOV2013	Ongoing

被験者識別コード：7207-00005

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
22JUN2010 (743)	嘔吐 (VOMITING)	Yes	Mild/ Not related	No/ NA	None/not applicable	24JUN2010 (745)
10JAN2011 (945)	潰瘍性大腸炎 (WORSENING OF ULCERATIVE COLITIS)	Yes	Moderate/ Not related	No/ NA	Permanent discontinuation of study agent	15JAN2011 (950)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
08JAN2010 (578)	発熱 (FEVER)	Mild/ Possible	No/ NA	None/not applicable	10JAN2010 (580)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 3[redacted]
□ Sex: Female
□ Date of birth: 01FEB[redacted]
□ Height (cm): 163
□ Weight (kg): 76.8
□ Date of UC diagnosis: --APR2006
□ UC disease duration (years): 2.0
□ Relevant medical history at baseline: 関節痛

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 400mg -> 200mg SC

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/placebo in maintenance

□ Dose adjusted?: Yes

□ Adjusted treatment group: Golimumab 100 mg

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	08JUL2009	394	1	Golimumab	100 mg
Week 56 - EXT	08JUL2009	394	1	Placebo	0 mg
Week 56 - EXT	08JUL2009	394	1	Placebo	0 mg
Week 60 - EXT	06AUG2009	423	2	Golimumab	100 mg
Week 60 - EXT	06AUG2009	423	2	Placebo	0 mg
Week 60 - EXT	06AUG2009	423	2	Placebo	0 mg
Week 64 - EXT	01SEP2009	449	3	Placebo	0 mg
Week 64 - EXT	01SEP2009	449	3	Placebo	0 mg
Week 64 - EXT	01SEP2009	449	3	Golimumab	100 mg
Week 68 - EXT	29SEP2009	477	4	Placebo	0 mg
Week 68 - EXT	29SEP2009	477	4	Placebo	0 mg
Week 68 - EXT	29SEP2009	477	4	Golimumab	100 mg
Week 72 - EXT	21OCT2009	499	5	Placebo	0 mg
Week 72 - EXT	21OCT2009	499	5	Placebo	0 mg
Week 72 - EXT	21OCT2009	499	5	Golimumab	100 mg
Week 76 - EXT	18NOV2009	527	6	Golimumab	100 mg
Week 76 - EXT	18NOV2009	527	6	Placebo	0 mg
Week 76 - EXT	18NOV2009	527	6	Placebo	0 mg
Week 80 - EXT	16DEC2009	555	7	Golimumab	100 mg
Week 80 - EXT	16DEC2009	555	7	Placebo	0 mg
Week 80 - EXT	16DEC2009	555	7	Placebo	0 mg
Week 84 - EXT	11JAN2010	581	8	Placebo	0 mg
Week 84 - EXT	11JAN2010	581	8	Golimumab	100 mg
Week 84 - EXT	11JAN2010	581	8	Placebo	0 mg
Week 88 - EXT	11FEB2010	612	9	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 88 - EXT	11FEB2010	612	9	Placebo	0 mg
Week 88 - EXT	11FEB2010	612	9	Golimumab	100 mg
Week 92 - EXT	15MAR2010	644	10	Placebo	0 mg
Week 92 - EXT	15MAR2010	644	10	Golimumab	100 mg
Week 96 - EXT	12APR2010	672	11	Placebo	0 mg
Week 96 - EXT	12APR2010	672	11	Golimumab	100 mg
Week 100 - EXT	17MAY2010	707	12	Placebo	0 mg
Week 100 - EXT	17MAY2010	707	12	Golimumab	100 mg
Week 104 - EXT	10JUN2010	731	13	Placebo	0 mg
Week 104 - EXT	10JUN2010	731	13	Golimumab	100 mg
Week 108 - EXT	13JUL2010	764	14	Placebo	0 mg
Week 108 - EXT	13JUL2010	764	14	Golimumab	100 mg
Week 112 - EXT	05AUG2010	787	15	Golimumab	100 mg
Week 112 - EXT	05AUG2010	787	15	Placebo	0 mg
Week 116 - EXT	02SEP2010	815	16	Golimumab	100 mg
Week 116 - EXT	02SEP2010	815	16	Placebo	0 mg
Week 120 - EXT	07OCT2010	850	17	Placebo	0 mg
Week 120 - EXT	07OCT2010	850	17	Golimumab	100 mg
Week 124 - EXT	01NOV2010	875	18	Golimumab	100 mg
Week 124 - EXT	01NOV2010	875	18	Placebo	0 mg
Week 128 - EXT	06DEC2010	910	19	Golimumab	100 mg
Week 128 - EXT	06DEC2010	910	19	Placebo	0 mg

■ **Treatment and Study Status**

□ Date of study discontinuation: 10JAN2011

□ Reason for noncompletion: Other

□ Other reason for noncompletion/details: Adverse event

□ Date of disposition status: 10jan2011

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
LEKOVIT CA,Oral	10JAN2011	Ongoing
PANTOPRAZOLE,Oral	10JAN2011	Ongoing
PREDNISOLONE,Oral	10JAN2011	Ongoing
IRON,Oral	10JAN2011	Ongoing

被験者識別コード：7502-00003

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
10FEB2012 (705)	潰瘍性大腸炎 (UC FLARE)	Yes	Moderate/ Unlikely	No/ NA	Permanent discontinuation of study agent	27FEB2012 (722)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
15NOV2011 (618)	注射部位紅斑 (LOCAL SKIN ERYTHEMA IN IP INJECTION SITE)	Mild/ Probable	No/ NA	None/not applicable	18NOV2011 (621)
13DEC2011 (646)	下気道感染 (LOWER AIRWAYS INFECTION)	Mild/ Possible	Yes/ Yes	None/not applicable	18DEC2011 (651)
13DEC2011 (646)	上気道感染 (UPPER AIRWAYS INFECTION)	Mild/ Possible	Yes/ Yes	None/not applicable	18DEC2011 (651)
15DEC2011 (648)	注射部位紅斑 (LOCAL SKIN ERYTHEMA IN PI INJECTION SITE)	Mild/ Probable	No/ NA	None/not applicable	17DEC2011 (650)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 3[redacted]
□ Sex: Female
□ Date of birth: 14APR[redacted]
□ Height (cm): 160
□ Weight (kg): 40.5
□ Date of UC diagnosis: 01MAY2002
□ UC disease duration (years): 7.7
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 400mg -> 200mg SC

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/placebo in maintenance

□ Dose adjusted?: Yes

□ Adjusted treatment group: Golimumab 100 mg

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	18APR2011	407	1	Placebo	0 mg
Week 56 - EXT	18APR2011	407	1	Golimumab	100 mg
Week 60 - EXT	16MAY2011	435	2	Golimumab	100 mg
Week 60 - EXT	16MAY2011	435	2	Placebo	0 mg
Week 64 - EXT	06JUN2011	456	3	Placebo	0 mg
Week 64 - EXT	06JUN2011	456	3	Golimumab	100 mg
Week 68 - EXT	07JUL2011	487	4	Placebo	0 mg
Week 68 - EXT	07JUL2011	487	4	Golimumab	100 mg
Week 72 - EXT	26JUL2011	506	5	Golimumab	100 mg
Week 72 - EXT	26JUL2011	506	5	Placebo	0 mg
Week 76 - EXT	22AUG2011	533	6	Placebo	0 mg
Week 76 - EXT	22AUG2011	533	6	Golimumab	100 mg
Week 80 - EXT	19SEP2011	561	7	Golimumab	100 mg
Week 80 - EXT	19SEP2011	561	7	Placebo	0 mg
Week 84 - EXT	18OCT2011	590	8	Placebo	0 mg
Week 84 - EXT	18OCT2011	590	8	Golimumab	100 mg
Week 88 - EXT	15NOV2011	618	9	Placebo	0 mg
Week 88 - EXT	15NOV2011	618	9	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 92 - EXT	15DEC2011	648	10	Placebo	0 mg
Week 92 - EXT	15DEC2011	648	10	Golimumab	100 mg
Week 96 - EXT	09JAN2012	673	11	Golimumab	100 mg

■ **Treatment and Study Status**

□ Date of study discontinuation: 10FEB2012

□ Reason for noncompletion: Other

□ Other reason for noncompletion/details: SAE resulting in hospitalization

□ Date of disposition status: 10Feb2012

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
AZITHROMYCIN,Oral	16DEC2011	18DEC2011
ERDOSTEINE,Oral	16DEC2011	22DEC2011
PREDNISONE,Oral	02FEB2012	Ongoing
METRONIDAZOLE,Oral	03FEB2012	Ongoing
HYLAK FORTE,Oral	10FEB2012	Ongoing
AZATHIOPRINE,Oral	15FEB2012	Ongoing
OMEPRAZOLE,Oral	15FEB2012	Ongoing
MESALAZINE,Oral	15FEB2012	Ongoing
CARBOHYDRATES NOS W/FATS NOS/MINERA/07459701/,Oral	15FEB2012	Ongoing
CALTRATE PLUS /01438001/,Oral	15FEB2012	Ongoing
CIPROFLOXACIN,Oral	23FEB2012	27FEB2012

b) 50 mg 群

被験者識別コード：6478-00003

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
16MAR2012 (1299)	脱髄 (DEMYELINATION)	No	Moderate/ Possible	No/ NA	Permanent discontinuation of study agent	Ongoing -
16MAR2012 (1299)	多発性硬化症 (CLINICALY ISOLATED SYNDROMA POSSIBLE FIRST MANIFESTATION OF MULTIPLE SCLEROSIS)	Yes	Moderate/ Possible	No/ NA	Permanent discontinuation of study agent	23MAR2012 (1306)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
17OCT2009 (418)	ウイルス性気道感染 (RESPIRATORY VIROSIS)	Moderate/ Unlikely	Yes/ Yes	None/not applicable	26OCT2009 (427)
19OCT2009 (420)	発疹 (SKIN RUSH)	Mild/ Unlikely	No/ NA	None/not applicable	09NOV2009 (441)
05FEB2010 (529)	ウイルス性気道感染 (RESPIRATORY VIROSIS)	Mild/ Not related	Yes/ No	None/not applicable	10FEB2010 (534)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 3[redacted]
□ Sex: Female
□ Date of birth: 19JAN[redacted]
□ Height (cm): 170
□ Weight (kg): 46.0
□ Date of UC diagnosis: 16JUL2007
□ UC disease duration (years): 1.0
□ Relevant medical history at baseline: 回腸炎，アフタ性口内炎，関節痛

■ **Treatment Groups**

□ Induction study: C0524T16

□ Treatment group in induction: 4 mg/kg IV

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/golimumab 50 mg in maintenance

□ Dose adjusted?: Yes

□ Adjusted treatment group: Golimumab 50 mg

□ Treatment group during start of LTE: Golimumab 50 mg

□ Dose adjusted during LTE: Yes

□ Adjusted treatment group during LTE: Golimumab 100 mg

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	23SEP2009	394	1	Golimumab	50 mg
Week 56 - EXT	23SEP2009	394	1	Placebo	0 mg
Week 56 - EXT	23SEP2009	394	1	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 60 - EXT	29OCT2009	430	2	Golimumab	50 mg
Week 60 - EXT	29OCT2009	430	2	Placebo	0 mg
Week 60 - EXT	29OCT2009	430	2	Placebo	0 mg
Week 64 - EXT	19NOV2009	451	3	Golimumab	50 mg
Week 64 - EXT	19NOV2009	451	3	Placebo	0 mg
Week 64 - EXT	19NOV2009	451	3	Placebo	0 mg
Week 68 - EXT	15DEC2009	477	4	Golimumab	50 mg
Week 68 - EXT	15DEC2009	477	4	Placebo	0 mg
Week 68 - EXT	15DEC2009	477	4	Placebo	0 mg
Week 72 - EXT	12JAN2010	505	5	Golimumab	50 mg
Week 72 - EXT	12JAN2010	505	5	Placebo	0 mg
Week 72 - EXT	12JAN2010	505	5	Placebo	0 mg
Week 76 - EXT	11FEB2010	535	6	Golimumab	50 mg
Week 76 - EXT	11FEB2010	535	6	Placebo	0 mg
Week 76 - EXT	11FEB2010	535	6	Placebo	0 mg
Week 80 - EXT	11MAR2010	563	7	Golimumab	50 mg
Week 80 - EXT	11MAR2010	563	7	Placebo	0 mg
Week 84 - EXT	08APR2010	591	8	Golimumab	50 mg
Week 84 - EXT	08APR2010	591	8	Placebo	0 mg
Week 88 - EXT	06MAY2010	619	9	Golimumab	50 mg
Week 88 - EXT	06MAY2010	619	9	Placebo	0 mg
Week 92 - EXT	31MAY2010	644	10	Golimumab	50 mg
Week 92 - EXT	31MAY2010	644	10	Placebo	0 mg
Week 96 - EXT	08JUL2010	682	11	Golimumab	50 mg
Week 96 - EXT	08JUL2010	682	11	Placebo	0 mg
Week 100 - EXT	02AUG2010	707	12	Golimumab	50 mg
Week 100 - EXT	02AUG2010	707	12	Placebo	0 mg
Week 104 - EXT	24AUG2010	729	13	Placebo	0 mg
Week 104 - EXT	24AUG2010	729	13	Golimumab	50 mg
Week 108 - EXT	22SEP2010	758	14	Placebo	0 mg
Week 108 - EXT	22SEP2010	758	14	Golimumab	50 mg
Week 112 - EXT	28OCT2010	794	15	Placebo	0 mg
Week 112 - EXT	28OCT2010	794	15	Golimumab	50 mg
Week 116 - EXT	18NOV2010	815	16	Placebo	0 mg
Week 116 - EXT	18NOV2010	815	16	Golimumab	50 mg
Week 120 - EXT	20DEC2010	847	17	Placebo	0 mg
Week 120 - EXT	20DEC2010	847	17	Golimumab	50 mg
Week 124 - EXT	17JAN2011	875	18	Golimumab	50 mg
Week 124 - EXT	17JAN2011	875	18	Placebo	0 mg
Week 128 - EXT	07FEB2011	896	19	Golimumab	50 mg
Week 128 - EXT	07FEB2011	896	19	Placebo	0 mg
Week 132 - EXT	10MAR2011	927	20	Placebo	0 mg
Week 132 - EXT	10MAR2011	927	20	Golimumab	50 mg
Week 136 - EXT	04APR2011	952	21	Placebo	0 mg
Week 136 - EXT	04APR2011	952	21	Golimumab	50 mg
Week 140 - EXT	09MAY2011	987	22	Placebo	0 mg
Week 140 - EXT	09MAY2011	987	22	Golimumab	50 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 144 - EXT	30MAY2011	1008	23	Placebo	0 mg
Week 144 - EXT	30MAY2011	1008	23	Golimumab	50 mg
Week 148 - EXT	27JUN2011	1036	24	Placebo	0 mg
Week 148 - EXT	27JUN2011	1036	24	Golimumab	50 mg
Week 152 - EXT	05AUG2011	1075	25	Placebo	0 mg
Week 152 - EXT	05AUG2011	1075	25	Golimumab	50 mg
Week 156 - EXT	05SEP2011	1106	26	Placebo	0 mg
Week 156 - EXT	05SEP2011	1106	26	Golimumab	50 mg
Week 160 - EXT	30SEP2011	1131	27	Placebo	0 mg
Week 160 - EXT	30SEP2011	1131	27	Golimumab	50 mg
Week 164 - EXT	28OCT2011	1159	28	Placebo	0 mg
Week 164 - EXT	28OCT2011	1159	28	Golimumab	50 mg
Week 168 - EXT	22NOV2011	1184	1	Golimumab	100 mg
Week 168 - EXT	22NOV2011	1184	1	Placebo	0 mg
Week 172 - EXT	21DEC2011	1213	2	Golimumab	100 mg
Week 176 - EXT	13JAN2012	1236	3	Golimumab	100 mg
Week 180 - EXT	10FEB2012	1264	4	Golimumab	100 mg
Week 184 - EXT	09MAR2012	1292	5	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
CIPROFLOXACIN,Oral	19OCT2009	26OCT2009
METHYLPREDNISOLONE,Intravenous	18MAR2012	22MAR2012
MESALAZINE,Oral	23MAR2012	15JUN2012
PANTOPRAZOLE,Oral	23MAR2012	30MAR2012
ALFACALCIDOL,Oral	15JUN2012	Ongoing
PREDNISONE,Oral	15JUN2012	Ongoing
MESALAZINE,Topical	15JUN2012	Ongoing
PANTOPRAZOLE,Oral	15JUN2012	Ongoing

被験者識別コード：6716-00008

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: Malignancy

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
25JUL2010 (614)	腎結石症 (LEFT RENAL PELVIC STONES)	Yes	Severe/ Unlikely	No/ NA	None/not applicable	17NOV2010 (729)
25JUL2010 (614)	尿路感染 (URINARY TRACT INFECTION)	Yes	Moderate/ Unlikely	Yes/ Yes	None/not applicable	05AUG2010 (625)

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
22NOV2010 (734)	変形性関節症 (WORSENING OSTEOARTHRITIS, LEFT KNEE)	Yes	Severe/ Unlikely	No/ NA	None/not applicable	24NOV2010 (736)
19JUL2012 (1339)	前立腺癌 (PROSTATE CANCER)	Yes	Severe/ Unlikely	No/ NA	Permanent discontinuation of study agent	Ongoing -

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
--JUL2011 -	毛包炎 (FOLICULTIS, FACE)	Moderate/ Possible	Yes/ No	None/not applicable	20DEC2011 (1127)
15FEB2010 (454)	副鼻腔炎 (SINUSITIS (SINUS INFECTIONS)	Moderate/ Unlikely	Yes/ Yes	None/not applicable	25FEB2010 (464)
07APR2010 (505)	季節性アレルギー (ENVIROMENTAL SEASONAL ALLERGIES)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
30APR2010 (528)	血便排泄 (HEMATOCHEZIA)	Moderate/ Unlikely	No/ NA	None/not applicable	30APR2010 (528)
21MAY2010 (549)	排便回数増加 (INCREASE FREQUENCY OF BOWEL MOVEMENTS)	Moderate/ Unlikely	No/ NA	None/not applicable	09JUN2010 (568)
01JUL2010 (590)	末梢性浮腫 (BILATERAL LOWER LEG EDEMA)	Mild/ Unlikely	No/ NA	None/not applicable	14FEB2011 (818)
01JUL2010 (590)	口腔咽頭痛 (SORE THROAT)	Mild/ Unlikely	No/ NA	None/not applicable	01JUL2010 (590)
01JUL2010 (590)	発熱 (FEVER)	Mild/ Unlikely	Yes/ No	None/not applicable	01JUL2010 (590)
25JUL2010 (614)	血中クレアチニン増加 (ABNORMALLY ELEVATED CREATANINE LEVEL)	Mild/ Unlikely	No/ NA	None/not applicable	06AUG2010 (626)
25JUL2010 (614)	後天性肝内胆管拡張症 (INTRAHEPATIC BILE DUCT DILATATION)	Mild/ Unlikely	No/ NA	None/not applicable	Ongoing -
25JUL2010 (614)	肝障害 (DIFFUSELY ABNORMAL LIVER)	Mild/ Unlikely	No/ NA	None/not applicable	Ongoing -
25JUL2010 (614)	脾腫 (SPENOMEGALY)	Mild/ Unlikely	No/ NA	None/not applicable	19MAY2011 (912)
05NOV2010 (717)	皮膚刺激 (SKIN IRRITATION, FACE)	Moderate/ Unlikely	No/ NA	None/not applicable	20NOV2010 (732)
22NOV2010 (734)	便秘 (CONSTIPATION)	Mild/ Unlikely	No/ NA	None/not applicable	23NOV2010 (735)
20DEC2010 (762)	皮膚乾燥 (DRY HANDS, PALMS OF HAND, BILATERAL)	Mild/ Possible	No/ NA	None/not applicable	14FEB2011 (818)
02MAR2011 (834)	血便排泄 (HEMATOCHEZIA)	Mild/ Not related	No/ NA	None/not applicable	04MAR2011 (836)

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
02MAR2011 (834)	大腸ポリープ (COLON POLYP)	Mild/ Not related	No/ NA	None/not applicable	02MAR2011 (834)
11APR2011 (874)	排便回数増加 (INCREASE FREQUENCY OF BOWEL MOVEMENTS)	Moderate/ Unlikely	No/ NA	None/not applicable	02JUN2011 (926)
11APR2011 (874)	ウイルス性胃腸炎 (VIRAL GASTROENTERITIS)	Moderate/ Unlikely	Yes/ No	None/not applicable	02JUN2011 (926)
11APR2011 (874)	血便排泄 (HEMATOCHEZIA)	Mild/ Unlikely	No/ NA	None/not applicable	02JUN2011 (926)
11APR2011 (874)	肛門周囲痛 (RECTAL PAIN)	Moderate/ Unlikely	No/ NA	None/not applicable	19MAY2011 (912)
28APR2011 (891)	上腹部痛 (UPPER ABDOMINAL PAIN)	Moderate/ Unlikely	No/ NA	None/not applicable	28JUN2011 (952)
28APR2011 (891)	発声障害 (HOARSENESS)	Mild/ Unlikely	No/ NA	None/not applicable	28JUN2011 (952)
28APR2011 (891)	嚥下痛 (PAINFUL SWALLOWING)	Moderate/ Unlikely	No/ NA	None/not applicable	02JUN2011 (926)
04MAY2011 (897)	下腹部痛 (LOWER ABDOMINAL PAIN)	Moderate/ Unlikely	No/ NA	None/not applicable	02JUN2011 (926)
04MAY2011 (897)	腹痛 (ABDOMINAL CRAMPING)	Mild/ Unlikely	No/ NA	None/not applicable	02JUN2011 (926)
19MAY2011 (912)	腹部ヘルニア (RIGHT ABDOMINAL WALL HERNIA)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
19MAY2011 (912)	血中クレアチニン増加 (ELEVATED CREATANINE LEVEL)	Moderate/ Unlikely	No/ NA	Temporary interruption/dose modification	01JUN2011 (925)
19MAY2011 (912)	血中尿素増加 (ELEVATED BUN)	Moderate/ Unlikely	No/ NA	Temporary interruption/dose modification	01JUN2011 (925)
19MAY2011 (912)	脱水 (DEHYDRATION)	Moderate/ Unlikely	No/ NA	None/not applicable	02JUN2011 (926)
19MAY2011 (912)	低血圧 (HYPOTENSION)	Moderate/ Unlikely	No/ NA	None/not applicable	02JUN2011 (926)
19MAY2011 (912)	鼠径ヘルニア (LEFT INGUINAL HERNIA)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
19MAY2011 (912)	リンパ節症 (SMALL LYMPH NODES MESENTERIC FAT ADJACENT TO ASCENDING COLON)	Mild/ Unlikely	No/ NA	None/not applicable	Ongoing -
19MAY2011 (912)	腎結石症 (SCATTERED CALCIFIED DENSITIES LEFT KIDNEY)	Mild/ Unlikely	No/ NA	None/not applicable	Ongoing -
19MAY2011 (912)	肺腫瘤 (5 MM RIGHT MIDDLE LOBE PULMONARY NODULE)	Mild/ Unlikely	No/ NA	None/not applicable	Ongoing -
19MAY2011 (912)	体重減少 (WEIGHT LOSS)	Moderate/ Unlikely	No/ NA	None/not applicable	02JUN2011 (926)

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
20MAY2011 (913)	十二指腸潰瘍 (DUODENAL ULCERATIONS)	Moderate/ Unlikely	No/ NA	Temporary interruption/dose modification	18OCT2011 (1064)
02JUN2011 (926)	鉄欠乏性貧血 (IRON DEFICIENCY ANEMIA)	Moderate/ Unlikely	No/ NA	None/not applicable	Ongoing -
24JUN2011 (948)	単純ヘルペス (HERPES SIMPLEX, FACE AND LIPS)	Moderate/ Unlikely	Yes/ Yes	None/not applicable	09AUG2011 (994)
14JUL2011 (968)	下痢 (INCREASE IN LOOSENESS OF STOOLS)	Moderate/ Unlikely	No/ NA	None/not applicable	18OCT2011 (1064)
03SEP2011 (1019)	骨挫傷 (LEFT RIB CONTUSION)	Moderate/ Not related	No/ NA	None/not applicable	18OCT2011 (1064)
24OCT2011 (1070)	咽頭炎 (THROAT INFECTION)	Moderate/ Unlikely	Yes/ Yes	None/not applicable	03NOV2011 (1080)
06JAN2012 (1144)	関節痛 (BILATERAL SHOULDER ARTHRITIC PAIN)	Moderate/ Not related	No/ NA	None/not applicable	07JAN2012 (1145)
08JAN2012 (1146)	上腹部痛 (UPPER ABDOMINAL PAIN)	Moderate/ Not related	No/ NA	None/not applicable	13JAN2012 (1151)
10APR2012 (1239)	関節痛 (ARTHRITIS PAIN, LEFT HIP)	Moderate/ Not related	No/ NA	None/not applicable	Ongoing -
10APR2012 (1239)	ヘマトクリット減少 (LOW HEMATOCRIT)	Mild/ Not related	No/ NA	None/not applicable	16APR2012 (1245)
16APR2012 (1245)	滑液包炎 (LEFT GREATER TROCHANTERIC BURSITIS)	Moderate/ Not related	No/ NA	None/not applicable	Ongoing -
20APR2012 (1249)	鼠径部膿瘍 (GROIN ABSCESS)	Moderate/ Unlikely	Yes/ Yes	None/not applicable	06JUN2012 (1296)
09JUN2012 (1299)	鼻出血 (EPISTAXIS)	Moderate/ Not related	No/ NA	None/not applicable	09JUN2012 (1299)
26JUN2012 (1316)	腎結石症 (KIDNEY STONES)	Mild/ Not related	No/ NA	None/not applicable	19JUL2012 (1339)
30JUL2012 (1350)	腱付着部症 (ANKLE AND TARSUS ENTHESOPATHY)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
29AUG2012 (1380)	リンパ節症 (ENLARGED RETROCURUAL LYMPH NODE,)	Moderate/ Unlikely	No/ NA	None/not applicable	Ongoing -
09OCT2012 (1421)	毛包炎 (FOLLICULTIS)	Mild/ Not related	Yes/ No	None/not applicable	Ongoing -

■ Demographics and Baseline Characteristics

□ Race: Caucasian
□ Age (yrs): 6[redacted]
□ Sex: Male
□ Date of birth: 01NOV[redacted]
□ Height (cm): 183
□ Weight (kg): 127.0
□ Date of UC diagnosis: 13SEP1999
□ UC disease duration (years): 9.1
□ Relevant medical history at baseline: 関節炎，硬化性胆管炎

■ Treatment Groups

□ Induction study: C0524T16

□ Treatment group in induction: 4 mg/kg IV

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/golimumab 50 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 50 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	18DEC2009	395	1	Placebo	0 mg
Week 56 - EXT	18DEC2009	395	1	Golimumab	50 mg
Week 56 - EXT	18DEC2009	395	1	Placebo	0 mg
Week 60 - EXT	13JAN2010	421	2	Placebo	0 mg
Week 60 - EXT	13JAN2010	421	2	Placebo	0 mg
Week 60 - EXT	13JAN2010	421	2	Golimumab	50 mg
Week 64 - EXT	12FEB2010	451	3	Placebo	0 mg
Week 64 - EXT	12FEB2010	451	3	Placebo	0 mg
Week 64 - EXT	12FEB2010	451	3	Golimumab	50 mg
Week 68 - EXT	08MAR2010	475	4	Placebo	0 mg
Week 68 - EXT	08MAR2010	475	4	Golimumab	50 mg
Week 72 - EXT	07APR2010	505	5	Placebo	0 mg
Week 72 - EXT	07APR2010	505	5	Golimumab	50 mg
Week 76 - EXT	05MAY2010	533	6	Placebo	0 mg
Week 76 - EXT	05MAY2010	533	6	Golimumab	50 mg
Week 80 - EXT	04JUN2010	563	7	Placebo	0 mg
Week 80 - EXT	04JUN2010	563	7	Golimumab	50 mg
Week 84 - EXT	30JUN2010	589	8	Golimumab	50 mg
Week 84 - EXT	30JUN2010	589	8	Placebo	0 mg
Week 88 - EXT	11AUG2010	631	9	Placebo	0 mg
Week 88 - EXT	11AUG2010	631	9	Golimumab	50 mg
Week 92 - EXT	13SEP2010	664	10	Placebo	0 mg
Week 92 - EXT	13SEP2010	664	10	Golimumab	50 mg
Week 96 - EXT	29SEP2010	680	11	Golimumab	50 mg
Week 96 - EXT	29SEP2010	680	11	Placebo	0 mg
Week 100 - EXT	20OCT2010	701	12	Placebo	0 mg
Week 100 - EXT	20OCT2010	701	12	Golimumab	50 mg
Week 104 - EXT	15NOV2010	727	13	Placebo	0 mg
Week 104 - EXT	15NOV2010	727	13	Golimumab	50 mg
Week 108 - EXT	20DEC2010	762	14	Golimumab	50 mg
Week 108 - EXT	20DEC2010	762	14	Placebo	0 mg
Week 112 - EXT	18JAN2011	791	15	Placebo	0 mg
Week 112 - EXT	18JAN2011	791	15	Golimumab	50 mg
Week 116 - EXT	14FEB2011	818	16	Placebo	0 mg
Week 116 - EXT	14FEB2011	818	16	Golimumab	50 mg
Week 120 - EXT	15MAR2011	847	17	Golimumab	50 mg
Week 120 - EXT	15MAR2011	847	17	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 124 - EXT	15APR2011	878	18	Placebo	0 mg
Week 124 - EXT	15APR2011	878	18	Golimumab	50 mg
Week 132 - EXT	02JUN2011	926	19	Golimumab	50 mg
Week 132 - EXT	02JUN2011	926	19	Placebo	0 mg
Week 136 - EXT	28JUN2011	952	20	Golimumab	50 mg
Week 136 - EXT	28JUN2011	952	20	Placebo	0 mg
Week 140 - EXT	09AUG2011	994	21	Golimumab	50 mg
Week 140 - EXT	09AUG2011	994	21	Placebo	0 mg
Week 144 - EXT	29AUG2011	1014	22	Golimumab	50 mg
Week 144 - EXT	29AUG2011	1014	22	Placebo	0 mg
Week 148 - EXT	22SEP2011	1038	23	Placebo	0 mg
Week 148 - EXT	22SEP2011	1038	23	Golimumab	50 mg
Week 152 - EXT	18OCT2011	1064	24	Placebo	0 mg
Week 152 - EXT	18OCT2011	1064	24	Golimumab	50 mg
Week 156 - EXT	21NOV2011	1098	25	Golimumab	50 mg
Week 156 - EXT	21NOV2011	1098	25	Placebo	0 mg
Week 160 - EXT	20DEC2011	1127	26	Golimumab	50 mg
Week 164 - EXT	24JAN2012	1162	27	Golimumab	50 mg
Week 168 - EXT	13FEB2012	1182	28	Golimumab	50 mg
Week 172 - EXT	21MAR2012	1219	29	Golimumab	50 mg
Week 176 - EXT	10APR2012	1239	30	Golimumab	50 mg
Week 180 - EXT	08MAY2012	1267	31	Golimumab	50 mg
Week 184 - EXT	11JUN2012	1301	32	Golimumab	50 mg
Week 188 - EXT	10JUL2012	1330	33	Golimumab	50 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
AMOXICILLIN,Oral	15FEB2010	25FEB2010
ERGOCALCIFEROL,Oral	04MAR2010	04MAY2011
MOMETASONE,Intranasal	25MAR2010	Ongoing
DIPHENHYDRAMINE,Oral	07APR2010	Ongoing
LORATADINE,Oral	07APR2010	Ongoing
LOPERAMIDE,Oral	01JUN2010	11AUG2011
ENALAPRIL,Oral	01JUL2010	04MAY2011
HYDROCODONE,Oral	25JUL2010	29JUL2010
SODIUM CHLORIDE,Intravenous	25JUL2010	25JUL2010
MORPHINE,Intravenous	25JUL2010	26JUL2010
PARACETAMOL,Oral	25JUL2010	29JUL2010
LEVOFLOXACIN,Intravenous	25JUL2010	26JUL2010
ONDANSETRON,Intravenous	25JUL2010	25JUL2010
CIPROFLOXACIN,Oral	25JUL2010	10AUG2010
MIDAZOLAM,Intravenous	05AUG2010	05AUG2010
FENTANYL,Intravenous	05AUG2010	05AUG2010
HYDROCODONE,Oral	05AUG2010	08AUG2010
SUXAMETHONIUM,Intravenous	05AUG2010	05AUG2010
PARACETAMOL,Oral	05AUG2010	08AUG2010
RINGER-LACTATE,Intravenous	05AUG2010	05AUG2010
SEVOFLURANE,Inhalation	05AUG2010	05AUG2010

Prior/Concomitant Therapy, Route	Start Date	End Date
ROCURONIUM,Intravenous	05AUG2010	05AUG2010
ONDANSETRON,Intravenous	05AUG2010	05AUG2010
PROPOFOL,Intravenous	05AUG2010	05AUG2010
TRIMETHOPRIM,Oral	03NOV2010	18NOV2010
SULFAMETHOXAZOLE,Oral	03NOV2010	18NOV2010
HYDROCORTISONE-NEOMYCIN-POLYMYXIN B,Topical	05NOV2010	15FEB2011
BUPIVACAINE,Intravenous	22NOV2010	26NOV2010
NALOXONE,Intravenous	22NOV2010	22NOV2010
MAGNESIUM HYDROXIDE,Oral	22NOV2010	22NOV2010
DEXTROSE AND SODIUM CHLORIDE INJECTION,Intravenous	22NOV2010	22NOV2010
CEFAZOLIN,Intravenous	22NOV2010	23NOV2010
HYDROMORPHONE,Intravenous	22NOV2010	26NOV2010
SODIUM CHLORIDE,Intravenous	22NOV2010	22NOV2010
BISACODYL,Rectal	22NOV2010	22NOV2010
SODIUM CHLORIDE,Intravenous	22NOV2010	26NOV2010
HYDROCODONE,Oral	22NOV2010	19MAY2011
OXYCODONE,Oral	22NOV2010	26NOV2010
METOCLOPRAMIDE,Intravenous	22NOV2010	23NOV2010
DIPHENHYDRAMINE,Intravenous	22NOV2010	22NOV2010
DIPHENHYDRAMINE,Oral	22NOV2010	22NOV2010
PROCHLORPERAZINE,Intravenous	22NOV2010	23NOV2010
ACETYLSALICYLIC ACID,Oral	22NOV2010	22NOV2010
WARFARIN,Oral	22NOV2010	06DEC2010
PARACETAMOL,Oral	22NOV2010	19MAY2011
COLOXYL WITH SENNA,Oral	22NOV2010	23NOV2010
ONDANSETRON,Intravenous	22NOV2010	23NOV2010
IRON,Oral	24NOV2010	25NOV2010
IRON,Oral	25NOV2010	04MAY2011
ACETYLSALICYLIC ACID,Oral	10DEC2010	04MAY2011
MIDAZOLAM,Intravenous	02MAR2011	02MAR2011
FENTANYL,Intravenous	02MAR2011	02MAR2011
GLUCOSE,Intravenous	02MAR2011	02MAR2011
SODIUM CHLORIDE,Intravenous	02MAR2011	02MAR2011
IBUPROFEN,Oral	25APR2011	20MAY2011
OMEPRAZOLE,Oral	05MAY2011	12MAY2011
PREDNISONE,Oral	11MAY2011	24JUL2011
CALCIUM CARBONATE,Oral	13MAY2011	20MAY2011
MIDAZOLAM,Intravenous	20MAY2011	20MAY2011
DEXTROSE AND SODIUM CHLORIDE INJECTION,Intravenous	20MAY2011	20MAY2011
FENTANYL,Intravenous	20MAY2011	20MAY2011
BENZOCAINE,Topical	20MAY2011	20MAY2011
OMEPRAZOLE,Oral	20MAY2011	Ongoing
SUCRALFATE,Oral	21MAY2011	18OCT2011
URSODEOXYCHOLIC ACID,Oral	02JUN2011	Ongoing
ERGOCALCIFEROL,Oral	02JUN2011	Ongoing
IRON,Oral	02JUN2011	Ongoing
HYDROGEN PEROXIDE,Topical	01JUL2011	Ongoing

Prior/Concomitant Therapy, Route	Start Date	End Date
VALACICLOVIR,Oral	01JUL2011	06JUL2011
LOPERAMIDE,Oral	01SEP2011	Ongoing
TRAMADOL,Oral	03SEP2011	18OCT2011
INFLUENZA VACCINE,Intramuscular	28SEP2011	28SEP2011
AMOXICILLIN,Oral	24OCT2011	03NOV2011
TRAMADOL,Oral	06JAN2012	07JAN2012
SUCRALFATE,Oral	08JAN2012	13JAN2012
SUCRALFATE,Oral	20JAN2012	Ongoing
MAGNESIUM CITRATE,Oral	20MAR2012	20MAR2012
MACROGOL,Oral	20MAR2012	20MAR2012
MIDAZOLAM,Intravenous	21MAR2012	21MAR2012
FENTANYL,Intravenous	21MAR2012	21MAR2012
TETANUS VACCINE,Intramuscular	04APR2012	04APR2012
BUPIVACAINE,Intramuscular	16APR2012	16APR2012
LIDOCAINE,Intramuscular	16APR2012	16APR2012
TRIAMCINOLONE,Intramuscular	16APR2012	16APR2012
CLARITHROMYCIN,Oral	30APR2012	09MAY2012
CEFALEXIN,Oral	06JUN2012	09JUN2012
BUPIVACAINE,Epidural	06JUN2012	06JUN2012
HYDROCODONE,Oral	06JUN2012	07JUN2012
EPINEPHRINE,Epidural	06JUN2012	06JUN2012
PARACETAMOL,Oral	06JUN2012	07JUN2012
MIDAZOLAM,Intravenous	19JUL2012	19JUL2012
FENTANYL,Intravenous	19JUL2012	19JUL2012
GENTAMICIN,Intravenous	19JUL2012	19JUL2012
HYDROCODONE,Oral	19JUL2012	29JUL2012
LIDOCAINE,Intravenous	19JUL2012	19JUL2012
DEXAMETHASONE,Intravenous	19JUL2012	19JUL2012
PARACETAMOL,Oral	19JUL2012	29JUL2012
EPHEDRINE,Intravenous	19JUL2012	19JUL2012
SEVOFLURANE,Inhalation	19JUL2012	19JUL2012
LEVOFLOXACIN,Oral	19JUL2012	21JUL2012
ONDANSETRON,Intravenous	19JUL2012	19JUL2012
PROPOFOL,Intravenous	19JUL2012	19JUL2012
HYDROCORTISONE,Intravenous	14AUG2012	14AUG2012
DIPHENHYDRAMINE,Oral	14AUG2012	14AUG2012
PARACETAMOL,Oral	14AUG2012	14AUG2012
INFLIXIMAB,Intravenous	14AUG2012	Ongoing
MIDAZOLAM,Intravenous	20SEP2012	20SEP2012
FENTANYL,Intravenous	20SEP2012	20SEP2012
DROPERIDOL,Intravenous	20SEP2012	20SEP2012

被験者識別コード：6726-00024

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: Malignancy

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
12JAN2012 (878)	結腸異形成 (HIGH GRADE DISPLASIA IN THE AREA OF THE SPLENIC FLEXURE)	Yes	Severe/ Possible	No/ NA	Permanent discontinuation of study agent	19FEB2012 (916)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
--MAR2011 -	乳房痛 (LEFT BREAST PAIN)	Mild/ Possible	No/ NA	None/not applicable	Ongoing -
06OCT2010 (415)	ウイルス性胃腸炎 (STOMACH VIRUS)	Moderate/ Unlikely	No/ NA	None/not applicable	11OCT2010 (420)
09OCT2010 (418)	上気道感染 (UPPER RESPIRATORY INFECTION)	Mild/ Possible	Yes/ No	None/not applicable	14OCT2010 (423)
04NOV2010 (444)	肝機能検査異常 (ELEVATED LIVER FUNCTION)	Moderate/ Unlikely	No/ NA	None/not applicable	15DEC2010 (485)
04NOV2010 (444)	頻脈 (TACHACARDIA)	Mild/ Unlikely	No/ NA	None/not applicable	17FEB2011 (549)
18NOV2010 (458)	副鼻腔炎に伴う頭痛 (SINUS PAIN)	Mild/ Not related	No/ NA	None/not applicable	23NOV2010 (463)

■ **Demographics and Baseline Characteristics**

- □ Race: Caucasian
- □ Age (yrs): 4[redacted]
- □ Sex: Male
- □ Date of birth: 13MAY[redacted]
- □ Height (cm): 174
- □ Weight (kg): 101.8
- □ Date of UC diagnosis: 16OCT2002
- □ UC disease duration (years): 6.7
- □ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 200mg -> 100mg SC

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/golimumab 50 mg in maintenance

□ Dose adjusted?: Yes

□ Adjusted treatment group: Golimumab 100 mg

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	13SEP2010	392	1	Golimumab	100 mg
Week 56 - EXT	13SEP2010	392	1	Placebo	0 mg
Week 60 - EXT	12OCT2010	421	2	Placebo	0 mg
Week 60 - EXT	12OCT2010	421	2	Golimumab	100 mg
Week 64 - EXT	04NOV2010	444	3	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 64 - EXT	04NOV2010	444	3	Golimumab	100 mg
Week 68 - EXT	23NOV2010	463	4	Golimumab	100 mg
Week 68 - EXT	23NOV2010	463	4	Placebo	0 mg
Week 72 - EXT	21DEC2010	491	5	Placebo	0 mg
Week 72 - EXT	21DEC2010	491	5	Golimumab	100 mg
Week 76 - EXT	18JAN2011	519	6	Placebo	0 mg
Week 76 - EXT	18JAN2011	519	6	Golimumab	100 mg
Week 80 - EXT	17FEB2011	549	7	Golimumab	100 mg
Week 80 - EXT	17FEB2011	549	7	Placebo	0 mg
Week 84 - EXT	21MAR2011	581	8	Golimumab	100 mg
Week 84 - EXT	21MAR2011	581	8	Placebo	0 mg
Week 88 - EXT	14APR2011	605	9	Placebo	0 mg
Week 88 - EXT	14APR2011	605	9	Golimumab	100 mg
Week 92 - EXT	10MAY2011	631	10	Placebo	0 mg
Week 92 - EXT	10MAY2011	631	10	Golimumab	100 mg
Week 96 - EXT	10JUN2011	662	11	Golimumab	100 mg
Week 96 - EXT	10JUN2011	662	11	Placebo	0 mg
Week 100 - EXT	07JUL2011	689	12	Golimumab	100 mg
Week 100 - EXT	07JUL2011	689	12	Placebo	0 mg
Week 104 - EXT	02AUG2011	715	13	Placebo	0 mg
Week 104 - EXT	02AUG2011	715	13	Golimumab	100 mg
Week 108 - EXT	01SEP2011	745	14	Placebo	0 mg
Week 108 - EXT	01SEP2011	745	14	Golimumab	100 mg
Week 112 - EXT	28SEP2011	772	15	Golimumab	100 mg
Week 112 - EXT	28SEP2011	772	15	Placebo	0 mg
Week 116 - EXT	27OCT2011	801	16	Golimumab	100 mg
Week 116 - EXT	27OCT2011	801	16	Placebo	0 mg
Week 120 - EXT	28NOV2011	833	17	Golimumab	100 mg
Week 120 - EXT	28NOV2011	833	17	Placebo	0 mg
Week 124 - EXT	29DEC2011	864	18	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
PARACETAMOL,Oral	09OCT2010	11OCT2010
PARACETAMOL,Oral	18NOV2010	22NOV2010
MERCAPTOPURINE,Oral	18JAN2011	16JAN2012

■ **Liver Function Test Results**

Visit	Visit Date	ALT (IU/L)	AST (IU/L)	Total Bilirubin (mg/dL)
Week 56 - EXT	13SEP2010	64.00	29.00	0.50
Week 68 - EXT	23NOV2010	153.00	91.00	1.20
Week 68 - EXT	01DEC2010	195.00	122.00	1.60
Week 68 - EXT	21DEC2010	109.00	54.00	0.40
Week 80 - EXT	17FEB2011	30.00	19.00	0.20
Week 92 - EXT	10MAY2011	27.00	19.00	0.40
Week 104 - EXT	02AUG2011	38.00	20.00	0.30
Week 116 - EXT	27OCT2011	28.00	16.00	0.40
Unscheduled - MAIN	17JAN2012	34.00	14.00	0.40

被験者識別コード：7228-00001

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
20APR2010 (463)	肺炎 (PNEUMONIA)	Yes	Moderate/ Not related	Yes/ Yes	None/not applicable	18MAY2010 (491)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
07APR2010 (450)	インフルエンザ (FLU)	Mild/ Not related	Yes/ No	None/not applicable	14APR2010 (457)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 4[redacted]
□ Sex: Female
□ Date of birth: 16OCT[redacted]
□ Height (cm): 154
□ Weight (kg): 59.0
□ Date of UC diagnosis: 17APR2008
□ UC disease duration (years): 0.6
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 200mg -> 100mg SC

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/golimumab 50 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 50 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	10FEB2010	394	1	Golimumab	50 mg
Week 56 - EXT	10FEB2010	394	1	Placebo	0 mg
Week 56 - EXT	10FEB2010	394	1	Placebo	0 mg
Week 60 - EXT	10MAR2010	422	2	Golimumab	50 mg
Week 60 - EXT	10MAR2010	422	2	Placebo	0 mg
Week 64 - EXT	07APR2010	450	3	Placebo	0 mg
Week 64 - EXT	07APR2010	450	3	Golimumab	50 mg
Week 68 - EXT	19MAY2010	492	4	Placebo	0 mg
Week 68 - EXT	19MAY2010	492	4	Golimumab	50 mg
Week 72 - EXT	21JUN2010	525	5	Golimumab	50 mg
Week 72 - EXT	21JUN2010	525	5	Placebo	0 mg
Week 76 - EXT	12JUL2010	546	6	Golimumab	50 mg
Week 76 - EXT	12JUL2010	546	6	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 80 - EXT	02AUG2010	567	7	Golimumab	50 mg
Week 80 - EXT	02AUG2010	567	7	Placebo	0 mg
Week 84 - EXT	24AUG2010	589	8	Golimumab	50 mg
Week 84 - EXT	24AUG2010	589	8	Placebo	0 mg
Week 88 - EXT	20SEP2010	616	9	Placebo	0 mg
Week 88 - EXT	20SEP2010	616	9	Golimumab	50 mg
Week 92 - EXT	18OCT2010	644	10	Placebo	0 mg
Week 92 - EXT	18OCT2010	644	10	Golimumab	50 mg
Week 96 - EXT	15NOV2010	672	11	Golimumab	50 mg
Week 96 - EXT	15NOV2010	672	11	Placebo	0 mg
Week 100 - EXT	13DEC2010	700	12	Placebo	0 mg
Week 100 - EXT	13DEC2010	700	12	Golimumab	50 mg
Week 104 - EXT	10JAN2011	728	13	Golimumab	50 mg
Week 104 - EXT	10JAN2011	728	13	Placebo	0 mg
Week 108 - EXT	07FEB2011	756	14	Golimumab	50 mg
Week 108 - EXT	07FEB2011	756	14	Placebo	0 mg
Week 112 - EXT	07MAR2011	784	15	Golimumab	50 mg
Week 112 - EXT	07MAR2011	784	15	Placebo	0 mg
Week 116 - EXT	04APR2011	812	16	Placebo	0 mg
Week 116 - EXT	04APR2011	812	16	Golimumab	50 mg
Week 120 - EXT	02MAY2011	840	17	Placebo	0 mg
Week 120 - EXT	02MAY2011	840	17	Golimumab	50 mg
Week 124 - EXT	30MAY2011	868	18	Golimumab	50 mg
Week 124 - EXT	30MAY2011	868	18	Placebo	0 mg
Week 128 - EXT	27JUN2011	896	19	Golimumab	50 mg
Week 128 - EXT	27JUN2011	896	19	Placebo	0 mg
Week 132 - EXT	25JUL2011	924	20	Placebo	0 mg
Week 132 - EXT	25JUL2011	924	20	Golimumab	50 mg
Week 136 - EXT	22AUG2011	952	21	Placebo	0 mg
Week 136 - EXT	22AUG2011	952	21	Golimumab	50 mg
Week 140 - EXT	19SEP2011	980	22	Golimumab	50 mg
Week 140 - EXT	19SEP2011	980	22	Placebo	0 mg
Week 144 - EXT	17OCT2011	1008	23	Golimumab	50 mg
Week 144 - EXT	17OCT2011	1008	23	Placebo	0 mg
Week 148 - EXT	14NOV2011	1036	24	Placebo	0 mg
Week 148 - EXT	14NOV2011	1036	24	Golimumab	50 mg
Week 152 - EXT	12DEC2011	1064	25	Golimumab	50 mg
Week 152 - EXT	12DEC2011	1064	25	Placebo	0 mg
Week 156 - EXT	16JAN2012	1099	26	Golimumab	50 mg
Week 160 - EXT	06FEB2012	1120	27	Golimumab	50 mg
Week 164 - EXT	05MAR2012	1148	28	Golimumab	50 mg
Week 168 - EXT	02APR2012	1176	29	Golimumab	50 mg
Week 172 - EXT	02MAY2012	1206	30	Golimumab	50 mg
Week 176 - EXT	30MAY2012	1234	31	Golimumab	50 mg
Week 180 - EXT	25JUN2012	1260	32	Golimumab	50 mg
Week 184 - EXT	23JUL2012	1288	33	Golimumab	50 mg
Week 188 - EXT	21AUG2012	1317	34	Golimumab	50 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 192 - EXT	17SEP2012	1344	35	Golimumab	50 mg
Week 196 - EXT	15OCT2012	1372	36	Golimumab	50 mg
Week 200 - EXT	12NOV2012	1400	37	Golimumab	50 mg
Week 204 - EXT	10DEC2012	1428	38	Golimumab	50 mg
Week 208 - EXT	07JAN2013	1456	39	Golimumab	50 mg
Week 212 - EXT	04FEB2013	1484	40	Golimumab	50 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
ACETYLCYSTEINE,Oral	20APR2010	28APR2010
MOXIFLOXACIN,Intravenous	20APR2010	28APR2010

被験者識別コード：7278-00004

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
29MAR2011 (547)	潰瘍性大腸炎 (EXACERBATION OF UC)	Yes	Severe/ Unlikely	No/ NA	None/not applicable	05APR2011 (554)
07JUL2011 (647)	潰瘍性大腸炎 (EXACERBATION OF UC)	Yes	Severe/ Unlikely	No/ NA	Permanent discontinuation of study agent	11JUL2011 (651)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
--DEC2010 -	皮膚乳頭腫 (VIAL WARTS)	Moderate/ Not related	Yes/ No	None/not applicable	31JAN2011 (490)
10JUN2011 (620)	腹痛 (ABDOMINAL PAIN)	Moderate/ Not related	No/ NA	None/not applicable	Ongoing -

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 5[redacted]
□ Sex: Female
□ Date of birth: 08OCT[redacted]
□ Height (cm): 159
□ Weight (kg): 67.0
□ Date of UC diagnosis: --FEB1995
□ UC disease duration (years): 14.5
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 200mg -> 100mg SC

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/golimumab 50 mg in maintenance

□ Dose adjusted?: Yes

□ Adjusted treatment group: Golimumab 100 mg

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	08NOV2010	406	1	Golimumab	100 mg
Week 56 - EXT	08NOV2010	406	1	Placebo	0 mg
Week 60 - EXT	01DEC2010	429	2	Placebo	0 mg
Week 60 - EXT	01DEC2010	429	2	Golimumab	100 mg
Week 64 - EXT	29DEC2010	457	3	Golimumab	100 mg
Week 64 - EXT	29DEC2010	457	3	Placebo	0 mg
Week 68 - EXT	31JAN2011	490	4	Golimumab	100 mg
Week 68 - EXT	31JAN2011	490	4	Placebo	0 mg
Week 72 - EXT	21FEB2011	511	5	Placebo	0 mg
Week 72 - EXT	21FEB2011	511	5	Golimumab	100 mg
Week 76 - EXT	21MAR2011	539	6	Golimumab	100 mg
Week 76 - EXT	21MAR2011	539	6	Placebo	0 mg
Week 80 - EXT	11APR2011	560	7	Placebo	0 mg
Week 80 - EXT	11APR2011	560	7	Golimumab	100 mg
Week 84 - EXT	23MAY2011	602	8	Golimumab	100 mg
Week 84 - EXT	23MAY2011	602	8	Placebo	0 mg
Week 88 - EXT	13JUN2011	623	9	Golimumab	100 mg
Week 88 - EXT	13JUN2011	623	9	Placebo	0 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
FUSIDIC ACID,Topical	07DEC2010	07DEC2010
MESALAZINE,Rectal	20MAR2011	05APR2011
HYDROCORTISONE,Intravenous	29MAR2011	29MAR2011
POTASSIUM,Oral	05APR2011	Ongoing
PREDNISONE,Oral	06APR2011	08JUN2011
BENZOCAINE,Topical	07APR2011	07APR2011
VITAMIN D NOS,Oral	11APR2011	Ongoing
LEKOVIT CA,Oral	11APR2011	Ongoing
OMEPRAZOLE,Oral	11APR2011	Ongoing
HYDROCORTISONE,Intravenous	07JUL2011	08JUL2011
PREDNISONE,Oral	08JUL2011	Ongoing

被験者識別コード：6751-00018

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: Malignancy

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
21MAY2012 (791)	卵巣上皮癌 (OVARIAN INVASIVE MUCINOUS ADENOCARCINOMA)	Yes	Severe/ Possible	No/ NA	Permanent discontinuation of study agent	07AUG2012 (869)
24JUN2012 (825)	潰瘍性大腸炎 (ULCERATIVE COLITIS FLARE)	Yes	Moderate/ Not related	No/ NA	None/not applicable	13SEP2012 (906)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
02AUG2011 (498)	関節痛 (JOINT PAIN)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
10MAR2012 (719)	腹痛 (ABDOMINAL CRAMPING)	Moderate/ Not related	No/ NA	None/not applicable	21MAY2012 (791)
16MAR2012 (725)	卵巣嚢胞 (CYSTIC MASS IN RIGHT OVARY)	Moderate/ Not related	No/ NA	None/not applicable	21MAY2012 (791)
24JUN2012 (825)	関節痛 (JOINT PAIN)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
24JUN2012 (825)	骨痛 (BONE PAIN)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
02JUL2012 (833)	毛巣嚢胞 (PILONIDAL CYST)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -

■ **Demographics and Baseline Characteristics**

□ Race: Black
□ Age (yrs): 3[redacted]
□ Sex: Female
□ Date of birth: 23AUG[redacted]
□ Height (cm): 165
□ Weight (kg): 63.8
□ Date of UC diagnosis: -----1999
□ UC disease duration (years): 10.1
□ Relevant medical history at baseline: 関節炎

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 400mg -> 200mg SC

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/golimumab 50 mg in maintenance

□ Dose adjusted?: Yes

□ Adjusted treatment group: Golimumab 50 mg

□ Treatment group during start of LTE: Golimumab 50 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: Not applicable or n/a

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	22APR2011	396	1	Golimumab	50 mg
Week 56 - EXT	22APR2011	396	1	Placebo	0 mg
Week 60 - EXT	17MAY2011	421	2	Placebo	0 mg
Week 60 - EXT	17MAY2011	421	2	Golimumab	50 mg
Week 64 - EXT	16JUN2011	451	3	Placebo	0 mg
Week 64 - EXT	16JUN2011	451	3	Golimumab	50 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 68 - EXT	15JUL2011	480	4	Placebo	0 mg
Week 68 - EXT	15JUL2011	480	4	Golimumab	50 mg
Week 72 - EXT	12AUG2011	508	5	Placebo	0 mg
Week 72 - EXT	12AUG2011	508	5	Golimumab	50 mg
Week 76 - EXT	01SEP2011	528	6	Placebo	0 mg
Week 76 - EXT	01SEP2011	528	6	Golimumab	50 mg
Week 80 - EXT	06OCT2011	563	7	Placebo	0 mg
Week 80 - EXT	06OCT2011	563	7	Golimumab	50 mg
Week 84 - EXT	03NOV2011	591	8	Placebo	0 mg
Week 84 - EXT	03NOV2011	591	8	Golimumab	50 mg
Week 88 - EXT	08DEC2011	626	9	Placebo	0 mg
Week 88 - EXT	08DEC2011	626	9	Golimumab	50 mg
Week 92 - EXT	27DEC2011	645	10	Golimumab	50 mg
Week 96 - EXT	23JAN2012	672	11	Golimumab	50 mg
Week 100 - EXT	23FEB2012	703	12	Golimumab	50 mg
Week 104 - EXT	20MAR2012	729	13	Golimumab	50 mg
Week 108 - EXT	19APR2012	759	14	Golimumab	50 mg
Week 112 - EXT	18MAY2012	788	15	Golimumab	50 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
PARACETAMOL,Oral	12AUG2011	Ongoing
HYDROCODONE,Oral	16MAR2012	30MAR2012
PARACETAMOL,Oral	16MAR2012	21MAY2012
FENTANYL,Intravenous	21MAY2012	21MAY2012
CEFAZOLIN,Intravenous	21MAY2012	21MAY2012
GLYCOPYRRONIUM,Intravenous	21MAY2012	21MAY2012
LIDOCAINE,Intravenous	21MAY2012	21MAY2012
NEOSTIGMINE,Intravenous	21MAY2012	21MAY2012
HYDROMORPHONE,Intravenous	21MAY2012	21MAY2012
FLEBOBAG RING LACT,Intravenous	21MAY2012	21MAY2012
ROCURONIUM,Intravenous	21MAY2012	21MAY2012
ONDANSETRON,Intravenous	21MAY2012	21MAY2012
PROPOFOL,Intravenous	21MAY2012	21MAY2012
MIDAZOLAM,Intravenous	21MAY2012	21MAY2012
DOCUSATE,Oral	22MAY2012	Ongoing
DOCUSATE,Oral	22MAY2012	Ongoing
CETIRIZINE,Oral	22MAY2012	Ongoing
OMEPRAZOLE,Oral	22MAY2012	21JUN2012
CONTRAST MEDIA,Oral	08JUN2012	08JUN2012
CONTRAST MEDIA,Intravenous	08JUN2012	08JUN2012
ESOMEPRAZOLE,Oral	12JUN2012	07AUG2012
CEFAZOLIN,Intravenous	22JUN2012	22JUN2012
FENTANYL,Oral	22JUN2012	22JUN2012
SODIUM CHLORIDE,Intravenous	22JUN2012	07AUG2012
DEXAMETHASONE,Intravenous	22JUN2012	07AUG2012
DIPHENHYDRAMINE,Intravenous	22JUN2012	07AUG2012
PEGFILGRASTIM,Intravenous	22JUN2012	07AUG2012

Prior/Concomitant Therapy, Route	Start Date	End Date
PACLITAXEL,Intravenous	22JUN2012	07AUG2012
MESALAZINE,Oral	22JUN2012	Ongoing
ONDANSETRON,Intravenous	22JUN2012	07AUG2012
CARBOPLATIN,Intravenous	22JUN2012	07AUG2012
FAMOTIDINE,Oral	22JUN2012	07AUG2012
MIDAZOLAM,Intravenous	22JUN2012	22JUN2012
VANCOMYCIN,Intravenous	02JUL2012	--JUL2012
LORAZEPAM,Intravenous	02JUL2012	06JUL2012
LORAZEPAM,Oral	02JUL2012	06JUL2012
PROMETHAZINE,Rectal	02JUL2012	06JUL2012
MORPHINE,Intravenous	02JUL2012	06JUL2012
PARACETAMOL,Rectal	02JUL2012	06JUL2012
TUCKS /02050101/,Topical	02JUL2012	06JUL2012
ENOXAPARIN,Subcutaneous	02JUL2012	06JUL2012
FLEBOBAG RING LACT,Intravenous	02JUL2012	06JUL2012
PIP/TAZO,Oral	02JUL2012	06JUL2012
LORATADINE,Oral	02JUL2012	06JUL2012
ONDANSETRON,Intravenous	02JUL2012	06JUL2012
METRONIDAZOLE,Oral	03JUL2012	--JUL2012
METHYLPREDNISOLONE,Intravenous	05JUL2012	--JUL2012
FENTANYL,Intravenous	06JUL2012	06JUL2012
MORPHINE,Intravenous	06JUL2012	06JUL2012
PREDNISONE,Oral	06JUL2012	02AUG2012
MESALAZINE,Rectal	06JUL2012	--JUL2012
MIDAZOLAM,Intravenous	06JUL2012	06JUL2012

被験者識別コード：7584-00004

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
06APR2010 (391)	大葉性肺炎 (RIGHT SIDE LOWER LOBE PNEUMONIA)	Yes	Moderate/ Not related	Yes/ Yes	None/not applicable	21APR2010 (406)

■ **Other Adverse Events**

No Other Adverse Events reported

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 5[redacted]
□ Sex: Female
□ Date of birth: 30SEP[redacted]
□ Height (cm): 173
□ Weight (kg): 68.0
□ Date of UC diagnosis: 04OCT2007
□ UC disease duration (years): 1.3
□ Relevant medical history at baseline: 裂肛

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 400mg -> 200mg SC

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/golimumab 50 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 50 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	06MAY2010	421	1	Placebo	0 mg
Week 56 - EXT	06MAY2010	421	1	Golimumab	50 mg
Week 60 - EXT	08JUN2010	454	2	Placebo	0 mg
Week 60 - EXT	08JUN2010	454	2	Golimumab	50 mg
Week 64 - EXT	06JUL2010	482	3	Placebo	0 mg
Week 64 - EXT	06JUL2010	482	3	Golimumab	50 mg

■ **Treatment and Study Status**

□ Date of study discontinuation: 29Jul2010

□ Reason for noncompletion: Withdrawal of consent

□ Other reason for noncompletion/details: -

□ Date of disposition status: 29Jul2010

■ **Concomitant Medications**

No Concomitant Medications reported.

c) 100 mg 群

被験者識別コード：6716-00006

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: Opportunistic infection

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
27APR2010 (597)	うつ病 (SEVERE DEPRESSION)	Yes	Severe/ Unlikely	No/ NA	None/not applicable	28APR2010 (598)
27MAR2011 (931)	希死念慮を有するうつ病 (SUICIDAL DEPRESSION)	Yes	Severe/ Unlikely	No/ NA	None/not applicable	30MAR2011 (934)
19JUL2011 (1045)	肝炎 (LEGIONELLA HEPATITIS)	Yes	Moderate/ Not related	Yes/ No	Permanent discontinuation of study agent	05AUG2011 (1062)
19JUL2011 (1045)	胸水 (LEFT LARGE PARAPNEUMONIC EFFUSION)	Yes	Severe/ Unlikely	No/ NA	Permanent discontinuation of study agent	24JUL2011 (1050)
19JUL2011 (1045)	レジオネラ菌性肺炎 (BILATERAL LEGIONELLA PNEUMONIA)	Yes	Severe/ Unlikely	Yes/ Yes	Permanent discontinuation of study agent	25AUG2011 (1082)
19JUL2011 (1045)	呼吸不全 (RESPITORY FAILURE)	Yes	Severe/ Unlikely	Yes/ Yes	Permanent discontinuation of study agent	29JUL2011 (1055)
19JUL2011 (1045)	血小板増加症 (THROMBOCYTOSIS)	Yes	Moderate/ Unlikely	No/ NA	Permanent discontinuation of study agent	25AUG2011 (1082)
22JUL2011 (1048)	低ナトリウム血症 (HYPONATREMIA)	Yes	Mild/ Not related	No/ NA	Permanent discontinuation of study agent	28JUL2011 (1054)
24JUL2011 (1050)	細菌性敗血症 (BACTERIAL SEPSIS)	Yes	Moderate/ Unlikely	Yes/ Yes	Permanent discontinuation of study agent	Ongoing -
24JUL2011 (1050)	肺塞栓症 (PULMONARY EMBOLIZATION)	Yes	Moderate/ Unlikely	No/ NA	Permanent discontinuation of study agent	Ongoing -

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
12DEC2009 (461)	腹痛 (ABDOMINAL CRAMPING)	Moderate/ Unlikely	No/ NA	None/not applicable	Ongoing -
22DEC2009 (471)	排便回数増加 (INCREASE FREQUENCY OF BM'S)	Moderate/ Unlikely	No/ NA	None/not applicable	22JAN2010 (502)
22DEC2009 (471)	血便排泄 (HEMATOCHEZIA)	Mild/ Unlikely	No/ NA	None/not applicable	22JAN2010 (502)

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
22JAN2010 (502)	好中球数増加 (ELEVATED NEUTROPHIL COUNT)	Mild/ Unlikely	No/ NA	None/not applicable	09APR2010 (579)
27APR2010 (597)	アルコール乱用 (ALCOHOL ABUSE)	Moderate/ Not related	No/ NA	None/not applicable	28APR2010 (598)
28APR2010 (598)	うつ病 (DEPRESSION)	Mild/ Unlikely	No/ NA	None/not applicable	27MAR2011 (931)
12JUL2010 (673)	下痢 (LOOSE STOOLS)	Moderate/ Unlikely	No/ NA	None/not applicable	10SEP2010 (733)
16DEC2010 (830)	咳嗽 (COUGH)	Moderate/ Unlikely	Yes/ Yes	None/not applicable	24DEC2010 (838)
16DEC2010 (830)	副鼻腔うっ血 (SINUS CONGESTION)	Moderate/ Unlikely	Yes/ Yes	None/not applicable	24DEC2010 (838)
30MAR2011 (934)	うつ病 (DEPRESSION)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -

■ **Demographics and Baseline Characteristics**

□ Race: Other
□ Age (yrs): 2[redacted]
□ Sex: Male
□ Date of birth: 28JUL[redacted]
□ Height (cm): 180
□ Weight (kg): 88.9
□ Date of UC diagnosis: 20JUN2003
□ UC disease duration (years): 5.1
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T16

□ Treatment group in induction: 1 mg/kg IV

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	09OCT2009	397	1	Placebo	0 mg
Week 56 - EXT	09OCT2009	397	1	Placebo	0 mg
Week 56 - EXT	09OCT2009	397	1	Golimumab	100 mg
Week 60 - EXT	20NOV2009	439	2	Golimumab	100 mg
Week 60 - EXT	20NOV2009	439	2	Placebo	0 mg
Week 60 - EXT	20NOV2009	439	2	Placebo	0 mg
Week 64 - EXT	07JAN2010	487	3	Placebo	0 mg
Week 64 - EXT	07JAN2010	487	3	Golimumab	100 mg
Week 64 - EXT	07JAN2010	487	3	Placebo	0 mg
Week 68 - EXT	22JAN2010	502	4	Placebo	0 mg
Week 68 - EXT	22JAN2010	502	4	Golimumab	100 mg
Week 68 - EXT	22JAN2010	502	4	Placebo	0 mg
Week 72 - EXT	12FEB2010	523	5	Golimumab	100 mg
Week 72 - EXT	12FEB2010	523	5	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 72 - EXT	12FEB2010	523	5	Placebo	0 mg
Week 76 - EXT	12MAR2010	551	6	Placebo	0 mg
Week 76 - EXT	12MAR2010	551	6	Golimumab	100 mg
Week 80 - EXT	09APR2010	579	7	Placebo	0 mg
Week 80 - EXT	09APR2010	579	7	Golimumab	100 mg
Week 84 - EXT	23APR2010	593	8	Placebo	0 mg
Week 84 - EXT	23APR2010	593	8	Golimumab	100 mg
Week 88 - EXT	07MAY2010	607	9	Golimumab	100 mg
Week 88 - EXT	07MAY2010	607	9	Placebo	0 mg
Week 92 - EXT	15JUL2010	676	10	Golimumab	100 mg
Week 92 - EXT	15JUL2010	676	10	Placebo	0 mg
Week 100 - EXT	13AUG2010	705	11	Golimumab	100 mg
Week 100 - EXT	13AUG2010	705	11	Placebo	0 mg
Week 104 - EXT	10SEP2010	733	12	Golimumab	100 mg
Week 104 - EXT	10SEP2010	733	12	Placebo	0 mg
Week 108 - EXT	13OCT2010	766	13	Placebo	0 mg
Week 108 - EXT	13OCT2010	766	13	Golimumab	100 mg
Week 112 - EXT	16NOV2010	800	14	Golimumab	100 mg
Week 112 - EXT	16NOV2010	800	14	Placebo	0 mg
Week 116 - EXT	17DEC2010	831	15	Placebo	0 mg
Week 116 - EXT	17DEC2010	831	15	Golimumab	100 mg
Week 124 - EXT	28JAN2011	873	16	Golimumab	100 mg
Week 124 - EXT	28JAN2011	873	16	Placebo	0 mg
Week 136 - EXT	11APR2011	946	17	Golimumab	100 mg
Week 136 - EXT	11APR2011	946	17	Placebo	0 mg
Week 140 - EXT	10MAY2011	975	18	Placebo	0 mg
Week 140 - EXT	10MAY2011	975	18	Golimumab	100 mg
Week 144 - EXT	14JUN2011	1010	19	Placebo	0 mg
Week 144 - EXT	14JUN2011	1010	19	Golimumab	100 mg

■ **Treatment and Study Status**

□ Date of study discontinuation: 25Aug2011

□ Reason for noncompletion: Other

□ Other reason for noncompletion/details: SAE #1 ae#15

□ Date of disposition status: 25Aug2011

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
PREDNISONE,Oral	03JAN2010	13FEB2010
BUPROPION,Oral	01JUL2010	15APR2011
LOPERAMIDE,Oral	12JUL2010	Ongoing
RANITIDINE,Oral	02AUG2010	Ongoing
VICKS FORMULA 44M /01056501/,Oral	17DEC2010	20DEC2010
AZITHROMYCIN,Oral	17DEC2010	24DEC2010
CITALOPRAM,Oral	01APR2011	Ongoing
TRAZODONE,Oral	28APR2011	01JUN2011
FLUOXETINE,Oral	28APR2011	01JUN2011
AMITRIPTYLINE,Oral	01JUN2011	29JUL2011

Prior/Concomitant Therapy, Route	Start Date	End Date
OXYGEN,Inhalation	19JUL2011	29JUL2011
SODIUM CHLORIDE,Intravenous	19JUL2011	19JUL2011
LACTOBACILLUS ACIDOPHILUS,Oral	19JUL2011	04AUG2011
POTASSIUM,Intravenous	19JUL2011	21JUL2011
PARACETAMOL,Oral	19JUL2011	04AUG2011
LEVOFLOXACIN,Intravenous	19JUL2011	29JUL2011
FENTANYL,Intravenous	20JUL2011	25JUL2011
MIDAZOLAM,Intravenous	20JUL2011	20JUL2011
LIDOCAINE,Topical	20JUL2011	20JUL2011
PIPERACILLIN W/TAZOBACTAM /01606301/,Intravenous	20JUL2011	21JUL2011
ONDANSETRON,Intravenous	20JUL2011	29JUL2011
RIFAMPICIN,Oral	21JUL2011	29JUL2011
SODIUM CHLORIDE,Intravenous	21JUL2011	21JUL2011
ENOXAPARIN,Subcutaneous	23JUL2011	29JUL2011
ZOLPIDEM,Oral	23JUL2011	29JUL2011
NALOXONE,Intravenous	24JUL2011	27JUL2011
SODIUM CHLORIDE,Intravenous	24JUL2011	24JUL2011
MORPHINE,Intravenous	24JUL2011	27JUL2011
METOCLOPRAMIDE,Intravenous	24JUL2011	29JUL2011
WARFARIN,Oral	24JUL2011	Ongoing
HEPARIN,Oral	24JUL2011	25JUL2011
FUROSEMIDE,Intravenous	25JUL2011	25JUL2011
KETOROLAC,Intravenous	25JUL2011	26JUL2011
AZITHROMYCIN,Intravenous	25JUL2011	28JUL2011
METHYLPREDNISOLONE,Intravenous	27JUL2011	28JUL2011
ACETYLSALICYLIC ACID,Oral	27JUL2011	Ongoing
OXYCOCET,Oral	27JUL2011	28JUL2011
CLOPIDOGREL,Oral	28JUL2011	29JUL2011
PNEUMOCOCCAL VACCINE,Intramuscular	25AUG2011	25AUG2011
SULFASALAZINE,Oral	25AUG2011	Ongoing
INFLUENZA VACCINE,Intramuscular	25AUG2011	25AUG2011

被験者識別コード：6027-00002

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
15JUL2009 (561)	ダニ媒介ウイルス脳炎 (VIRAL MENINGOENCEPHALITIS DUE TO TICK-BONE ENCEPHALITIS)	Yes	Moderate/ Unlikely	Yes/ Yes	Temporary interruption/dose modification	28JUL2009 (574)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
--FEB2012 -	紅斑 (ERYTHEMA)	Mild/ Unlikely	No/ NA	None/not applicable	--MAR2012 -
30JAN2009 (395)	インフルエンザ (COMMON FLU)	Mild/ Unlikely	Yes/ No	None/not applicable	06FEB2009 (402)
15MAY2009 (500)	上腹部痛 (STOMACH ACHE)	Mild/ Not related	No/ NA	None/not applicable	14JUN2009 (530)
15MAY2009 (500)	頭痛 (HEADACHE)	Mild/ Not related	No/ NA	None/not applicable	14JUN2009 (530)
15MAY2009 (500)	回転性めまい (VERTIGO)	Mild/ Not related	No/ NA	None/not applicable	14JUN2009 (530)
01OCT2009 (639)	鼻咽頭炎 (COMMON COLD)	Mild/ Not related	Yes/ No	None/not applicable	03NOV2009 (672)
19JAN2010 (749)	胃腸炎 (GASTROENTERITIS)	Moderate/ Not related	Yes/ No	None/not applicable	24JAN2010 (754)
19JAN2010 (749)	頭痛 (HEADACHE)	Mild/ Not related	No/ NA	None/not applicable	24JAN2010 (754)
23FEB2010 (784)	頭痛 (INTERMITTING HEADACHE)	Mild/ Unlikely	No/ NA	None/not applicable	23MAR2010 (812)
23MAR2010 (812)	口腔ヘルペス (HERPES LABIALIS)	Mild/ Unlikely	Yes/ No	None/not applicable	20APR2010 (840)
16OCT2010 (1019)	末梢性浮腫 (EDEMA LEGS)	Mild/ Not related	No/ NA	None/not applicable	02NOV2010 (1036)
19OCT2010 (1022)	胸痛 (RETROSTERNAL PAIN)	Mild/ Not related	No/ NA	None/not applicable	02NOV2010 (1036)
01JAN2011 (1096)	鼻咽頭炎 (COMMON COLD)	Mild/ Unlikely	Yes/ No	None/not applicable	18JAN2011 (1113)
01JUN2011 (1247)	口腔ヘルペス (HERPES LABIALIS)	Mild/ Unlikely	Yes/ Yes	None/not applicable	11JUL2011 (1287)
08AUG2011 (1315)	脱毛症 (HAIR LOSS)	Mild/ Unlikely	No/ NA	None/not applicable	05SEP2011 (1343)
12APR2012 (1563)	静脈炎 (PHLEBITIS)	Mild/ Unlikely	No/ NA	None/not applicable	--MAY2012 -

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 3[redacted]
□ Sex: Female
□ Date of birth: 01JUN[redacted]
□ Height (cm): 163
□ Weight (kg): 58.0
□ Date of UC diagnosis: -----1990
□ UC disease duration (years): 16.9
□ Relevant medical history at baseline: 喫煙（過去/現在）

■ **Treatment Groups**

□ Induction study: C0524T16

□ Treatment group in induction: 2 mg/kg IV

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	04FEB2009	400	1	Placebo	0 mg
Week 56 - EXT	04FEB2009	400	1	Placebo	0 mg
Week 56 - EXT	04FEB2009	400	1	Golimumab	100 mg
Week 60 - EXT	02MAR2009	426	2	Golimumab	100 mg
Week 60 - EXT	02MAR2009	426	2	Placebo	0 mg
Week 60 - EXT	02MAR2009	426	2	Placebo	0 mg
Week 64 - EXT	25MAR2009	449	3	Placebo	0 mg
Week 64 - EXT	25MAR2009	449	3	Placebo	0 mg
Week 64 - EXT	25MAR2009	449	3	Golimumab	100 mg
Week 68 - EXT	22APR2009	477	4	Placebo	0 mg
Week 68 - EXT	22APR2009	477	4	Golimumab	100 mg
Week 68 - EXT	22APR2009	477	4	Placebo	0 mg
Week 72 - EXT	18MAY2009	503	5	Placebo	0 mg
Week 72 - EXT	18MAY2009	503	5	Placebo	0 mg
Week 72 - EXT	18MAY2009	503	5	Golimumab	100 mg
Week 76 - EXT	15JUN2009	531	6	Golimumab	100 mg
Week 76 - EXT	15JUN2009	531	6	Placebo	0 mg
Week 76 - EXT	15JUN2009	531	6	Placebo	0 mg
Week 88 - EXT	09SEP2009	617	7	Golimumab	100 mg
Week 88 - EXT	09SEP2009	617	7	Placebo	0 mg
Week 88 - EXT	09SEP2009	617	7	Placebo	0 mg
Week 92 - EXT	07OCT2009	645	8	Placebo	0 mg
Week 92 - EXT	07OCT2009	645	8	Golimumab	100 mg
Week 92 - EXT	07OCT2009	645	8	Placebo	0 mg
Week 96 - EXT	04NOV2009	673	9	Placebo	0 mg
Week 96 - EXT	04NOV2009	673	9	Golimumab	100 mg
Week 96 - EXT	04NOV2009	673	9	Placebo	0 mg
Week 100 - EXT	01DEC2009	700	10	Golimumab	100 mg
Week 100 - EXT	01DEC2009	700	10	Placebo	0 mg
Week 100 - EXT	01DEC2009	700	10	Placebo	0 mg
Week 104 - EXT	29DEC2009	728	11	Placebo	0 mg
Week 104 - EXT	29DEC2009	728	11	Placebo	0 mg
Week 104 - EXT	29DEC2009	728	11	Golimumab	100 mg
Week 108 - EXT	26JAN2010	756	12	Golimumab	100 mg
Week 108 - EXT	26JAN2010	756	12	Placebo	0 mg
Week 108 - EXT	26JAN2010	756	12	Placebo	0 mg
Week 112 - EXT	23FEB2010	784	13	Placebo	0 mg
Week 112 - EXT	23FEB2010	784	13	Golimumab	100 mg
Week 116 - EXT	23MAR2010	812	14	Golimumab	100 mg
Week 116 - EXT	23MAR2010	812	14	Placebo	0 mg
Week 120 - EXT	20APR2010	840	15	Placebo	0 mg
Week 120 - EXT	20APR2010	840	15	Golimumab	100 mg
Week 124 - EXT	18MAY2010	868	16	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 124 - EXT	18MAY2010	868	16	Placebo	0 mg
Week 128 - EXT	15JUN2010	896	17	Golimumab	100 mg
Week 128 - EXT	15JUN2010	896	17	Placebo	0 mg
Week 132 - EXT	13JUL2010	924	18	Placebo	0 mg
Week 132 - EXT	13JUL2010	924	18	Golimumab	100 mg
Week 136 - EXT	10AUG2010	952	19	Placebo	0 mg
Week 136 - EXT	10AUG2010	952	19	Golimumab	100 mg
Week 140 - EXT	31AUG2010	973	20	Placebo	0 mg
Week 140 - EXT	31AUG2010	973	20	Golimumab	100 mg
Week 144 - EXT	05OCT2010	1008	21	Golimumab	100 mg
Week 144 - EXT	05OCT2010	1008	21	Placebo	0 mg
Week 148 - EXT	02NOV2010	1036	22	Golimumab	100 mg
Week 148 - EXT	02NOV2010	1036	22	Placebo	0 mg
Week 152 - EXT	30NOV2010	1064	23	Placebo	0 mg
Week 152 - EXT	30NOV2010	1064	23	Golimumab	100 mg
Week 156 - EXT	28DEC2010	1092	24	Golimumab	100 mg
Week 156 - EXT	28DEC2010	1092	24	Placebo	0 mg
Week 160 - EXT	25JAN2011	1120	25	Golimumab	100 mg
Week 160 - EXT	25JAN2011	1120	25	Placebo	0 mg
Week 164 - EXT	22FEB2011	1148	26	Placebo	0 mg
Week 164 - EXT	22FEB2011	1148	26	Golimumab	100 mg
Week 168 - EXT	22MAR2011	1176	27	Placebo	0 mg
Week 168 - EXT	22MAR2011	1176	27	Golimumab	100 mg
Week 172 - EXT	19APR2011	1204	28	Placebo	0 mg
Week 172 - EXT	19APR2011	1204	28	Golimumab	100 mg
Week 176 - EXT	17MAY2011	1232	29	Golimumab	100 mg
Week 176 - EXT	17MAY2011	1232	29	Placebo	0 mg
Week 180 - EXT	14JUN2011	1260	30	Placebo	0 mg
Week 180 - EXT	14JUN2011	1260	30	Golimumab	100 mg
Week 184 - EXT	12JUL2011	1288	31	Golimumab	100 mg
Week 184 - EXT	12JUL2011	1288	31	Placebo	0 mg
Week 188 - EXT	09AUG2011	1316	32	Placebo	0 mg
Week 188 - EXT	09AUG2011	1316	32	Golimumab	100 mg
Week 192 - EXT	06SEP2011	1344	33	Golimumab	100 mg
Week 192 - EXT	06SEP2011	1344	33	Placebo	0 mg
Week 196 - EXT	18OCT2011	1386	34	Placebo	0 mg
Week 196 - EXT	18OCT2011	1386	34	Golimumab	100 mg
Week 200 - EXT	15NOV2011	1414	35	Placebo	0 mg
Week 200 - EXT	15NOV2011	1414	35	Golimumab	100 mg
Week 204 - EXT	13DEC2011	1442	36	Placebo	0 mg
Week 204 - EXT	13DEC2011	1442	36	Golimumab	100 mg
Week 208 - EXT	10JAN2012	1470	37	Golimumab	100 mg
Week 212 - EXT	07FEB2012	1498	38	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
IMIDAPRIL,Oral	02MAR2009	21APR2009
IMIDAPRIL,Oral	22APR2009	28JUL2009

Prior/Concomitant Therapy, Route	Start Date	End Date
PARACETAMOL,Intravenous	15JUL2009	16JUL2009
AMPHOTERICIN B,Intravenous	16JUL2009	23JUL2009
PIRITRAMIDE,Subcutaneous	16JUL2009	19JUL2009
PARACETAMOL,Oral	16JUL2009	16JUL2009
DEXIBUPROFEN,Oral	16JUL2009	16JUL2009
PANTOPRAZOLE,Oral	16JUL2009	28JUL2009
ENOXAPARIN,Subcutaneous	16JUL2009	28JUL2009
CEFTRIAXONE,Intravenous	16JUL2009	23JUL2009
PARACETAMOL,Rectal	17JUL2009	17JUL2009
PARACETAMOL,Oral	17JUL2009	21JUL2009
PARACETAMOL,Intravenous	18JUL2009	18JUL2009
METAMIZOLE,Oral	18JUL2009	18JUL2009
POTASSIUM,Oral	19JUL2009	20JUL2009
NAPROXEN,Oral	19JUL2009	19JUL2009
METOCLOPRAMIDE,Oral	20JUL2009	20JUL2009
TRAMADOL,Oral	20JUL2009	20JUL2009
PIRITRAMIDE,Subcutaneous	20JUL2009	20JUL2009
AMPHOTERICIN B,Oral	21JUL2009	22JUL2009
DOXYCYCLINE,Oral	21JUL2009	24JUL2009
TRAMADOL,Oral	21JUL2009	28JUL2009
METAMIZOLE,Oral	21JUL2009	21JUL2009
METOCLOPRAMIDE,Oral	22JUL2009	22JUL2009
METOCLOPRAMIDE,Oral	23JUL2009	26JUL2009
AMPHOTERICIN B,Oral	23JUL2009	28JUL2009
DICLOFENAC,Intravenous	23JUL2009	24JUL2009
NEUROBION /00176001/,Oral	25AUG2009	08SEP2010
IMIDAPRIL,Oral	29DEC2009	09AUG2010
AMLODIPINE,Oral	29DEC2009	30NOV2010
ACICLOVIR,Topical	23MAR2010	23MAR2010
IMIDAPRIL,Oral	10AUG2010	30NOV2010
PARACETAMOL,Oral	05OCT2010	01NOV2010
HYDROCHLOROTHIAZIDE,Oral	02NOV2010	30NOV2010
DROSPIRENONE W/ETHINYLESTRADIOL,Oral	02NOV2010	Ongoing
DIOVAN TRIPLE,Oral	01DEC2010	Ongoing
VALACICLOVIR,Oral	01JUN2011	11JUN2011
IBUPROFEN,Oral	12APR2012	Ongoing
DIOSMIN,Oral	12APR2012	Ongoing
DALTEPARIN,Intravenous	12APR2012	25APR2012

被験者識別コード：6402-00002

■ **REASON FOR NARRATIVE SELECTION**

Death

SAE

Discontinuation of study agent due to AE

Event of interest: Malignancy

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
04MAY2011 (1051)	腹痛 (SEVERE ABDOMINAL PAIN)	Yes	Severe/ Unlikely	No/ NA	Permanent discontinuation of study agent	20AUG2011 (1159)
12MAY2011 (1059)	貧血 (ANAEMIA)	No	Severe/ Unlikely	No/ NA	Permanent discontinuation of study agent	20AUG2011 (1159)
12MAY2011 (1059)	胆汁うっ滞 (CHOLESTASIS)	Yes	Severe/ Unlikely	No/ NA	Permanent discontinuation of study agent	20AUG2011 (1159)
16MAY2011 (1063)	胆嚢癌 (GALL BLADDER CARCINOMA)	Yes	Severe/ Unlikely	No/ NA	None/not applicable	20AUG2011 (1159)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
22SEP2009 (462)	上気道感染 (UPPER RESPIRATORY TRACT INFECTION)	Moderate/ Not related	Yes/ Yes	None/not applicable	29SEP2009 (469)
15FEB2011 (973)	ボルデテラ感染 (BRODATELLA PERTUSSIS INFECTION)	Moderate/ Possible	Yes/ Yes	None/not applicable	20APR2011 (1037)
15FEB2011 (973)	咳嗽 (COUGH)	Moderate/ Unlikely	Yes/ Yes	None/not applicable	20APR2011 (1037)

■ **Demographics and Baseline Characteristics**

- □ Race: Caucasian
- □ Age (yrs): 3[redacted]
- □ Sex: Male
- □ Date of birth: 06JUN[redacted]
- □ Height (cm): 176
- □ Weight (kg): 87.5
- □ Date of UC diagnosis: 24FEB2004
- □ UC disease duration (years): 4.2
- □ Relevant medical history at baseline: 結節性紅斑

■ **Treatment Groups**

□ Induction study: C0524T16

□ Treatment group in induction: 2 mg/kg IV

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/golimumab 100 mg in maintenance

□ Dose adjusted in maintenance?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	14JUL2009	392	1	Golimumab	100 mg
Week 56 - EXT	14JUL2009	392	1	Placebo	0 mg
Week 56 - EXT	14JUL2009	392	1	Placebo	0 mg
Week 60 - EXT	11AUG2009	420	2	Placebo	0 mg
Week 60 - EXT	11AUG2009	420	2	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 60 - EXT	11AUG2009	420	2	Golimumab	100 mg
Week 64 - EXT	08SEP2009	448	3	Golimumab	100 mg
Week 64 - EXT	08SEP2009	448	3	Placebo	0 mg
Week 64 - EXT	08SEP2009	448	3	Placebo	0 mg
Week 68 - EXT	05OCT2009	475	4	Golimumab	100 mg
Week 68 - EXT	05OCT2009	475	4	Placebo	0 mg
Week 68 - EXT	05OCT2009	475	4	Placebo	0 mg
Week 72 - EXT	03NOV2009	504	5	Golimumab	100 mg
Week 72 - EXT	03NOV2009	504	5	Placebo	0 mg
Week 72 - EXT	03NOV2009	504	5	Placebo	0 mg
Week 76 - EXT	02DEC2009	533	6	Placebo	0 mg
Week 76 - EXT	02DEC2009	533	6	Golimumab	100 mg
Week 76 - EXT	02DEC2009	533	6	Placebo	0 mg
Week 80 - EXT	30DEC2009	561	7	Placebo	0 mg
Week 80 - EXT	30DEC2009	561	7	Golimumab	100 mg
Week 80 - EXT	30DEC2009	561	7	Placebo	0 mg
Week 84 - EXT	25JAN2010	587	8	Placebo	0 mg
Week 84 - EXT	25JAN2010	587	8	Golimumab	100 mg
Week 84 - EXT	25JAN2010	587	8	Placebo	0 mg
Week 88 - EXT	23FEB2010	616	9	Placebo	0 mg
Week 88 - EXT	23FEB2010	616	9	Golimumab	100 mg
Week 92 - EXT	23MAR2010	644	10	Golimumab	100 mg
Week 92 - EXT	23MAR2010	644	10	Placebo	0 mg
Week 96 - EXT	20APR2010	672	11	Placebo	0 mg
Week 96 - EXT	20APR2010	672	11	Golimumab	100 mg
Week 100 - EXT	18MAY2010	700	12	Placebo	0 mg
Week 100 - EXT	18MAY2010	700	12	Golimumab	100 mg
Week 104 - EXT	08JUN2010	721	13	Placebo	0 mg
Week 104 - EXT	08JUN2010	721	13	Golimumab	100 mg
Week 108 - EXT	01JUL2010	744	14	Golimumab	100 mg
Week 108 - EXT	01JUL2010	744	14	Placebo	0 mg
Week 112 - EXT	03AUG2010	777	15	Golimumab	100 mg
Week 112 - EXT	03AUG2010	777	15	Placebo	0 mg
Week 116 - EXT	31AUG2010	805	16	Golimumab	100 mg
Week 116 - EXT	31AUG2010	805	16	Placebo	0 mg
Week 120 - EXT	21SEP2010	826	17	Placebo	0 mg
Week 120 - EXT	21SEP2010	826	17	Golimumab	100 mg
Week 124 - EXT	15OCT2010	850	18	Placebo	0 mg
Week 124 - EXT	15OCT2010	850	18	Golimumab	100 mg
Week 128 - EXT	18NOV2010	884	19	Golimumab	100 mg
Week 128 - EXT	18NOV2010	884	19	Placebo	0 mg
Week 132 - EXT	16DEC2010	912	20	Golimumab	100 mg
Week 132 - EXT	16DEC2010	912	20	Placebo	0 mg
Week 136 - EXT	25JAN2011	952	21	Placebo	0 mg
Week 136 - EXT	25JAN2011	952	21	Golimumab	100 mg
Week 140 - EXT	22FEB2011	980	22	Placebo	0 mg
Week 140 - EXT	22FEB2011	980	22	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 144 - EXT	22MAR2011	1008	23	Placebo	0 mg
Week 144 - EXT	22MAR2011	1008	23	Golimumab	100 mg
Week 148 - EXT	20APR2011	1037	24	Golimumab	100 mg
Week 148 - EXT	20APR2011	1037	24	Placebo	0 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
CIPROFLOXACIN,Oral	22SEP2009	29SEP2009
AZATHIOPRINE,Oral	24FEB2010	18MAY2010
CIPROFLOXACIN,Oral	23FEB2011	04MAR2011
AMBROXOL,Oral	23FEB2011	21MAR2011
AMOXICILLIN,Oral	05MAR2011	14MAR2011
AZITHROMYCIN,Oral	15MAR2011	21MAR2011
ENOXAPARIN,Subcutaneous	03JUN2011	20JUN2011
CIPROFLOXACIN,Intravenous	03JUN2011	12JUN2011
MORPHINE,Oral	03JUN2011	20AUG2011
LACTULOSE,Oral	03JUN2011	20AUG2011
FENTANYL,Topical	03JUN2011	20AUG2011

■ **Liver Function Test Results**

Visit	Visit Date	ALT (IU/L)	AST (IU/L)	Total Bilirubin (mg/dL)
Week 56 - EXT	14JUL2009	26.00	25.00	0.30
Week 68 - EXT	05OCT2009	32.00	25.00	0.40
Week 80 - EXT	30DEC2009	29.00	26.00	0.40
Week 92 - EXT	23MAR2010	21.00	21.00	0.20
Week 104 - EXT	08JUN2010	28.00	24.00	0.10
Week 116 - EXT	31AUG2010	29.00	22.00	0.40
Week 128 - EXT	18NOV2010	33.00	25.00	0.40
Week 140 - EXT	22FEB2011	35.00	28.00	0.40
Unscheduled - MAIN	11MAY2011	199.00	150.00	1.20

被験者識別コード：6730-00001

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
21MAR2011 (1013)	クロストリジウム・ディフィシレ感染 (CLOSTRIDIUM DIFFICILE INFECTION)	Yes	Severe/ Not related	Yes/ Yes	None/not applicable	24MAR2011 (1016)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
21JUL2009 (405)	潰瘍性大腸炎 (WORSENING ULCERATIVE COLITIS)	Moderate/ Unlikely	No/ NA	None/not applicable	27JUL2009 (411)
06OCT2009 (482)	注射部位紅斑 (INJECTION SITE ERYTHEMA)	Mild/ Probable	No/ NA	None/not applicable	06OCT2009 (482)
19OCT2009 (495)	ウイルス性上気道感染 (VIRAL UPPER RESPIRATORY INFECTION)	Mild/ Not related	Yes/ No	None/not applicable	24OCT2009 (500)
02DEC2009 (539)	注射部位浮腫 (INJECTION SITE EDEMA)	Mild/ Probable	No/ NA	None/not applicable	02DEC2009 (539)
26JAN2010 (594)	注射部位浮腫 (INJECTION SITE EDEMA)	Mild/ Probable	No/ NA	None/not applicable	26JAN2010 (594)
13FEB2010 (612)	靭帯捻挫 (RIGHT FOOT SPRAIN)	Moderate/ Not related	No/ NA	None/not applicable	31MAR2010 (658)
15MAR2010 (642)	ウイルス性胃腸炎 (VIRAL GASTROENTERITIS)	Mild/ Unlikely	Yes/ No	None/not applicable	16MAR2010 (643)
31MAR2010 (658)	靭帯捻挫 (RIGHT FOOT SPRAIN)	Mild/ Not related	No/ NA	None/not applicable	01MAY2010 (689)
05JUN2010 (724)	季節性アレルギー (WORSENING SEASONAL ALLERGIES)	Mild/ Not related	No/ NA	None/not applicable	14JUN2010 (733)
26JUL2010 (775)	ウイルス性上気道感染 (VIRAL UPPER RESPIRATORY INFECTION)	Mild/ Not related	Yes/ No	None/not applicable	05AUG2010 (785)
01AUG2010 (781)	放屁 (INCREASED GASTROINTESTINAL GAS)	Moderate/ Not related	No/ NA	None/not applicable	06SEP2010 (817)
04SEP2010 (815)	末梢性浮腫 (EDEMA IN LOWER EXTREMITIES)	Mild/ Unlikely	No/ NA	None/not applicable	16SEP2010 (827)
25SEP2010 (836)	ウイルス性上気道感染 (VIRAL UPPER RESPIRATORY INFECTION)	Mild/ Not related	Yes/ No	None/not applicable	10OCT2010 (851)
24OCT2010 (865)	潰瘍性大腸炎 (WORSENING ULCERATIVE COLITIS)	Moderate/ Unlikely	No/ NA	None/not applicable	05NOV2010 (877)
28OCT2010 (869)	筋痙縮 (MUSCLE CRAMPS IN LOWER EXTREMITIES)	Severe/ Unlikely	No/ NA	None/not applicable	28OCT2010 (869)
03NOV2010 (875)	知覚過敏 (HYPERASTHESIA OF THROAT)	Moderate/ Unlikely	No/ NA	None/not applicable	29DEC2010 (931)
19NOV2010 (891)	潰瘍性大腸炎 (WORSENING ULCERATIVE COLITIS)	Mild/ Unlikely	No/ NA	None/not applicable	18DEC2010 (920)
25NOV2010 (897)	消化不良 (OCCASIONAL HEARTBURN)	Mild/ Not related	No/ NA	None/not applicable	18DEC2010 (920)
29NOV2010 (901)	クロストリジウム・ディフィシレ感染 (CLOSTRIDIUM DIFFICILE INFECTION NOT CONFIRMED)	Mild/ Unlikely	Yes/ Yes	None/not applicable	27DEC2010 (929)

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
20DEC2010 (922)	貧血 (WORSENED ANEMIA)	Moderate/ Not related	No/ NA	None/not applicable	25JAN2011 (958)
27DEC2010 (929)	上気道感染 (UPPER RESPIRATORY INFECTION)	Mild/ Not related	Yes/ Yes	None/not applicable	28JAN2011 (961)
14JAN2011 (947)	潰瘍性大腸炎 (WORSENING ULCERATIVE COLITIS)	Mild/ Unlikely	No/ NA	None/not applicable	21JAN2011 (954)
19FEB2011 (983)	クロストリジウム・ディフィシレ感染 (CLOSTRIDIUM DIFFICILE INFECTION)	Moderate/ Not related	Yes/ No	None/not applicable	21MAR2011 (1013)
21MAR2011 (1013)	悪心 (NAUSEA)	Severe/ Not related	No/ NA	None/not applicable	30MAR2011 (1022)
24MAR2011 (1016)	クロストリジウム・ディフィシレ感染 (CLOSTRIDIUM DIFFICILE INFECTION)	Moderate/ Not related	Yes/ Yes	None/not applicable	04APR2011 (1027)
27MAR2011 (1019)	静脈炎 (LEFT ANTECUBITAL PHLEBITIS)	Moderate/ Not related	No/ NA	None/not applicable	07APR2011 (1030)
07APR2011 (1030)	末梢性浮腫 (EDEMA IN LOWER EXTREMITIES)	Mild/ Unlikely	No/ NA	None/not applicable	24APR2011 (1047)
15APR2011 (1038)	潰瘍性大腸炎 (WORSENING ULCERATIVE COLITIS)	Moderate/ Unlikely	No/ NA	None/not applicable	07JUL2011 (1121)
20APR2011 (1043)	筋痙縮 (CRAMPING OF BILATERAL CALF MUSCLES)	Severe/ Unlikely	No/ NA	None/not applicable	29APR2011 (1052)
28APR2011 (1051)	好酸球増加症 (TOXIC EOSINOPHILIA)	Mild/ Not related	No/ NA	None/not applicable	29APR2011 (1052)
05MAY2011 (1058)	貧血 (WORSENED ANEMIA)	Moderate/ Not related	No/ NA	None/not applicable	13MAY2011 (1066)
08MAY2011 (1061)	末梢性浮腫 (EDEMA IN LOWER EXTREMITIES)	Mild/ Unlikely	No/ NA	None/not applicable	23MAY2011 (1076)
18MAY2011 (1071)	各種物質毒性 (PREDNISONE TOXICITY)	Moderate/ Not related	No/ NA	None/not applicable	13JUL2011 (1127)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 2[redacted]
□ Sex: Female
□ Date of birth: 23FEB[redacted]
□ Height (cm): 172
□ Weight (kg): 59.6
□ Date of UC diagnosis: --MAY2003
□ UC disease duration (years): 4.9
□ Relevant medical history at baseline: 喫煙（過去/現在）, 関節痛

■ **Treatment Groups**

□ Induction study: C0524T16

□ Treatment group in induction: 2 mg/kg IV

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/golimumab 100 mg in maintenance

□ Dose adjusted?: Yes

□ Adjusted treatment group: Golimumab 200 mg

□ Treatment group during start of LTE: Golimumab 200 mg

□ Dose adjusted during LTE: Yes

□ Adjusted treatment group during LTE: Golimumab 100 mg

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	17JUL2009	401	1	Placebo	0 mg
Week 56 - EXT	17JUL2009	401	1	Golimumab	100 mg
Week 56 - EXT	17JUL2009	401	1	Golimumab	100 mg
Week 60 - EXT	10AUG2009	425	2	Golimumab	100 mg
Week 60 - EXT	10AUG2009	425	2	Placebo	0 mg
Week 60 - EXT	10AUG2009	425	2	Golimumab	100 mg
Week 64 - EXT	01SEP2009	447	3	Placebo	0 mg
Week 64 - EXT	01SEP2009	447	3	Golimumab	100 mg
Week 64 - EXT	01SEP2009	447	3	Golimumab	100 mg
Week 68 - EXT	06OCT2009	482	4	Placebo	0 mg
Week 68 - EXT	06OCT2009	482	4	Golimumab	100 mg
Week 68 - EXT	06OCT2009	482	4	Golimumab	100 mg
Week 72 - EXT	27OCT2009	503	5	Golimumab	100 mg
Week 72 - EXT	27OCT2009	503	5	Placebo	0 mg
Week 72 - EXT	27OCT2009	503	5	Golimumab	100 mg
Week 76 - EXT	02DEC2009	539	6	Golimumab	100 mg
Week 76 - EXT	02DEC2009	539	6	Golimumab	100 mg
Week 76 - EXT	02DEC2009	539	6	Placebo	0 mg
Week 80 - EXT	22DEC2009	559	7	Placebo	0 mg
Week 80 - EXT	22DEC2009	559	7	Golimumab	100 mg
Week 80 - EXT	22DEC2009	559	7	Golimumab	100 mg
Week 84 - EXT	26JAN2010	594	8	Placebo	0 mg
Week 84 - EXT	26JAN2010	594	8	Golimumab	100 mg
Week 84 - EXT	26JAN2010	594	8	Golimumab	100 mg
Week 88 - EXT	16FEB2010	615	9	Golimumab	100 mg
Week 88 - EXT	16FEB2010	615	9	Golimumab	100 mg
Week 88 - EXT	16FEB2010	615	9	Placebo	0 mg
Week 92 - EXT	16MAR2010	643	1	Placebo	0 mg
Week 92 - EXT	16MAR2010	643	1	Golimumab	100 mg
Week 96 - EXT	13APR2010	671	2	Placebo	0 mg
Week 96 - EXT	13APR2010	671	2	Golimumab	100 mg
Week 100 - EXT	13MAY2010	701	3	Golimumab	100 mg
Week 100 - EXT	13MAY2010	701	3	Placebo	0 mg
Week 104 - EXT	11JUN2010	730	4	Golimumab	100 mg
Week 104 - EXT	11JUN2010	730	4	Placebo	0 mg
Week 108 - EXT	06JUL2010	755	5	Golimumab	100 mg
Week 108 - EXT	06JUL2010	755	5	Placebo	0 mg
Week 112 - EXT	03AUG2010	783	1	Golimumab	100 mg
Week 112 - EXT	03AUG2010	783	1	Placebo	0 mg
Week 116 - EXT	31AUG2010	811	2	Placebo	0 mg
Week 116 - EXT	31AUG2010	811	2	Golimumab	100 mg
Week 120 - EXT	05OCT2010	846	3	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 120 - EXT	05OCT2010	846	3	Golimumab	100 mg
Week 124 - EXT	27OCT2010	868	4	Placebo	0 mg
Week 124 - EXT	27OCT2010	868	4	Golimumab	100 mg
Week 128 - EXT	02DEC2010	904	5	Golimumab	100 mg
Week 128 - EXT	02DEC2010	904	5	Placebo	0 mg
Week 132 - EXT	20DEC2010	922	6	Placebo	0 mg
Week 132 - EXT	20DEC2010	922	6	Golimumab	100 mg
Week 136 - EXT	19JAN2011	952	7	Placebo	0 mg
Week 136 - EXT	19JAN2011	952	7	Golimumab	100 mg
Week 140 - EXT	22FEB2011	986	8	Placebo	0 mg
Week 140 - EXT	22FEB2011	986	8	Golimumab	100 mg
Week 144 - EXT	10MAR2011	1002	9	Placebo	0 mg
Week 144 - EXT	10MAR2011	1002	9	Golimumab	100 mg
Week 148 - EXT	07APR2011	1030	10	Placebo	0 mg
Week 148 - EXT	07APR2011	1030	10	Golimumab	100 mg
Week 152 - EXT	05MAY2011	1058	11	Golimumab	100 mg
Week 152 - EXT	05MAY2011	1058	11	Placebo	0 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
DIPHENHYDRAMINE,Oral	21JUL2009	Ongoing
TUSSIN DM,Oral	19OCT2009	24OCT2009
MACROGOL,Oral	18NOV2009	Ongoing
VICODIN,Oral	13FEB2010	13FEB2010
PARACETAMOL,Oral	14FEB2010	14FEB2010
TRAMADOL,Oral	15FEB2010	18FEB2010
CETIRIZINE,Oral	13JUN2010	Ongoing
TUSSIN DM,Oral	27JUL2010	05AUG2010
POTASSIUM,Oral	10SEP2010	16SEP2010
FUROSEMIDE,Oral	10SEP2010	16SEP2010
TUSSIN DM,Oral	25SEP2010	29SEP2010
TUSSIN DM,Oral	25SEP2010	10OCT2010
BENZONATATE,Oral	29SEP2010	10OCT2010
PREDNISONE,Oral	29OCT2010	03NOV2010
CIPROFLOXACIN,Oral	29OCT2010	05NOV2010
FLUCONAZOLE,Oral	09NOV2010	09NOV2010
PREDNISONE,Oral	22NOV2010	18DEC2010
VANCOMYCIN,Oral	29NOV2010	12DEC2010
FLUCONAZOLE,Oral	02DEC2010	09DEC2010
PHENOL,Oral	03DEC2010	05DEC2010
SUCRALFATE,Oral	09DEC2010	29DEC2010
VANCOMYCIN,Oral	15DEC2010	27DEC2010
BIFERARX,Oral	22DEC2010	21MAR2011
PSEUDOEPHEDRINE,Oral	27DEC2010	31DEC2010
CIPROFLOXACIN,Oral	14JAN2011	19JAN2011
MOXIFLOXACIN,Oral	19JAN2011	28JAN2011
IRON,Intravenous	21MAR2011	24MAR2011
SUCRALFATE,Oral	21MAR2011	23MAR2011

Prior/Concomitant Therapy, Route	Start Date	End Date
METHYLPREDNISOLONE,Intravenous	21MAR2011	23MAR2011
OSMOTAN,Intravenous	21MAR2011	24MAR2011
ONDANSETRON,Intravenous	21MAR2011	23MAR2011
VANCOMYCIN,Oral	22MAR2011	13APR2011
PROMETHAZINE,Oral	22MAR2011	23MAR2011
OMEPRAZOLE,Oral	22MAR2011	24MAR2011
ESOMEPRAZOLE,Oral	25MAR2011	10JUN2011
ONDANSETRON,Oral	25MAR2011	30MAR2011
PARACETAMOL,Oral	27MAR2011	07APR2011
BIFERARX,Oral	04APR2011	Ongoing
VANCOMYCIN,Oral	16APR2011	Ongoing
ONDANSETRON,Oral	21APR2011	12JUN2011
SUCRALFATE,Oral	22APR2011	07JUL2011
PREDNISONE,Oral	29APR2011	29APR2011
PREDNISONE,Oral	03MAY2011	07JUL2011
INFLIXIMAB,Intravenous	06JUN2011	Ongoing
CALCIUM CARBONATE,Oral	11JUN2011	13JUN2011
ZEGERID /06027801/,Oral	11JUN2011	13JUN2011
OMEPRAZOLE,Oral	14JUN2011	Ongoing
IRON,Intravenous	16AUG2011	Ongoing

被験者識別コード：6231-00014

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
25MAR2010 (543)	肺炎 (PNEUMONIA)	Yes	Moderate/ Not related	Yes/ Yes	None/not applicable	07APR2010 (556)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
--DEC2010 -	パートナーの妊娠 (PARTNER PREGNANCY)	/ Not related	No/ NA	None/not applicable	18SEP2011 (1085)
--JAN2012 -	腎障害 (RENAL COMPLAINTS)	Mild/ Not related	No/ NA	None/not applicable	12MAR2012 (1261)
19JUN2011 (994)	裂傷 (CUT OF THUMB ON RIGHT HAND)	Mild/ Not related	No/ NA	None/not applicable	21JUN2011 (996)

■ **Demographics and Baseline Characteristics**

□ Race:Caucasian
□ Age (yrs):3[redacted]
□ Sex:Male
□ Date of birth:23SEP[redacted]
□ Height (cm):184
□ Weight (kg):78.0
□ Date of UC diagnosis:08MAR2004
□ UC disease duration (years):4.4
□ Relevant medical history at baseline:-

■ **Treatment Groups**

□ Induction study:C0524T16

□ Treatment group in induction:4 mg/kg IV

□ Treatment group in maintenance:Randomized subject/responder to golimumab induction dosing/golimumab 100 mg in maintenance

□ Dose adjusted?:No

□ Adjusted treatment group:-

□ Treatment group during start of LTE:Golimumab 100 mg

□ Dose adjusted during LTE:No

□ Adjusted treatment group during LTE:-

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	26OCT2009	393	1	Placebo	0 mg
Week 56 - EXT	26OCT2009	393	1	Placebo	0 mg
Week 56 - EXT	26OCT2009	393	1	Golimumab	100 mg
Week 60 - EXT	24NOV2009	422	2	Placebo	0 mg
Week 60 - EXT	24NOV2009	422	2	Placebo	0 mg
Week 60 - EXT	24NOV2009	422	2	Golimumab	100 mg
Week 64 - EXT	22DEC2009	450	3	Placebo	0 mg
Week 64 - EXT	22DEC2009	450	3	Placebo	0 mg
Week 64 - EXT	22DEC2009	450	3	Golimumab	100 mg
Week 68 - EXT	18JAN2010	477	4	Placebo	0 mg
Week 68 - EXT	18JAN2010	477	4	Placebo	0 mg
Week 68 - EXT	18JAN2010	477	4	Golimumab	100 mg
Week 72 - EXT	15FEB2010	505	5	Placebo	0 mg
Week 72 - EXT	15FEB2010	505	5	Placebo	0 mg
Week 72 - EXT	15FEB2010	505	5	Golimumab	100 mg
Week 76 - EXT	16MAR2010	534	6	Placebo	0 mg
Week 76 - EXT	16MAR2010	534	6	Golimumab	100 mg
Week 80 - EXT	12APR2010	561	7	Placebo	0 mg
Week 80 - EXT	12APR2010	561	7	Golimumab	100 mg
Week 84 - EXT	10MAY2010	589	8	Golimumab	100 mg
Week 84 - EXT	10MAY2010	589	8	Placebo	0 mg
Week 88 - EXT	07JUN2010	617	9	Golimumab	100 mg
Week 88 - EXT	07JUN2010	617	9	Placebo	0 mg
Week 92 - EXT	05JUL2010	645	10	Golimumab	100 mg
Week 92 - EXT	05JUL2010	645	10	Placebo	0 mg
Week 96 - EXT	09AUG2010	680	11	Golimumab	100 mg
Week 96 - EXT	09AUG2010	680	11	Placebo	0 mg
Week 100 - EXT	30AUG2010	701	12	Placebo	0 mg
Week 100 - EXT	30AUG2010	701	12	Golimumab	100 mg
Week 104 - EXT	28SEP2010	730	13	Golimumab	100 mg
Week 104 - EXT	28SEP2010	730	13	Placebo	0 mg
Week 108 - EXT	28OCT2010	760	14	Placebo	0 mg
Week 108 - EXT	28OCT2010	760	14	Golimumab	100 mg
Week 112 - EXT	22NOV2010	785	15	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 112 - EXT	22NOV2010	785	15	Golimumab	100 mg
Week 116 - EXT	20DEC2010	813	16	Placebo	0 mg
Week 116 - EXT	20DEC2010	813	16	Golimumab	100 mg
Week 120 - EXT	17JAN2011	841	17	Placebo	0 mg
Week 120 - EXT	17JAN2011	841	17	Golimumab	100 mg
Week 124 - EXT	14FEB2011	869	18	Golimumab	100 mg
Week 124 - EXT	14FEB2011	869	18	Placebo	0 mg
Week 128 - EXT	17MAR2011	900	19	Placebo	0 mg
Week 128 - EXT	17MAR2011	900	19	Golimumab	100 mg
Week 132 - EXT	11APR2011	925	20	Golimumab	100 mg
Week 132 - EXT	11APR2011	925	20	Placebo	0 mg
Week 136 - EXT	09MAY2011	953	21	Placebo	0 mg
Week 136 - EXT	09MAY2011	953	21	Golimumab	100 mg
Week 140 - EXT	08JUN2011	983	22	Placebo	0 mg
Week 140 - EXT	08JUN2011	983	22	Golimumab	100 mg
Week 144 - EXT	04JUL2011	1009	23	Placebo	0 mg
Week 144 - EXT	04JUL2011	1009	23	Golimumab	100 mg
Week 148 - EXT	29JUL2011	1034	24	Golimumab	100 mg
Week 148 - EXT	29JUL2011	1034	24	Placebo	0 mg
Week 152 - EXT	30AUG2011	1066	25	Golimumab	100 mg
Week 152 - EXT	30AUG2011	1066	25	Placebo	0 mg
Week 156 - EXT	27SEP2011	1094	26	Golimumab	100 mg
Week 156 - EXT	27SEP2011	1094	26	Placebo	0 mg
Week 160 - EXT	26OCT2011	1123	27	Golimumab	100 mg
Week 160 - EXT	26OCT2011	1123	27	Placebo	0 mg
Week 164 - EXT	23NOV2011	1151	28	Placebo	0 mg
Week 164 - EXT	23NOV2011	1151	28	Golimumab	100 mg
Week 168 - EXT	20DEC2011	1178	29	Placebo	0 mg
Week 168 - EXT	20DEC2011	1178	29	Golimumab	100 mg
Week 172 - EXT	16JAN2012	1205	30	Golimumab	100 mg
Week 176 - EXT	14FEB2012	1234	31	Golimumab	100 mg
Week 180 - EXT	12MAR2012	1261	32	Golimumab	100 mg
Week 184 - EXT	10APR2012	1290	33	Golimumab	100 mg
Week 188 - EXT	09MAY2012	1319	34	Golimumab	100 mg
Week 192 - EXT	05JUN2012	1346	35	Golimumab	100 mg
Week 196 - EXT	02JUL2012	1373	36	Golimumab	100 mg
Week 200 - EXT	25JUL2012	1396	37	Golimumab	100 mg
Week 204 - EXT	30AUG2012	1432	38	Golimumab	100 mg
Week 208 - EXT	24SEP2012	1457	39	Golimumab	100 mg
Week 212 - EXT	29OCT2012	1492	40	Golimumab	100 mg

■ **Treatment and Study Status**

□ Date of study discontinuation:21FEB2013

□ Reason for noncompletion:Other

□ Other reason for noncompletion/details:Patient notified the PI via phone that he do not want to participate on last visit (week 228).

□ Date of disposition status:21feb2013

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
LEVOFLOXACIN,Intravenous	26MAR2010	28MAR2010
LEVOFLOXACIN,Oral	29MAR2010	07APR2010

被験者識別コード：6281-00007

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
10JUL2012 (1221)	発疹 (RASH OF UNKNOWN ORIGIN)	Yes	Severe/ Possible	No/ NA	Permanent discontinuation of study agent	17JUL2012 (1228)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
02JUN2010 (452)	白内障 (MILD CATARACT LEFT EYE)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
16OCT2010 (588)	浮動性めまい (DIZZINESS NOS)	Mild/ Not related	No/ NA	None/not applicable	18OCT2010 (590)
15APR2012 (1135)	湿疹 (ECZEMA ON BOTH ARMS)	Mild/ Not related	No/ NA	None/not applicable	18MAY2012 (1168)
19MAY2012 (1169)	湿疹 (ECZEMA ON ARMS AND LEGS)	Moderate/ Not related	No/ NA	None/not applicable	19JUN2012 (1200)
20JUN2012 (1201)	乾癬 (PSORIASIS)	Moderate/ Not related	No/ NA	None/not applicable	Ongoing -
11JUL2012 (1222)	爪囲炎 (PARONYCHIA, RIGHT THUMB)	Mild/ Not related	Yes/ Yes	None/not applicable	20JUL2012 (1231)

■ **Demographics and Baseline Characteristics**

- □ Race: Caucasian
- □ Age (yrs): 4[redacted]
- □ Sex: Male
- □ Date of birth: 11MAR[redacted]
- □ Height (cm): 178
- □ Weight (kg): 78.5
- □ Date of UC diagnosis: --MAR1996
- □ UC disease duration (years): 12.8
- □ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T16

□ Treatment group in induction: 4 mg/kg IV

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/golimumab 100 mg in maintenance

□ Dose adjusted?: Yes

□ Adjusted treatment group: Golimumab 100 mg

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	12APR2010	401	1	Placebo	0 mg
Week 56 - EXT	12APR2010	401	1	Golimumab	100 mg
Week 60 - EXT	05MAY2010	424	2	Golimumab	100 mg
Week 60 - EXT	05MAY2010	424	2	Placebo	0 mg
Week 64 - EXT	26MAY2010	445	3	Placebo	0 mg
Week 64 - EXT	26MAY2010	445	3	Golimumab	100 mg
Week 68 - EXT	23JUN2010	473	4	Placebo	0 mg
Week 68 - EXT	23JUN2010	473	4	Golimumab	100 mg
Week 72 - EXT	27JUL2010	507	5	Placebo	0 mg
Week 72 - EXT	27JUL2010	507	5	Golimumab	100 mg
Week 76 - EXT	05SEP2010	547	6	Golimumab	100 mg
Week 76 - EXT	05SEP2010	547	6	Placebo	0 mg
Week 80 - EXT	03OCT2010	575	7	Golimumab	100 mg
Week 80 - EXT	03OCT2010	575	7	Placebo	0 mg
Week 84 - EXT	26OCT2010	598	8	Golimumab	100 mg
Week 84 - EXT	26OCT2010	598	8	Placebo	0 mg
Week 88 - EXT	23NOV2010	626	9	Placebo	0 mg
Week 88 - EXT	23NOV2010	626	9	Golimumab	100 mg
Week 92 - EXT	22DEC2010	655	10	Golimumab	100 mg
Week 92 - EXT	22DEC2010	655	10	Placebo	0 mg
Week 96 - EXT	18JAN2011	682	11	Placebo	0 mg
Week 96 - EXT	18JAN2011	682	11	Golimumab	100 mg
Week 100 - EXT	15FEB2011	710	12	Placebo	0 mg
Week 100 - EXT	15FEB2011	710	12	Golimumab	100 mg
Week 104 - EXT	08MAR2011	731	13	Golimumab	100 mg
Week 104 - EXT	08MAR2011	731	13	Placebo	0 mg
Week 108 - EXT	05APR2011	759	14	Placebo	0 mg
Week 108 - EXT	05APR2011	759	14	Golimumab	100 mg
Week 112 - EXT	03MAY2011	787	15	Placebo	0 mg
Week 112 - EXT	03MAY2011	787	15	Golimumab	100 mg
Week 116 - EXT	31MAY2011	815	16	Placebo	0 mg
Week 116 - EXT	31MAY2011	815	16	Golimumab	100 mg
Week 120 - EXT	05JUL2011	850	17	Golimumab	100 mg
Week 120 - EXT	05JUL2011	850	17	Placebo	0 mg
Week 124 - EXT	02AUG2011	878	18	Golimumab	100 mg
Week 124 - EXT	02AUG2011	878	18	Placebo	0 mg
Week 128 - EXT	31AUG2011	907	19	Golimumab	100 mg
Week 128 - EXT	31AUG2011	907	19	Placebo	0 mg
Week 132 - EXT	02OCT2011	939	20	Placebo	0 mg
Week 132 - EXT	02OCT2011	939	20	Golimumab	100 mg
Week 136 - EXT	06NOV2011	974	21	Golimumab	100 mg
Week 136 - EXT	06NOV2011	974	21	Placebo	0 mg
Week 140 - EXT	27NOV2011	995	22	Golimumab	100 mg
Week 140 - EXT	27NOV2011	995	22	Placebo	0 mg
Week 144 - EXT	21DEC2011	1019	23	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 148 - EXT	11JAN2012	1040	24	Golimumab	100 mg
Week 152 - EXT	08FEB2012	1068	25	Golimumab	100 mg
Week 156 - EXT	25MAR2012	1114	26	Golimumab	100 mg
Week 160 - EXT	23APR2012	1143	27	Golimumab	100 mg
Week 164 - EXT	16MAY2012	1166	28	Golimumab	100 mg
Week 168 - EXT	13JUN2012	1194	29	Golimumab	100 mg
Week 172 - EXT	04JUL2012	1215	30	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
MOMETASONE,Topical	20MAY2012	29MAY2012
MOMETASONE,Topical	03JUN2012	10JUN2012
CLOBETASOL,Topical	11JUN2012	27JUN2012
BETAMETHASONE,Topical	27JUN2012	05JUL2012
CALCIPOTRIOL,Topical	27JUN2012	05JUL2012
HYDROCORTISONE,Topical	10JUL2012	15JUL2012
CEFALEXIN,Oral	12JUL2012	17JUL2012
ALL OTHER THERAPEUTIC PRODUCTS,Topical	13JUL2012	13JUL2012
FUSIDIC ACID,Topical	17JUL2012	23JUL2012
CHLORPHENAMINE,Oral	18JUL2012	31JUL2012
FEXOFENADINE,Oral	18JUL2012	16SEP2012
OTHER EMOLLIENTS AND PROTECTIVES,Topical	18JUL2012	16SEP2012
DESLORATADINE,Oral	01SEP2012	20SEP2012

被験者識別コード：7258-00004

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: TB related

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
10APR2012 (1303)	肺結核 (PULMONARY TUBERCLOSIS)	Yes	Mild/ Probable	Yes/ Yes	Permanent discontinuation of study agent	04FEB2013 (1603)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
26NOV2011 (1167)	発熱 (FEVER)	Mild/ Not related	Yes/ Yes	None/not applicable	09DEC2011 (1180)

■ **Demographics and Baseline Characteristics**

□ Race: Asian
□ Age (yrs): 1[redacted]
□ Sex: Male
□ Date of birth: 13APR[redacted]
□ Height (cm): 165
□ Weight (kg): 53.0
□ Date of UC diagnosis: 07MAR2008
□ UC disease duration (years): 0.4
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 200mg -> 100mg SC

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	15OCT2009	395	1	Golimumab	100 mg
Week 56 - EXT	15OCT2009	395	1	Placebo	0 mg
Week 56 - EXT	15OCT2009	395	1	Placebo	0 mg
Week 60 - EXT	12NOV2009	423	2	Golimumab	100 mg
Week 60 - EXT	12NOV2009	423	2	Placebo	0 mg
Week 60 - EXT	12NOV2009	423	2	Placebo	0 mg
Week 64 - EXT	08DEC2009	449	3	Golimumab	100 mg
Week 64 - EXT	08DEC2009	449	3	Placebo	0 mg
Week 64 - EXT	08DEC2009	449	3	Placebo	0 mg
Week 68 - EXT	05JAN2010	477	4	Golimumab	100 mg
Week 68 - EXT	05JAN2010	477	4	Placebo	0 mg
Week 68 - EXT	05JAN2010	477	4	Placebo	0 mg
Week 72 - EXT	03FEB2010	506	5	Golimumab	100 mg
Week 72 - EXT	03FEB2010	506	5	Placebo	0 mg
Week 72 - EXT	03FEB2010	506	5	Placebo	0 mg
Week 76 - EXT	05MAR2010	536	6	Golimumab	100 mg
Week 76 - EXT	05MAR2010	536	6	Placebo	0 mg
Week 80 - EXT	03APR2010	565	7	Golimumab	100 mg
Week 80 - EXT	03APR2010	565	7	Placebo	0 mg
Week 84 - EXT	27APR2010	589	8	Golimumab	100 mg
Week 84 - EXT	27APR2010	589	8	Placebo	0 mg
Week 88 - EXT	27MAY2010	619	9	Golimumab	100 mg
Week 88 - EXT	27MAY2010	619	9	Placebo	0 mg
Week 92 - EXT	23JUN2010	646	10	Golimumab	100 mg
Week 92 - EXT	23JUN2010	646	10	Placebo	0 mg
Week 96 - EXT	27JUL2010	680	11	Golimumab	100 mg
Week 96 - EXT	27JUL2010	680	11	Placebo	0 mg
Week 100 - EXT	17AUG2010	701	12	Placebo	0 mg
Week 100 - EXT	17AUG2010	701	12	Golimumab	100 mg
Week 104 - EXT	16SEP2010	731	13	Placebo	0 mg
Week 104 - EXT	16SEP2010	731	13	Golimumab	100 mg
Week 108 - EXT	12OCT2010	757	14	Placebo	0 mg
Week 108 - EXT	12OCT2010	757	14	Golimumab	100 mg
Week 112 - EXT	09NOV2010	785	15	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 112 - EXT	09NOV2010	785	15	Golimumab	100 mg
Week 116 - EXT	07DEC2010	813	16	Placebo	0 mg
Week 116 - EXT	07DEC2010	813	16	Golimumab	100 mg
Week 120 - EXT	04JAN2011	841	17	Golimumab	100 mg
Week 120 - EXT	04JAN2011	841	17	Placebo	0 mg
Week 124 - EXT	01FEB2011	869	18	Golimumab	100 mg
Week 124 - EXT	01FEB2011	869	18	Placebo	0 mg
Week 128 - EXT	01MAR2011	897	19	Golimumab	100 mg
Week 128 - EXT	01MAR2011	897	19	Placebo	0 mg
Week 132 - EXT	31MAR2011	927	20	Golimumab	100 mg
Week 132 - EXT	31MAR2011	927	20	Placebo	0 mg
Week 136 - EXT	29APR2011	956	21	Placebo	0 mg
Week 136 - EXT	29APR2011	956	21	Golimumab	100 mg
Week 140 - EXT	24MAY2011	981	22	Golimumab	100 mg
Week 140 - EXT	24MAY2011	981	22	Placebo	0 mg
Week 144 - EXT	24JUN2011	1012	23	Placebo	0 mg
Week 144 - EXT	24JUN2011	1012	23	Golimumab	100 mg
Week 148 - EXT	19JUL2011	1037	24	Placebo	0 mg
Week 148 - EXT	19JUL2011	1037	24	Golimumab	100 mg
Week 152 - EXT	16AUG2011	1065	25	Placebo	0 mg
Week 152 - EXT	16AUG2011	1065	25	Golimumab	100 mg
Week 156 - EXT	17SEP2011	1097	26	Golimumab	100 mg
Week 156 - EXT	17SEP2011	1097	26	Placebo	0 mg
Week 160 - EXT	12OCT2011	1122	27	Golimumab	100 mg
Week 160 - EXT	12OCT2011	1122	27	Placebo	0 mg
Week 164 - EXT	11NOV2011	1152	28	Placebo	0 mg
Week 164 - EXT	11NOV2011	1152	28	Golimumab	100 mg
Week 168 - EXT	10DEC2011	1181	29	Golimumab	100 mg
Week 168 - EXT	10DEC2011	1181	29	Placebo	0 mg
Week 172 - EXT	13JAN2012	1215	30	Golimumab	100 mg
Week 176 - EXT	13FEB2012	1246	31	Golimumab	100 mg
Week 180 - EXT	09MAR2012	1271	32	Golimumab	100 mg
Week 184 - EXT	11APR2012	1304	33	Golimumab	100 mg

■ **Treatment and Study Status**

□ Date of study discontinuation: 20Jul2012

□ Reason for noncompletion: Other

□ Other reason for noncompletion/details: Subject was discontinued due to pulmonary tuberculosis

□ Date of disposition status: 20Jul2012

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
PARACETAMOL,Oral	26NOV2011	09DEC2011
OFLOXACIN,Oral	26NOV2011	29NOV2011
RIFAMPICIN,Oral	13APR2012	Ongoing
PYRIDOXINE,Oral	13APR2012	Ongoing
PYRAZINAMIDE,Oral	13APR2012	Ongoing
ISONIAZID,Oral	13APR2012	Ongoing

Prior/Concomitant Therapy, Route	Start Date	End Date
ETHAMBUTOL,Oral	13APR2012	Ongoing

被験者識別コード：7460-00005

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
11MAR2012 (536)	肺炎 (BILATERAL PNEUMONIA)	Yes	Severe/ Unlikely	Yes/ Yes	Temporary interruption/dose modification	21MAR2012 (546)

■ **Other Adverse Events**

No Other Adverse Events reported

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 4[redacted]
□ Sex: Female
□ Date of birth: 12MAR[redacted]
□ Height (cm): 164
□ Weight (kg): 68.3
□ Date of UC diagnosis: 02DEC2005
□ UC disease duration (years): 4.7
□ Relevant medical history at baseline: 関節痛

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 200mg -> 100mg SC

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/golimumab 100 mg in maintenance

□ Dose adjusted?: Yes

□ Adjusted treatment group: Golimumab 100 mg

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	02NOV2011	406	1	Placebo	0 mg
Week 56 - EXT	02NOV2011	406	1	Golimumab	100 mg
Week 60 - EXT	15NOV2011	419	2	Placebo	0 mg
Week 60 - EXT	15NOV2011	419	2	Golimumab	100 mg
Week 64 - EXT	22DEC2011	456	3	Golimumab	100 mg
Week 68 - EXT	17JAN2012	482	4	Golimumab	100 mg
Week 72 - EXT	10FEB2012	506	5	Golimumab	100 mg
Week 80 - EXT	17APR2012	573	6	Golimumab	100 mg
Week 84 - EXT	16MAY2012	602	7	Golimumab	100 mg
Week 88 - EXT	19JUN2012	636	8	Golimumab	100 mg
Week 92 - EXT	03JUL2012	650	9	Golimumab	100 mg
Week 96 - EXT	24JUL2012	671	10	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 100 - EXT	29AUG2012	707	11	Golimumab	100 mg
Week 104 - EXT	17SEP2012	726	12	Golimumab	100 mg
Week 108 - EXT	29OCT2012	768	13	Golimumab	100 mg
Week 112 - EXT	22NOV2012	792	14	Golimumab	100 mg
Week 116 - EXT	13DEC2012	813	15	Golimumab	100 mg
Week 120 - EXT	16JAN2013	847	16	Golimumab	100 mg
Week 124 - EXT	19FEB2013	881	17	Golimumab	100 mg
Week 128 - EXT	20MAR2013	910	18	Golimumab	100 mg
Week 132 - EXT	12APR2013	933	19	Golimumab	100 mg
Week 136 - EXT	27MAY2013	978	20	Golimumab	100 mg
Week 140 - EXT	11JUN2013	993	21	Golimumab	100 mg
Week 144 - EXT	19JUL2013	1031	22	Golimumab	100 mg
Week 148 - EXT	22AUG2013	1065	23	Golimumab	100 mg
Week 152 - EXT	11SEP2013	1085	24	Golimumab	100 mg
Week 156 - EXT	09OCT2013	1113	25	Golimumab	100 mg
Week 160 - EXT	04NOV2013	1139	26	Golimumab	100 mg
Week 164 - EXT	14NOV2013	1149	27	Golimumab	100 mg
Week 168 - EXT	23DEC2013	1188	28	Golimumab	100 mg
Week 172 - EXT	21JAN2014	1217	29	Golimumab	100 mg
Week 176 - EXT	18FEB2014	1245	30	Golimumab	100 mg
Week 180 - EXT	18MAR2014	1273	31	Golimumab	100 mg
Week 184 - EXT	13APR2014	1299	32	Golimumab	100 mg
Week 188 - EXT	14MAY2014	1330	33	Golimumab	100 mg
Week 192 - EXT	05JUN2014	1352	34	Golimumab	100 mg
Week 196 - EXT	04JUL2014	1381	35	Golimumab	100 mg
Week 200 - EXT	31JUL2014	1408	36	Golimumab	100 mg
Week 204 - EXT	01SEP2014	1440	37	Golimumab	100 mg
Week 208 - EXT	21SEP2014	1460	38	Golimumab	100 mg
Week 212 - EXT	21OCT2014	1490	39	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
CEFOTAXIME,Intramuscular	11MAR2012	21MAR2012
PEFLOXACIN,Intravenous	11MAR2012	21MAR2012
PEFLOXACIN,Oral	22MAR2012	26MAR2012

被験者識別コード：7743-00009

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
08JAN2012 (882)	肺炎 (PNEUMONIA)	Yes	Severe/ Probable	Yes/ Yes	Temporary interruption/dose modification	02MAR2012 (936)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
07SEP2010 (394)	悪心 (NAUSEA)	Moderate/ Probable	No/ NA	None/not applicable	10SEP2010 (397)
04DEC2010 (482)	胃腸炎 (GASTROENTERITIS)	Moderate/ Unlikely	Yes/ Yes	None/not applicable	09DEC2010 (487)
11AUG2011 (732)	上気道感染 (UPPER RESPIRATORY INFECTION)	Mild/ Not related	Yes/ No	None/not applicable	14AUG2011 (735)
02JAN2012 (876)	副鼻腔炎 (SINUSITIS)	Moderate/ Probable	Yes/ Yes	None/not applicable	06JAN2012 (880)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 4[redacted]
□ Sex: Male
□ Date of birth: 30NOV[redacted]
□ Height (cm): 180
□ Weight (kg): 83.9
□ Date of UC diagnosis: -----1998
□ UC disease duration (years): 10.5
□ Relevant medical history at baseline: 喫煙（過去/現在）

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 200mg -> 100mg SC

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	07SEP2010	394	1	Golimumab	100 mg
Week 56 - EXT	07SEP2010	394	1	Placebo	0 mg
Week 60 - EXT	13OCT2010	430	2	Placebo	0 mg
Week 60 - EXT	13OCT2010	430	2	Golimumab	100 mg
Week 64 - EXT	11NOV2010	459	3	Golimumab	100 mg
Week 64 - EXT	11NOV2010	459	3	Placebo	0 mg
Week 68 - EXT	09DEC2010	487	4	Golimumab	100 mg
Week 68 - EXT	09DEC2010	487	4	Placebo	0 mg
Week 72 - EXT	18JAN2011	527	5	Golimumab	100 mg
Week 72 - EXT	18JAN2011	527	5	Placebo	0 mg
Week 80 - EXT	16FEB2011	556	6	Golimumab	100 mg
Week 80 - EXT	16FEB2011	556	6	Placebo	0 mg
Week 84 - EXT	14MAR2011	582	7	Golimumab	100 mg
Week 84 - EXT	14MAR2011	582	7	Placebo	0 mg
Week 88 - EXT	19APR2011	618	8	Golimumab	100 mg
Week 88 - EXT	19APR2011	618	8	Placebo	0 mg
Week 92 - EXT	17MAY2011	646	9	Golimumab	100 mg
Week 92 - EXT	17MAY2011	646	9	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 96 - EXT	22JUN2011	682	10	Placebo	0 mg
Week 96 - EXT	22JUN2011	682	10	Golimumab	100 mg
Week 100 - EXT	14JUL2011	704	11	Placebo	0 mg
Week 100 - EXT	14JUL2011	704	11	Golimumab	100 mg
Week 104 - EXT	16AUG2011	737	12	Golimumab	100 mg
Week 104 - EXT	16AUG2011	737	12	Placebo	0 mg
Week 108 - EXT	13SEP2011	765	13	Golimumab	100 mg
Week 108 - EXT	13SEP2011	765	13	Placebo	0 mg
Week 112 - EXT	11OCT2011	793	14	Golimumab	100 mg
Week 112 - EXT	11OCT2011	793	14	Placebo	0 mg
Week 120 - EXT	22NOV2011	835	15	Golimumab	100 mg
Week 120 - EXT	22NOV2011	835	15	Placebo	0 mg
Week 124 - EXT	20DEC2011	863	16	Golimumab	100 mg
Week 124 - EXT	20DEC2011	863	16	Placebo	0 mg
Week 132 - EXT	02MAR2012	936	17	Golimumab	100 mg
Week 136 - EXT	28MAR2012	962	18	Golimumab	100 mg
Week 144 - EXT	23MAY2012	1018	19	Golimumab	100 mg
Week 148 - EXT	12JUN2012	1038	20	Golimumab	100 mg
Week 152 - EXT	18JUL2012	1074	21	Golimumab	100 mg
Week 156 - EXT	15AUG2012	1102	22	Golimumab	100 mg
Week 160 - EXT	11SEP2012	1129	23	Golimumab	100 mg

■ **Treatment and Study Status**

□ Date of study discontinuation: 21Jan2013

□ Reason for noncompletion: Lost to follow-up

□ Other reason for noncompletion/details: -

□ Date of disposition status: 21Jan2013

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
DULOXETINE,Oral	--NOV2011	Ongoing
CIPROFLOXACIN,Oral	05DEC2010	09DEC2010
CITALOPRAM,Oral	03JAN2011	Ongoing
TESTOSTERONE,Topical	29AUG2011	Ongoing
INSULIN,Subcutaneous	09SEP2011	Ongoing
VICODIN,Oral	20OCT2011	--NOV2011
AZITHROMYCIN,Oral	03JAN2012	05JAN2012
FONDAPARINUX,Subcutaneous	08JAN2012	10JAN2012
MOXIFLOXACIN,Intravenous	09JAN2012	10JAN2012
LEVOFLOXACIN,Oral	10JAN2012	Ongoing
LISINOPRIL,Oral	11JAN2012	Ongoing
MELOXICAM,Oral	11JAN2012	Ongoing
CYANOCOBALAMIN,Oral	11JAN2012	Ongoing
IRON,Oral	11JAN2012	Ongoing
MESALAZINE,Oral	29MAR2012	Ongoing

被験者識別コード：6177-00016

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: New autoimmune disorder

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
--SEP2011 -	過敏性血管炎 (LEUKOCYTOCLASTIC VASCULITIS)	Yes	Severe/ Unlikely	No/ NA	Permanent discontinuation of study agent	--SEP2013 -

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
--NOV2011 -	無力症 (ASTHENIA)	Mild/ Not related	No/ NA	None/not applicable	--SEP2012 -
--DEC2011 -	気管支炎 (BRONCHIAL SUPERINFECTION)	Mild/ Not related	Yes/ Yes	None/not applicable	--JAN2012 -
--JUL2012 -	潰瘍性大腸炎 (FLARE UP OF UC)	Mild/ Not related	No/ NA	None/not applicable	--AUG2012 -
--JUL2012 -	不眠症 (INSOMNIA)	Mild/ Not related	No/ NA	None/not applicable	--SEP2012 -
--OCT2011 -	筋肉痛 (MUSCULAR PAIN (RIGHT ARM))	Mild/ Not related	No/ NA	None/not applicable	--DEC2011 -
--NOV2011 -	鼻咽頭炎 (COLD)	Mild/ Not related	Yes/ No	None/not applicable	--DEC2011 -
--JUN2012 -	寝汗 (NIGHT SWEATS)	Mild/ Not related	No/ NA	None/not applicable	--JUL2012 -
--DEC2011 -	血栓後症候群 (WORSENING OF POST THROMBOTIC SYNDROME)	Moderate/ Not related	No/ NA	None/not applicable	--OCT2012 -
--JUL2012 -	直腸出血 (PROCTORRAGIA)	Mild/ Not related	No/ NA	None/not applicable	--AUG2012 -
07JUL2011 (385)	紅斑 (SKIN REDNESS)	Mild/ Definite	No/ NA	None/not applicable	07JUL2011 (385)
11AUG2011 (420)	丘疹 (PAPULE)	Mild/ Definite	No/ NA	None/not applicable	12AUG2011 (421)
08SEP2011 (448)	紅斑 (SKIN REDNESS)	Mild/ Definite	No/ NA	None/not applicable	09SEP2011 (449)
13OCT2011 (483)	丘疹 (PAPULE)	Mild/ Definite	No/ NA	None/not applicable	13OCT2011 (483)
03NOV2011 (504)	丘疹 (PAPULE)	Mild/ Definite	No/ NA	None/not applicable	03NOV2011 (504)
04NOV2011 (505)	潰瘍性大腸炎 (FLARE UP OF UC)	Mild/ Not related	No/ NA	None/not applicable	--JAN2012 -
08DEC2011 (539)	丘疹 (PAPULE)	Mild/ Definite	No/ NA	None/not applicable	08DEC2011 (539)
26DEC2011 (557)	うつ病 (DEPRESSION)	Mild/ Not related	No/ NA	None/not applicable	--FEB2012 -

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
05JAN2012 (567)	丘疹 (PAPULE)	Mild/ Definite	No/ NA	None/not applicable	05JAN2012 (567)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 4[redacted]
□ Sex: Male
□ Date of birth: 28MAY[redacted]
□ Height (cm): 175
□ Weight (kg): 96.6
□ Date of UC diagnosis: --NOV2007
□ UC disease duration (years): 2.4
□ Relevant medical history at baseline: 喫煙（過去/現在），裂肛

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 400mg -> 200mg SC

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	07JUL2011	385	1	Placebo	0 mg
Week 56 - EXT	07JUL2011	385	1	Golimumab	100 mg
Week 60 - EXT	11AUG2011	420	2	Golimumab	100 mg
Week 60 - EXT	11AUG2011	420	2	Placebo	0 mg
Week 64 - EXT	08SEP2011	448	3	Golimumab	100 mg
Week 64 - EXT	08SEP2011	448	3	Placebo	0 mg
Week 68 - EXT	13OCT2011	483	4	Placebo	0 mg
Week 68 - EXT	13OCT2011	483	4	Golimumab	100 mg
Week 72 - EXT	03NOV2011	504	5	Placebo	0 mg
Week 72 - EXT	03NOV2011	504	5	Golimumab	100 mg
Week 76 - EXT	08DEC2011	539	6	Golimumab	100 mg
Week 76 - EXT	08DEC2011	539	6	Placebo	0 mg
Week 80 - EXT	05JAN2012	567	7	Golimumab	100 mg
Week 84 - EXT	26JAN2012	588	8	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
APOREX,Oral	--MAR2012	--MAR2012
PANADEINE CO,Oral	--MAR2012	--MAR2012
TRAMADOL,Oral	--MAR2012	--MAR2012
DIFLUCORTOLONE,Topical	--MAY2012	--OCT2012
OXYCODONE,Oral	--JAN2013	--FEB2013
PAROXETINE,Oral	--NOV2012	--JAN2013
ZOLPIDEM,Oral	--AUG2012	--SEP2012
LAMALINE /01708901/,Oral	--MAR2012	--MAR2012
LEVOFLOXACIN,Oral	--DEC2011	--JAN2012

Prior/Concomitant Therapy, Route	Start Date	End Date
FERVEX /00959901/,Oral	30NOV2011	02DEC2011
DIFLUCORTOLONE,Topical	14DEC2011	--JAN2012
AUGMENTIN /00756801/,Oral	14DEC2011	--JAN2012
PAROXETINE,Oral	26DEC2011	--NOV2012
SACCHAROMYCES BOULARDII,Oral	23FEB2012	01MAR2012
AUGMENTIN /00756801/,Oral	23FEB2012	01MAR2012
SULFADIAZINE,Topical	16APR2012	--JUN2012
ULTRACET,Oral	16APR2012	12SEP2012
CELESTAMINE /00252801/,Oral	25JUN2012	--JUL2012
DESLORATADINE,Oral	25JUN2012	--JUL2012
COLCHIMAX /00728901/,Oral	24JUL2012	--AUG2012
MESALAZINE,Rectal	27JUL2012	27AUG2012
PREDNISONE,Oral	03SEP2012	24SEP2012
LEKOVIT CA,Oral	03SEP2012	Ongoing
ESOMEPRAZOLE,Oral	03SEP2012	Ongoing
PARACETAMOL,Oral	06SEP2012	12SEP2012
TRAMADOL,Oral	06SEP2012	12SEP2012
FENTANYL,Other	12SEP2012	--OCT2012
OXYCODONE,Oral	12SEP2012	--OCT2012
PREDNISONE,Oral	25SEP2012	01OCT2012
PREDNISONE,Oral	02OCT2012	08OCT2012
PREDNISONE,Oral	09OCT2012	15OCT2012
PREDNISONE,Oral	16OCT2012	22OCT2012
PREDNISONE,Oral	23OCT2012	29OCT2012
PREDNISONE,Oral	30OCT2012	13NOV2012
PREDNISONE,Oral	14NOV2012	20NOV2012
PREDNISONE,Oral	21NOV2012	27NOV2012
PREDNISONE,Oral	28NOV2012	04DEC2012
PREDNISONE,Oral	05DEC2012	11DEC2012
PREDNISONE,Oral	12DEC2012	18DEC2012
PREDNISONE,Oral	19DEC2012	25DEC2012
PREDNISONE,Oral	26DEC2012	01JAN2013
PREDNISONE,Oral	02JAN2013	08JAN2013
PREDNISONE,Oral	09JAN2013	15JAN2013
PREDNISONE,Oral	16JAN2013	29JAN2013
PREDNISONE,Oral	30JAN2013	12FEB2013
PREDNISONE,Oral	13FEB2013	19FEB2013
PREDNISONE,Oral	20FEB2013	26FEB2013
PREDNISONE,Oral	27FEB2013	Ongoing

被験者識別コード：6404-00017

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
21JUN2012 (815)	大腸狭窄 (SEVERE SIGMOID COLON STENOSIS)	Yes	Severe/ Not related	No/ NA	Permanent discontinuation of study agent	28AUG2012 (883)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
20MAY2011 (417)	潰瘍性大腸炎 (EXACERBATION OF ULCERATIVE COLITIS)	Moderate/ Not related	No/ NA	Temporary interruption/dose modification	14JUN2011 (442)
28AUG2012 (883)	大腸狭窄 (SIGMOID COLON STENOSIS)	Moderate/ Not related	No/ NA	None/not applicable	Ongoing -

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 6[redacted]
□ Sex: Female
□ Date of birth: 04JAN[redacted]
□ Height (cm): 152
□ Weight (kg): 64.0
□ Date of UC diagnosis: 06AUG2004
□ UC disease duration (years): 5.5
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 400mg -> 200mg SC

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: Yes

□ Adjusted treatment group during LTE: Golimumab 100 mg

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	26APR2011	393	1	Golimumab	100 mg
Week 56 - EXT	26APR2011	393	1	Placebo	0 mg
Week 60 - EXT	24MAY2011	421	1	Placebo	0 mg
Week 60 - EXT	24MAY2011	421	1	Golimumab	100 mg
Week 64 - EXT	21JUN2011	449	2	Placebo	0 mg
Week 64 - EXT	21JUN2011	449	2	Golimumab	100 mg
Week 68 - EXT	19JUL2011	477	3	Placebo	0 mg
Week 68 - EXT	19JUL2011	477	3	Golimumab	100 mg
Week 72 - EXT	16AUG2011	505	4	Placebo	0 mg
Week 72 - EXT	16AUG2011	505	4	Golimumab	100 mg
Week 76 - EXT	13SEP2011	533	5	Golimumab	100 mg
Week 76 - EXT	13SEP2011	533	5	Placebo	0 mg
Week 80 - EXT	11OCT2011	561	6	Golimumab	100 mg
Week 80 - EXT	11OCT2011	561	6	Placebo	0 mg
Week 84 - EXT	08NOV2011	589	7	Placebo	0 mg
Week 84 - EXT	08NOV2011	589	7	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 88 - EXT	06DEC2011	617	8	Placebo	0 mg
Week 88 - EXT	06DEC2011	617	8	Golimumab	100 mg
Week 92 - EXT	03JAN2012	645	9	Golimumab	100 mg
Week 96 - EXT	30JAN2012	672	10	Golimumab	100 mg
Week 100 - EXT	28FEB2012	701	11	Golimumab	100 mg
Week 104 - EXT	27MAR2012	729	12	Golimumab	100 mg
Week 108 - EXT	24APR2012	757	13	Golimumab	100 mg
Week 112 - EXT	22MAY2012	785	14	Golimumab	100 mg
Week 116 - EXT	19JUN2012	813	15	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
MEBEVERINE,Oral	21JUN2011	07NOV2011
MEDAZEPAM,Oral	15SEP2011	28FEB2012
METEOSPASMYL /01017401/,Oral	08NOV2011	Ongoing
BUTYRIC ACID,Oral	08NOV2011	02JAN2012
BUTYRIC ACID,Oral	24APR2012	Ongoing
SENNA ALEXANDRINA,Oral	20JUN2012	20JUN2012

被験者識別コード：6404-00026

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
06APR2014 (1335)	発熱 (FEVER)	Yes	Moderate/ Not related	Yes/ Yes	None/not applicable	16APR2014 (1345)
17APR2014 (1346)	発熱 (FEVER)	No	Mild/ Not related	Yes/ Yes	Permanent discontinuation of study agent	20MAY2014 (1379)
20MAY2014 (1379)	関節痛 (ARTHRALGIA)	Yes	Moderate/ Not related	No/ NA	None/not applicable	03JUN2014 (1393)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
10AUG2012 (731)	潰瘍性大腸炎 (EXACERBATION OF ULCERATIVE COLITIS.)	Mild/ Not related	No/ NA	None/not applicable	07JAN2013 (881)
20OCT2012 (802)	貧血 (ANEMIA)	Mild/ Not related	No/ NA	None/not applicable	30JAN2013 (904)
20OCT2012 (802)	静脈炎 (PHLEBITIS OF LEFT POPLITEAL VEIN.)	Mild/ Not related	No/ NA	None/not applicable	05DEC2012 (848)
14MAY2013 (1008)	腎超音波検査異常 (HYPOECHOGENIC AREA IN THE UPPER POLE OF LEFT KIDNEJ.)	Mild/ Not related	No/ NA	None/not applicable	28MAY2013 (1022)

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
28MAY2013 (1022)	脂肪肝 (FATTY DEGENERATION OF THE LIVER.)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
28MAY2013 (1022)	子宮平滑筋腫 (UTERINE MYOMA.)	Mild/ Not related	No/ NA	None/not applicable	28MAR2014 (1326)
10AUG2013 (1096)	潰瘍性大腸炎 (EXACERBATION OF ULCERATIVE COLITIS.)	Mild/ Not related	No/ NA	None/not applicable	04OCT2013 (1151)
21AUG2013 (1107)	腎嚢胞 (RIGHT RENAL CYSTS.)	Mild/ Not related	No/ NA	None/not applicable	28MAR2014 (1326)
12OCT2013 (1159)	紅斑 (ERYTHEMA OF THE LEFT LOWER LEG.)	Mild/ Not related	No/ NA	None/not applicable	19OCT2013 (1166)
29JAN2014 (1268)	インフルエンザ (INFLUENZA)	Moderate/ Not related	Yes/ Yes	None/not applicable	06FEB2014 (1276)
15MAR2014 (1313)	発熱 (FEVER)	Moderate/ Not related	Yes/ No	None/not applicable	05APR2014 (1334)
28MAR2014 (1326)	尿路感染 (INFECTION OF URINARY SYSTEM)	Mild/ Not related	Yes/ Yes	None/not applicable	02APR2014 (1331)
28MAR2014 (1326)	回転性めまい (VERTIGO)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
29MAR2014 (1327)	関節痛 (ARTHRALGIA)	Moderate/ Not related	No/ NA	None/not applicable	16APR2014 (1345)
06APR2014 (1335)	貧血 (ANEMIA)	Mild/ Not related	No/ NA	None/not applicable	24APR2014 (1353)
20MAY2014 (1379)	鼻炎 (RHINITIS)	Mild/ Not related	Yes/ No	None/not applicable	03JUN2014 (1393)

■ **Demographics and Baseline Characteristics**

□ Race:Caucasian
□ Age (yrs):5[redacted]
□ Sex:Female
□ Date of birth:25MAY[redacted]
□ Height (cm):169
□ Weight (kg):102.0
□ Date of UC diagnosis:20JUN2001
□ UC disease duration (years):9.0
□ Relevant medical history at baseline:関節炎

■ **Treatment Groups**

□ Induction study:C0524T17

□ Treatment group in induction:400mg -> 200mg SC

□ Treatment group in maintenance:Randomized subject/responder to golimumab induction dosing/golimumab 100 mg in maintenance

□ Dose adjusted?:Yes

□ Adjusted treatment group:Golimumab 100 mg

□ Treatment group during start of LTE:Golimumab 100 mg

□ Dose adjusted during LTE:No

□ Adjusted treatment group during LTE:-

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	07SEP2011	393	1	Placebo	0 mg
Week 56 - EXT	07SEP2011	393	1	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 60 - EXT	05OCT2011	421	2	Placebo	0 mg
Week 60 - EXT	05OCT2011	421	2	Golimumab	100 mg
Week 64 - EXT	02NOV2011	449	3	Placebo	0 mg
Week 64 - EXT	02NOV2011	449	3	Golimumab	100 mg
Week 68 - EXT	29NOV2011	476	4	Golimumab	100 mg
Week 68 - EXT	29NOV2011	476	4	Placebo	0 mg
Week 72 - EXT	02JAN2012	510	5	Golimumab	100 mg
Week 76 - EXT	30JAN2012	538	6	Golimumab	100 mg
Week 80 - EXT	28FEB2012	567	7	Golimumab	100 mg
Week 84 - EXT	28MAR2012	596	8	Golimumab	100 mg
Week 88 - EXT	23APR2012	622	9	Golimumab	100 mg
Week 92 - EXT	24MAY2012	653	10	Golimumab	100 mg
Week 96 - EXT	21JUN2012	681	11	Golimumab	100 mg
Week 100 - EXT	19JUL2012	709	12	Golimumab	100 mg
Week 104 - EXT	23AUG2012	744	13	Golimumab	100 mg
Week 108 - EXT	18SEP2012	770	14	Golimumab	100 mg
Week 112 - EXT	09OCT2012	791	15	Golimumab	100 mg
Week 116 - EXT	06NOV2012	819	16	Golimumab	100 mg
Week 120 - EXT	12DEC2012	855	17	Golimumab	100 mg
Week 124 - EXT	07JAN2013	881	18	Golimumab	100 mg
Week 128 - EXT	30JAN2013	904	19	Golimumab	100 mg
Week 132 - EXT	27FEB2013	932	20	Golimumab	100 mg
Week 136 - EXT	27MAR2013	960	21	Golimumab	100 mg
Week 140 - EXT	24APR2013	988	22	Golimumab	100 mg
Week 144 - EXT	22MAY2013	1016	23	Golimumab	100 mg
Week 148 - EXT	24JUN2013	1049	24	Golimumab	100 mg
Week 152 - EXT	16JUL2013	1071	25	Golimumab	100 mg
Week 156 - EXT	14AUG2013	1100	26	Golimumab	100 mg
Week 160 - EXT	10SEP2013	1127	27	Golimumab	100 mg
Week 164 - EXT	04OCT2013	1151	28	Golimumab	100 mg
Week 168 - EXT	30OCT2013	1177	29	Golimumab	100 mg
Week 172 - EXT	28NOV2013	1206	30	Golimumab	100 mg
Week 176 - EXT	20DEC2013	1228	31	Golimumab	100 mg
Week 180 - EXT	20JAN2014	1259	32	Golimumab	100 mg
Week 184 - EXT	17FEB2014	1287	33	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
PANTOPRAZOLE,Oral	23APR2012	23MAY2012
OMEPRAZOLE,Oral	24MAY2012	06JAN2013
ZOLPIDEM,Oral	21JUN2012	08OCT2012
MEBEVERINE,Oral	09OCT2012	13AUG2013
MEDAZEPAM,Oral	09OCT2012	06APR2014
NADROPARIN,Subcutaneous	20OCT2012	05DEC2012
KENDURAL C,Oral	06NOV2012	13AUG2013
ESOMEPRAZOLE,Oral	07JAN2013	24JUN2013
FOLIC ACID,Oral	14AUG2013	09SEP2013
SIDROS,Oral	14AUG2013	09SEP2013

Prior/Concomitant Therapy, Route	Start Date	End Date
ESOMEPRAZOLE,Oral	14AUG2013	19MAY2014
AZITHROMYCIN,Oral	15OCT2013	19OCT2013
AZITHROMYCIN,Oral	03FEB2014	05FEB2014
PARACETAMOL,Oral	15MAR2014	31MAR2014
CETIRIZINE,Oral	15MAR2014	31MAR2014
DOXYCYCLINE,Subcutaneous	20MAR2014	27MAR2014
SODIUM CHLORIDE,Intravenous	28MAR2014	28MAR2014
ELECTROLYTE SOLUTIONS,Intravenous	28MAR2014	28MAR2014
CEFUROXIME,Oral	29MAR2014	02APR2014
LACTOBACILLUS NOS,Oral	29MAR2014	23APR2014
NIMESULIDE,Oral	29MAR2014	06APR2014
AZITHROMYCIN,Oral	06APR2014	19APR2014
VINPOCETINE,Oral	11APR2014	19MAY2014
PARACETAMOL,Oral	20MAY2014	03JUN2014
ASCORUTIN,Oral	20MAY2014	03JUN2014
PSEUDOEPHEDRINE,Oral	20MAY2014	03JUN2014
ULTRACET,Oral	20MAY2014	Ongoing
VINPOCETINE,Oral	20MAY2014	Ongoing
OMEPRAZOLE,Oral	20MAY2014	03JUN2014
DIPROSPAN /00582101/,Intraarticular	25MAY2014	25MAY2014
OMEPRAZOLE,Oral	04JUN2014	Ongoing

被験者識別コード：7008-00004

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Malignancy

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
08JUN2011 (841)	胃腸炎 (INFECTIOUS GASTROENTERITIS)	Yes	Moderate/ Possible	Yes/ No	None/not applicable	11JUN2011 (844)
16MAY2013 (1549)	扁平上皮癌 (SQUAMOUS CELL CARCINOMA SKIN LESION - LEFT HAND (FULLY EXCISED))	No	Mild/ Unlikely	No/ NA	None/not applicable	16MAY2013 (1549)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
--MAR2012 -	靭帯捻挫 (SPRAINED LEFT ANKLE)	Moderate/ Unlikely	No/ NA	None/not applicable	31OCT2012 (1352)
17MAR2010 (393)	咳嗽 (COUGH)	Mild/ Possible	No/ NA	None/not applicable	20MAR2010 (396)

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
01MAY2010 (438)	潰瘍性大腸炎 (WORSENING OF UC SYMPTOMS)	Mild/ Unlikely	No/ NA	None/not applicable	08DEC2010 (659)
12MAY2010 (449)	口腔咽頭痛 (SORE THROAT)	Mild/ Possible	Yes/ No	None/not applicable	20MAY2010 (457)
19MAY2010 (456)	口腔ヘルペス (COLD SORE)	Mild/ Possible	Yes/ No	None/not applicable	26MAY2010 (463)
08JUN2010 (476)	恥骨上痛 (SUPRA PUBIC PAIN)	Mild/ Possible	No/ NA	None/not applicable	10DEC2010 (661)
17NOV2010 (638)	胃食道逆流性疾患 (REFLUX (GORD))	Mild/ Unlikely	No/ NA	None/not applicable	28JAN2011 (710)
23FEB2011 (736)	咳嗽 (MILD DRY COUGH)	Mild/ Unlikely	Yes/ No	None/not applicable	24MAR2011 (765)
24FEB2011 (737)	胃食道逆流性疾患 (REFLUX (GORD))	Mild/ Unlikely	No/ NA	None/not applicable	Ongoing -
28APR2011 (800)	上気道感染 (UPPER RESPIRATORY TRACT INFECTION)	Mild/ Unlikely	Yes/ No	None/not applicable	10MAY2011 (812)
08JUN2011 (841)	うつ病 (DEPRESSION)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
26AUG2011 (920)	そう痒症 (ITCH (HANDS))	Mild/ Unlikely	No/ NA	None/not applicable	24JAN2012 (1071)
03SEP2011 (928)	上気道感染 (UPPER RESPIRATORY TRACT INFECTION)	Mild/ Possible	Yes/ Yes	None/not applicable	24SEP2011 (949)
26SEP2011 (951)	背部痛 (BACK PAIN)	Mild/ Not related	No/ NA	None/not applicable	02JAN2013 (1415)
21JAN2012 (1068)	尿路感染 (URINARY TRACT INFECTION)	Mild/ Unlikely	Yes/ Yes	None/not applicable	10FEB2012 (1088)
25JAN2012 (1072)	腎感染 (KIDNEY INFECTION)	Mild/ Unlikely	Yes/ Yes	None/not applicable	01FEB2012 (1079)
21FEB2012 (1099)	尿路感染 (URINARY TRACT INFECTION)	Mild/ Unlikely	Yes/ Yes	None/not applicable	01MAR2012 (1108)
22FEB2012 (1100)	筋骨格痛 (MUSCULOSKELETAL PAIN)	Mild/ Unlikely	No/ NA	None/not applicable	02JAN2013 (1415)
16MAY2012 (1184)	呼吸困難 (WORSENING DYSPNOEA)	Moderate/ Possible	No/ NA	None/not applicable	05SEP2012 (1296)
28MAY2012 (1196)	肺腫瘤 (PULMONARY NODULES)	Mild/ Possible	No/ NA	None/not applicable	Ongoing -
06JUN2012 (1205)	湿性咳嗽 (PRODUCTIVE COUGH)	Mild/ Unlikely	No/ NA	None/not applicable	19JUN2012 (1218)
20AUG2012 (1280)	尿路感染 (URINARY TRACT INFECTION)	Mild/ Unlikely	Yes/ Yes	None/not applicable	27AUG2012 (1287)
28AUG2012 (1288)	知覚過敏 (INCREASED FACIAL SENSITIVITY RIGHT SIDE)	Mild/ Possible	No/ NA	None/not applicable	01SEP2012 (1292)
24OCT2012 (1345)	歯肉痛 (SORE GUMS)	Mild/ Unlikely	No/ NA	None/not applicable	26OCT2012 (1347)
31OCT2012 (1352)	ラ音 (FINE CRACKLING LEFT BASE OF LUNG)	Mild/ Unlikely	No/ NA	None/not applicable	28NOV2012 (1380)

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
26NOV2012 (1378)	口腔ヘルペス (COLD SORE (TOP LIP))	Mild/ Possible	Yes/ No	None/not applicable	17DEC2012 (1399)
11DEC2012 (1393)	外陰部腟カンジダ症 (VAGINAL CANDIDIASIS)	Mild/ Unlikely	Yes/ No	None/not applicable	26DEC2012 (1408)
03JAN2013 (1416)	疲労 (FATIGUE)	Mild/ Unlikely	No/ NA	None/not applicable	13MAR2013 (1485)
30JAN2013 (1443)	口唇炎 (ANGULAR STOMATITIS)	Mild/ Unlikely	No/ NA	None/not applicable	13MAR2013 (1485)
04APR2013 (1507)	不安 (ANXIETY)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
04APR2013 (1507)	高血圧 (HYPERTENSION)	Mild/ Unlikely	No/ NA	None/not applicable	Ongoing -
04APR2013 (1507)	上気道感染 (UPPER RESPIRATORY TRACT INFECTION)	Mild/ Unlikely	No/ NA	None/not applicable	11APR2013 (1514)
18JUL2013 (1612)	発疹 (RASH - NECK AND TRUNK)	Moderate/ Not related	No/ NA	None/not applicable	28JUL2013 (1622)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 5[redacted]
□ Sex: Female
□ Date of birth: 12JUN[redacted]
□ Height (cm): 163
□ Weight (kg): 96.0
□ Date of UC diagnosis: -----1998
□ UC disease duration (years): 10.0
□ Relevant medical history at baseline: 喫煙（過去/現在）

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 400mg -> 200mg SC

□ Treatment group in maintenance: Randomized subject/responder to golimumab induction dosing/golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: Not applicable or N/A

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: Yes

□ Adjusted treatment group during LTE: Golimumab 100 mg

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	17MAR2010	393	1	Golimumab	100 mg
Week 56 - EXT	17MAR2010	393	1	Placebo	0 mg
Week 60 - EXT	14APR2010	421	2	Placebo	0 mg
Week 60 - EXT	14APR2010	421	2	Golimumab	100 mg
Week 64 - EXT	19MAY2010	456	3	Placebo	0 mg
Week 64 - EXT	19MAY2010	456	3	Golimumab	100 mg
Week 68 - EXT	09JUN2010	477	1	Golimumab	100 mg
Week 68 - EXT	09JUN2010	477	1	Placebo	0 mg
Week 72 - EXT	30JUN2010	498	2	Placebo	0 mg
Week 72 - EXT	30JUN2010	498	2	Golimumab	100 mg
Week 76 - EXT	04AUG2010	533	3	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 76 - EXT	04AUG2010	533	3	Golimumab	100 mg
Week 80 - EXT	01SEP2010	561	4	Placebo	0 mg
Week 80 - EXT	01SEP2010	561	4	Golimumab	100 mg
Week 84 - EXT	29SEP2010	589	5	Placebo	0 mg
Week 84 - EXT	29SEP2010	589	5	Golimumab	100 mg
Week 88 - EXT	27OCT2010	617	6	Placebo	0 mg
Week 88 - EXT	27OCT2010	617	6	Golimumab	100 mg
Week 92 - EXT	17NOV2010	638	7	Placebo	0 mg
Week 92 - EXT	17NOV2010	638	7	Golimumab	100 mg
Week 96 - EXT	15DEC2010	666	8	Golimumab	100 mg
Week 96 - EXT	15DEC2010	666	8	Placebo	0 mg
Week 100 - EXT	19JAN2011	701	9	Placebo	0 mg
Week 100 - EXT	19JAN2011	701	9	Golimumab	100 mg
Week 104 - EXT	16FEB2011	729	10	Placebo	0 mg
Week 104 - EXT	16FEB2011	729	10	Golimumab	100 mg
Week 108 - EXT	16MAR2011	757	11	Placebo	0 mg
Week 108 - EXT	16MAR2011	757	11	Golimumab	100 mg
Week 112 - EXT	13APR2011	785	12	Golimumab	100 mg
Week 112 - EXT	13APR2011	785	12	Placebo	0 mg
Week 116 - EXT	04MAY2011	806	13	Golimumab	100 mg
Week 116 - EXT	04MAY2011	806	13	Placebo	0 mg
Week 120 - EXT	01JUN2011	834	14	Placebo	0 mg
Week 120 - EXT	01JUN2011	834	14	Golimumab	100 mg
Week 124 - EXT	29JUN2011	862	15	Placebo	0 mg
Week 124 - EXT	29JUN2011	862	15	Golimumab	100 mg
Week 128 - EXT	27JUL2011	890	16	Golimumab	100 mg
Week 128 - EXT	27JUL2011	890	16	Placebo	0 mg
Week 132 - EXT	24AUG2011	918	17	Placebo	0 mg
Week 132 - EXT	24AUG2011	918	17	Golimumab	100 mg
Week 136 - EXT	28SEP2011	953	18	Golimumab	100 mg
Week 136 - EXT	28SEP2011	953	18	Placebo	0 mg
Week 140 - EXT	26OCT2011	981	19	Placebo	0 mg
Week 140 - EXT	26OCT2011	981	19	Golimumab	100 mg
Week 144 - EXT	23NOV2011	1009	20	Golimumab	100 mg
Week 144 - EXT	23NOV2011	1009	20	Placebo	0 mg
Week 148 - EXT	21DEC2011	1037	21	Golimumab	100 mg
Week 152 - EXT	25JAN2012	1072	22	Golimumab	100 mg
Week 156 - EXT	15FEB2012	1093	23	Golimumab	100 mg
Week 160 - EXT	14MAR2012	1121	24	Golimumab	100 mg
Week 164 - EXT	11APR2012	1149	25	Golimumab	100 mg
Week 168 - EXT	09MAY2012	1177	26	Golimumab	100 mg
Week 176 - EXT	05JUL2012	1234	27	Golimumab	100 mg
Week 180 - EXT	01AUG2012	1261	28	Golimumab	100 mg
Week 184 - EXT	05SEP2012	1296	29	Golimumab	100 mg
Week 188 - EXT	03OCT2012	1324	30	Golimumab	100 mg
Week 192 - EXT	31OCT2012	1352	31	Golimumab	100 mg
Week 196 - EXT	28NOV2012	1380	32	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 200 - EXT	02JAN2013	1415	33	Golimumab	100 mg
Week 204 - EXT	16JAN2013	1429	34	Golimumab	100 mg
Week 208 - EXT	13FEB2013	1457	35	Golimumab	100 mg
Week 212 - EXT	13MAR2013	1485	36	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
MELOXICAM,Oral	14APR2010	Ongoing
CODRAL COLD & FLU TABLETS,Oral	12MAY2010	14MAY2010
ALLOPURINOL,Oral	28OCT2010	Ongoing
ESOMEPRAZOLE,Oral	18NOV2010	16FEB2011
PREDNISONE,Oral	03DEC2010	24FEB2011
ESOMEPRAZOLE,Oral	24FEB2011	Ongoing
MAGNESIUM,Oral	19MAR2011	08SEP2011
AMOXICILLIN,Oral	05MAY2011	10MAY2011
METOCLOPRAMIDE,Intravenous	09JUN2011	11JUN2011
OXYCODONE,Oral	09JUN2011	10JUN2011
HYDROCORTISONE,Intravenous	09JUN2011	10JUN2011
HEPARIN,Subcutaneous	09JUN2011	11JUN2011
PARAFFIN, LIQUID,Rectal	10JUN2011	10JUN2011
OXYCODONE,Oral	10JUN2011	10JUN2011
MIDAZOLAM,Intravenous	10JUN2011	10JUN2011
PROPOFOL,Intravenous	10JUN2011	10JUN2011
POTASSIUM,Oral	11JUN2011	11JUN2011
PREDNISONE,Oral	15JUN2011	29JUN2011
FLUVOXAMINE,Oral	15JUN2011	Ongoing
DOXYCYCLINE,Oral	14SEP2011	28SEP2011
CORTISONE,Topical	11OCT2011	18OCT2011
AVENA SATIVA,Topical	12OCT2011	18OCT2011
LIDOCAINE,Topical	24OCT2011	24OCT2011
PROMETHAZINE,Oral	07NOV2011	22NOV2011
LIDOCAINE,Topical	17NOV2011	17NOV2011
SODIUM CITROTARTRATE,Oral	21JAN2012	25JAN2012
AMOXICILLIN W/CLAVULANATE POTASSIUM,Oral	25JAN2012	10FEB2012
NORFLOXACIN,Oral	21FEB2012	24FEB2012
SODIUM CITROTARTRATE,Oral	28FEB2012	01MAR2012
HYDROCORTISONE,Intraarticular	27APR2012	27APR2012
INFLUENZA VACCINE,Intramuscular	17MAY2012	17MAY2012
AMOXICILLIN,Oral	02JUN2012	12JUN2012
CLARITHROMYCIN,Oral	20JUN2012	25JUN2012
DELCOPREP,Oral	01JUL2012	02JUL2012
FENTANYL,Intravenous	02JUL2012	02JUL2012
MIDAZOLAM,Intravenous	02JUL2012	02JUL2012
PROPOFOL,Intravenous	02JUL2012	02JUL2012
NORFLOXACIN,Oral	20AUG2012	27AUG2012
VALACICLOVIR,Oral	29AUG2012	05SEP2012
AZELAIC ACID,Topical	26SEP2012	Ongoing
ANTIVIRALS, TOPICAL,Topical	26NOV2012	17DEC2012

Prior/Concomitant Therapy, Route	Start Date	End Date
LYSINE,Oral	27NOV2012	17DEC2012
NYSTATIN,Oral	15DEC2012	27DEC2012
CLOTRIMAZOLE,Topical	15DEC2012	21DEC2012
AMOXICILLIN,Oral	04APR2013	11APR2013
METOPROLOL,Oral	04APR2013	Ongoing
PROMETHAZINE,Oral	19JUN2013	23JUN2013

2) 寛解維持試験の 0 週にランダム割付けされなかった被験者

a) プラセボ寛解導入 responder

被験者識別コード：6101-00001

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: Malignancy

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
20SEP2010 (902)	卵巣癌 (RIGHT OVARY PT1A CLEAR CELL CARCINOMA.)	Yes	Severe/ Unlikely	No/ NA	Permanent discontinuation of study agent	22SEP2010 (904)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
30OCT2009 (577)	インフルエンザ (INFLUENZA)	Moderate/ Unlikely	Yes/ No	None/not applicable	05NOV2009 (583)
24NOV2009 (602)	歯の障害 (BAD TOOTH.)	Moderate/ Unlikely	No/ NA	None/not applicable	24NOV2009 (602)
16DEC2009 (624)	膀胱炎 (BLADDER INFECTION.)	Moderate/ Unlikely	Yes/ No	None/not applicable	06JAN2010 (645)
30DEC2009 (638)	上気道うっ血 (UPPER RESPIRATORY CONGESTION)	Moderate/ Unlikely	No/ NA	None/not applicable	03JAN2010 (642)
07APR2010 (736)	歯の障害 (DENTAL WORK - TOOTH IMPLANTATION DUE TO BAD TOOTH.)	Moderate/ Unlikely	No/ NA	None/not applicable	07APR2010 (736)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 5[redacted]
□ Sex: Female
□ Date of birth: 22SEP[redacted]
□ Height (cm): 168
□ Weight (kg): 70.1
□ Date of UC diagnosis: -----1984
□ UC disease duration (years): 23.1
□ Relevant medical history at baseline: 喫煙（過去/現在，関節炎，関節痛

■ **Treatment Groups**

□ Induction study: C0524T16

□ Treatment group in induction: Placebo IV

□ Treatment group in maintenance: Non-randomized subject/responder to placebo induction dosing/placebo in maintenance

□ Dose adjusted?: Yes

□ Adjusted treatment group: Golimumab 100 mg

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	30APR2009	394	1	Placebo	0 mg
Week 56 - EXT	30APR2009	394	1	Placebo	0 mg
Week 56 - EXT	30APR2009	394	1	Golimumab	100 mg
Week 60 - EXT	27MAY2009	421	2	Placebo	0 mg
Week 60 - EXT	27MAY2009	421	2	Placebo	0 mg
Week 60 - EXT	27MAY2009	421	2	Golimumab	100 mg
Week 64 - EXT	26JUN2009	451	3	Placebo	0 mg
Week 64 - EXT	26JUN2009	451	3	Placebo	0 mg
Week 64 - EXT	26JUN2009	451	3	Golimumab	100 mg
Week 68 - EXT	22JUL2009	477	4	Placebo	0 mg
Week 68 - EXT	22JUL2009	477	4	Placebo	0 mg
Week 68 - EXT	22JUL2009	477	4	Golimumab	100 mg
Week 72 - EXT	21AUG2009	507	5	Golimumab	100 mg
Week 72 - EXT	21AUG2009	507	5	Placebo	0 mg
Week 72 - EXT	21AUG2009	507	5	Placebo	0 mg
Week 76 - EXT	18SEP2009	535	6	Golimumab	100 mg
Week 76 - EXT	18SEP2009	535	6	Placebo	0 mg
Week 76 - EXT	18SEP2009	535	6	Placebo	0 mg
Week 80 - EXT	16OCT2009	563	7	Golimumab	100 mg
Week 80 - EXT	16OCT2009	563	7	Placebo	0 mg
Week 80 - EXT	16OCT2009	563	7	Placebo	0 mg
Week 84 - EXT	20NOV2009	598	8	Placebo	0 mg
Week 84 - EXT	20NOV2009	598	8	Placebo	0 mg
Week 84 - EXT	20NOV2009	598	8	Golimumab	100 mg
Week 88 - EXT	18DEC2009	626	9	Placebo	0 mg
Week 88 - EXT	18DEC2009	626	9	Placebo	0 mg
Week 88 - EXT	18DEC2009	626	9	Golimumab	100 mg
Week 92 - EXT	13JAN2010	652	10	Placebo	0 mg
Week 92 - EXT	13JAN2010	652	10	Placebo	0 mg
Week 92 - EXT	13JAN2010	652	10	Golimumab	100 mg
Week 96 - EXT	05FEB2010	675	11	Placebo	0 mg
Week 96 - EXT	05FEB2010	675	11	Golimumab	100 mg
Week 96 - EXT	05FEB2010	675	11	Placebo	0 mg
Week 100 - EXT	05MAR2010	703	12	Golimumab	100 mg
Week 100 - EXT	05MAR2010	703	12	Placebo	0 mg
Week 104 - EXT	29MAR2010	727	13	Golimumab	100 mg
Week 104 - EXT	29MAR2010	727	13	Placebo	0 mg
Week 108 - EXT	29APR2010	758	14	Golimumab	100 mg
Week 108 - EXT	29APR2010	758	14	Placebo	0 mg
Week 112 - EXT	28MAY2010	787	15	Placebo	0 mg
Week 112 - EXT	28MAY2010	787	15	Golimumab	100 mg
Week 116 - EXT	25JUN2010	815	16	Golimumab	100 mg
Week 116 - EXT	25JUN2010	815	16	Placebo	0 mg
Week 120 - EXT	23JUL2010	843	17	Golimumab	100 mg
Week 120 - EXT	23JUL2010	843	17	Placebo	0 mg
Week 124 - EXT	20AUG2010	871	18	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 124 - EXT	20AUG2010	871	18	Golimumab	100 mg
Week 128 - EXT	17SEP2010	899	19	Placebo	0 mg
Week 128 - EXT	17SEP2010	899	19	Golimumab	100 mg
Week 132 - EXT	22OCT2010	934	20	Placebo	0 mg
Week 132 - EXT	22OCT2010	934	20	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
PICO-SALAX,Oral	20AUG2009	20AUG2009
MIDAZOLAM,Intravenous	21AUG2009	21AUG2009
FENTANYL,Intravenous	21AUG2009	21AUG2009
HOMEOPATHIC PREPARATION,Oral	31OCT2009	01NOV2009
XYLOCAINE-EPINEPHRINE,Intrabuccal	24NOV2009	24NOV2009
INFLUENZA VACCINE,Intramuscular	07DEC2009	07DEC2009
INFLUENZA VACCINE,Intramuscular	07DEC2009	07DEC2009
D-MANNOSE,Oral	16DEC2009	06JAN2010
DIMETAPP DM /01518801/,Oral	31DEC2009	03JAN2010
PICO-SALAX,Oral	03FEB2010	04FEB2010
LIDOCAINE,Intrabuccal	07APR2010	07APR2010
PHENOXYMETHYLPENICILLIN,Oral	07APR2010	17APR2010

被験者識別コード：6177-00009

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
15APR2011 (527)	サイトメガロウイルス感染 (PRIMARY CMV INFECTION)	Yes	Moderate/ Possible	Yes/ Yes	Permanent discontinuation of study agent	-MAY2011 -

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
05FEB2011 (458)	気管支炎 (BRONCHITIS)	Mild/ Not related	Yes/ Yes	None/not applicable	19FEB2011 (472)
01APR2011 (513)	関節痛 (ARTHRALGIA)	Moderate/ Possible	No/ NA	Temporary interruption/dose modification	-- MAY2011 -
01APR2011 (513)	咳嗽 (COUGH)	Moderate/ Possible	Yes/ Yes	Temporary interruption/dose modification	-- MAY2011 -

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
01APR2011 (513)	サイトメガロウイルス感染 (NIGHT SWEATS (DUE TO PRIMARY CMV INFECTION))	Moderate/ Possible	Yes/ Yes	Temporary interruption/dose modification	-- MAY2011 -
01APR2011 (513)	頭痛 (HEADACHE)	Moderate/ Possible	No/ NA	Temporary interruption/dose modification	-- MAY2011 -

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 5[redacted]
□ Sex: Male
□ Date of birth: 29OCT[redacted]
□ Height (cm): 163
□ Weight (kg): 79.0
□ Date of UC diagnosis: -----2000
□ UC disease duration (years): 8.7
□ Relevant medical history at baseline: 喫煙（過去/現在）

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: Placebo SC

□ Treatment group in maintenance: Non-randomized subject/responder to placebo induction dosing/placebo in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Placebo

□ Dose adjusted during LTE: Yes

□ Adjusted treatment group during LTE: Golimumab 100 mg

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	14DEC2010	405	1	Placebo	0 mg
Week 56 - EXT	14DEC2010	405	1	Placebo	0 mg
Week 60 - EXT	20JAN2011	442	1	Placebo	0 mg
Week 60 - EXT	20JAN2011	442	1	Golimumab	100 mg
Week 64 - EXT	10FEB2011	463	2	Golimumab	100 mg
Week 64 - EXT	10FEB2011	463	2	Placebo	0 mg
Week 68 - EXT	09MAR2011	490	3	Golimumab	100 mg
Week 68 - EXT	09MAR2011	490	3	Placebo	0 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
GANCICLOVIR,Intravenous	--APR2011	21MAY2011
CLOXACILLIN,Oral	--MAY2011	06MAY2011
AUGMENTIN /00756801/,Oral	05FEB2011	19FEB2011
CLARITHROMYCIN,Oral	01APR2011	--APR2011
BETAMETHASONE,Oral	01APR2011	--APR2011
ROXITHROMYCIN,Oral	28APR2011	07MAY2011

■ **Liver Function Test Results**

Visit	Visit Date	ALT (IU/L)	AST (IU/L)	Total Bilirubin (mg/dL)
Week 56 - EXT	14DEC2010	15.00	18.00	0.50
Week 68 - EXT	09MAR2011	19.00	20.00	0.40
Unscheduled - MAIN	30MAY2011	31.00	34.00	0.40

被験者識別コード：7006-00002

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
29JAN2012 (1127)	帯状疱疹 (LOCALISED SHINGLES LEFT FLANK TO LEFT CHEST)	Yes	Moderate/ Possible	Yes/ Yes	Temporary interruption/dose modification	29FEB2012 (1158)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
28FEB2010 (427)	直腸出血 (RECTAL BLEEDING)	Mild/ Probable	No/ NA	None/not applicable	--JUL2011 -
02JUN2010 (521)	咳嗽 (DRY COUGH)	Mild/ Unlikely	Yes/ No	None/not applicable	30JUN2010 (549)
05OCT2010 (646)	直腸腺腫 (SESSILE SERRATED ADENOMA IN RECTUM)	Mild/ Unlikely	No/ NA	None/not applicable	05OCT2010 (646)
08OCT2010 (649)	群発頭痛 (WORSENING OF CLUSTER HEADACHES)	Moderate/ Possible	No/ NA	None/not applicable	23AUG2011 (968)
12DEC2010 (714)	下気道感染 (CHEST INFECTION)	Moderate/ Possible	Yes/ No	None/not applicable	25DEC2010 (727)
21MAR2011 (813)	靭帯捻挫 (TWISTED LEFT RING FINGER)	Mild/ Not related	No/ NA	None/not applicable	20MAY2011 (873)
25MAR2011 (817)	下気道感染 (LOWER RESPIRATORY TRACT INFECTION)	Mild/ Possible	Yes/ Yes	None/not applicable	14MAY2011 (867)
15MAY2011 (868)	肛門直腸不快感 (ANAL SPHINCTER DISCOMFORT)	Mild/ Possible	No/ NA	None/not applicable	15SEP2011 (991)
15MAY2011 (868)	気分変調性障害 (DYSTHYMIC)	Mild/ Possible	No/ NA	None/not applicable	28AUG2012 (1339)
12JUL2011 (926)	潰瘍性大腸炎 (ULCERATIVE COLITIS EXACERBATION)	Moderate/ Unlikely	No/ NA	None/not applicable	25JUL2011 (939)
13JAN2012 (1111)	湿疹 (BILATERAL ELBOW ECZEMA)	Mild/ Unlikely	No/ NA	None/not applicable	01DEC2012 (1434)
18MAR2012 (1176)	副鼻腔炎 (SINUSITIS)	Mild/ Not related	Yes/ Yes	None/not applicable	01AUG2012 (1312)
28SEP2012 (1370)	便秘 (CONSTIPATION)	Mild/ Not related	No/ NA	None/not applicable	28SEP2012 (1370)
19FEB2013 (1514)	胃腸炎 (GASTROENTERITIS)	Mild/ Possible	Yes/ No	None/not applicable	26FEB2013 (1521)

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
13APR2013 (1567)	副鼻腔炎 (SINUSITIS)	Mild/ Unlikely	Yes/ Yes	None/not applicable	Ongoing -

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 3[redacted] 02NOV[redacted]
□ Sex: Male
□ Height (cm): 185
□ Weight (kg): 82.0
□ Date of UC diagnosis: -----1996
□ UC disease duration (years): 11.9
□ Relevant medical history at baseline: 喫煙（過去/現在）

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: Placebo SC

□ Treatment group in maintenance: Non-randomized subject/responder to placebo induction dosing/placebo in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: Not applicable or N/A

□ Treatment group during start of LTE: Placebo

□ Dose adjusted during LTE: Yes

□ Adjusted treatment group during LTE: Golimumab 100 mg

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	25JAN2010	393	1	Placebo	0 mg
Week 56 - EXT	25JAN2010	393	1	Placebo	0 mg
Week 56 - EXT	25JAN2010	393	1	Placebo	0 mg
Week 60 - EXT	25FEB2010	424	2	Placebo	0 mg
Week 60 - EXT	25FEB2010	424	2	Placebo	0 mg
Week 64 - EXT	22MAR2010	449	3	Placebo	0 mg
Week 64 - EXT	22MAR2010	449	3	Placebo	0 mg
Week 68 - EXT	19APR2010	477	4	Placebo	0 mg
Week 68 - EXT	19APR2010	477	4	Placebo	0 mg
Week 72 - EXT	19MAY2010	507	5	Placebo	0 mg
Week 72 - EXT	19MAY2010	507	5	Placebo	0 mg
Week 76 - EXT	16JUN2010	535	6	Placebo	0 mg
Week 76 - EXT	16JUN2010	535	6	Placebo	0 mg
Week 80 - EXT	12JUL2010	561	7	Placebo	0 mg
Week 80 - EXT	12JUL2010	561	7	Placebo	0 mg
Week 84 - EXT	09AUG2010	589	8	Placebo	0 mg
Week 84 - EXT	09AUG2010	589	8	Placebo	0 mg
Week 88 - EXT	06SEP2010	617	9	Placebo	0 mg
Week 88 - EXT	06SEP2010	617	9	Placebo	0 mg
Week 92 - EXT	04OCT2010	645	10	Placebo	0 mg
Week 92 - EXT	04OCT2010	645	10	Placebo	0 mg
Week 96 - EXT	01NOV2010	673	11	Placebo	0 mg
Week 96 - EXT	01NOV2010	673	11	Placebo	0 mg
Week 100 - EXT	29NOV2010	701	12	Placebo	0 mg
Week 100 - EXT	29NOV2010	701	12	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 104 - EXT	29DEC2010	731	13	Placebo	0 mg
Week 104 - EXT	29DEC2010	731	13	Placebo	0 mg
Week 108 - EXT	24JAN2011	757	14	Placebo	0 mg
Week 108 - EXT	24JAN2011	757	14	Placebo	0 mg
Week 112 - EXT	24FEB2011	788	15	Placebo	0 mg
Week 112 - EXT	24FEB2011	788	15	Placebo	0 mg
Week 116 - EXT	23MAR2011	815	16	Placebo	0 mg
Week 116 - EXT	23MAR2011	815	16	Placebo	0 mg
Week 120 - EXT	28APR2011	851	17	Placebo	0 mg
Week 120 - EXT	28APR2011	851	17	Placebo	0 mg
Week 124 - EXT	23MAY2011	876	18	Placebo	0 mg
Week 124 - EXT	23MAY2011	876	18	Placebo	0 mg
Week 128 - EXT	01JUL2011	915	19	Placebo	0 mg
Week 128 - EXT	01JUL2011	915	19	Placebo	0 mg
Week 132 - EXT	19JUL2011	933	1	Placebo	0 mg
Week 132 - EXT	19JUL2011	933	1	Golimumab	100 mg
Week 136 - EXT	17AUG2011	962	2	Placebo	0 mg
Week 136 - EXT	17AUG2011	962	2	Golimumab	100 mg
Week 140 - EXT	15SEP2011	991	3	Placebo	0 mg
Week 140 - EXT	15SEP2011	991	3	Golimumab	100 mg
Week 144 - EXT	03OCT2011	1009	4	Placebo	0 mg
Week 144 - EXT	03OCT2011	1009	4	Golimumab	100 mg
Week 148 - EXT	31OCT2011	1037	5	Placebo	0 mg
Week 148 - EXT	31OCT2011	1037	5	Golimumab	100 mg
Week 152 - EXT	28NOV2011	1065	6	Golimumab	100 mg
Week 152 - EXT	28NOV2011	1065	6	Placebo	0 mg
Week 156 - EXT	21DEC2011	1088	7	Golimumab	100 mg
Week 160 - EXT	16JAN2012	1114	8	Golimumab	100 mg
Week 168 - EXT	07MAR2012	1165	9	Golimumab	100 mg
Week 172 - EXT	02APR2012	1191	10	Golimumab	100 mg
Week 176 - EXT	30APR2012	1219	11	Golimumab	100 mg
Week 180 - EXT	28MAY2012	1247	12	Golimumab	100 mg
Week 184 - EXT	27JUN2012	1277	13	Golimumab	100 mg
Week 188 - EXT	23JUL2012	1303	14	Golimumab	100 mg
Week 192 - EXT	27AUG2012	1338	15	Golimumab	100 mg
Week 196 - EXT	17SEP2012	1359	16	Golimumab	100 mg
Week 200 - EXT	15OCT2012	1387	17	Golimumab	100 mg
Week 204 - EXT	13NOV2012	1416	18	Golimumab	100 mg
Week 208 - EXT	10DEC2012	1443	19	Golimumab	100 mg
Week 212 - EXT	14JAN2013	1478	20	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
GLYCERYL TRINITRATE,Rectal	19MAY2010	-----2012
THOMAPYRIN N,Oral	17NOV2010	03JAN2011
PARACETAMOL,Oral	04JAN2011	Ongoing
BUDESONIDE W/FORMOTEROL FUMARATE,Inhalation	01APR2011	01MAY2011
AMOXICILLIN,Oral	01APR2011	08APR2011

Prior/Concomitant Therapy, Route	Start Date	End Date
PROPOFOL,Intravenous	15JUL2011	15JUL2011
VACCIN IPAD D.T.C.,Intramuscular	02NOV2011	02NOV2011
TWINRIX,Intramuscular	02NOV2011	02NOV2011
PNEUMOCOCCAL VACCINE,Intramuscular	02NOV2011	02NOV2011
HYDROCORTISONE,Topical	16JAN2012	18JAN2012
AMITRIPTYLINE,Oral	30JAN2012	12FEB2012
PANADEINE CO,Oral	30JAN2012	11FEB2012
FAMCICLOVIR,Oral	01FEB2012	12FEB2012
METOCLOPRAMIDE,Oral	01FEB2012	01FEB2012
AMOXICILLIN,Oral	27MAR2012	01APR2012
DIPHENHYDRAMINE,Oral	28MAR2012	31MAR2012
ROXITHROMYCIN,Oral	12APR2012	17APR2012
BUDESONIDE,Intranasal	30MAY2012	31JUL2012
MIRTAZAPINE,Oral	26JUL2012	28AUG2012
AMOXICILLIN W/CLAVULANATE POTASSIUM,Oral	26JUL2012	01AUG2012
PROPOFOL,Intravenous	15OCT2012	15OCT2012
FENTANYL,Intravenous	15OCT2012	15OCT2012
AMOXICILLIN W/CLAVULANATE POTASSIUM,Oral	16APR2013	20APR2013

被験者識別コード：7079-00004

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: TB related

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
18NOV2011 (1062)	肺結核 (PULMONARY TUBERCULOSIS)	Yes	Moderate/ Not related	Yes/ Yes	Permanent discontinuation of study agent	13MAR2012 (1178)

■ **Other Adverse Events**

No Other Adverse Events reported

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 3[redacted]
□ Sex: Female
□ Date of birth: 05NOV[redacted]
□ Height (cm): 164
□ Weight (kg): 65.0
□ Date of UC diagnosis: 25NOV2007
□ UC disease duration (years): 1.0
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: Placebo SC

□ Treatment group in maintenance: Non-randomized subject/responder to placebo induction dosing/placebo in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Placebo

□ Dose adjusted during LTE: Yes

□ Adjusted treatment group during LTE: Golimumab 100 mg

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	25JAN2010	400	1	Placebo	0 mg
Week 56 - EXT	25JAN2010	400	1	Placebo	0 mg
Week 56 - EXT	25JAN2010	400	1	Placebo	0 mg
Week 60 - EXT	22FEB2010	428	2	Placebo	0 mg
Week 60 - EXT	22FEB2010	428	2	Placebo	0 mg
Week 60 - EXT	22FEB2010	428	2	Placebo	0 mg
Week 64 - EXT	22MAR2010	456	3	Placebo	0 mg
Week 64 - EXT	22MAR2010	456	3	Placebo	0 mg
Week 68 - EXT	19APR2010	484	4	Placebo	0 mg
Week 68 - EXT	19APR2010	484	4	Placebo	0 mg
Week 72 - EXT	17MAY2010	512	5	Placebo	0 mg
Week 72 - EXT	17MAY2010	512	5	Placebo	0 mg
Week 76 - EXT	14JUN2010	540	6	Placebo	0 mg
Week 76 - EXT	14JUN2010	540	6	Placebo	0 mg
Week 80 - EXT	12JUL2010	568	7	Placebo	0 mg
Week 80 - EXT	12JUL2010	568	7	Placebo	0 mg
Week 84 - EXT	09AUG2010	596	8	Placebo	0 mg
Week 84 - EXT	09AUG2010	596	8	Placebo	0 mg
Week 88 - EXT	07SEP2010	625	9	Placebo	0 mg
Week 88 - EXT	07SEP2010	625	9	Placebo	0 mg
Week 92 - EXT	04OCT2010	652	10	Placebo	0 mg
Week 92 - EXT	04OCT2010	652	10	Placebo	0 mg
Week 96 - EXT	01NOV2010	680	11	Placebo	0 mg
Week 96 - EXT	01NOV2010	680	11	Placebo	0 mg
Week 100 - EXT	29NOV2010	708	12	Placebo	0 mg
Week 100 - EXT	29NOV2010	708	12	Placebo	0 mg
Week 104 - EXT	27DEC2010	736	13	Placebo	0 mg
Week 104 - EXT	27DEC2010	736	13	Placebo	0 mg
Week 108 - EXT	24JAN2011	764	14	Placebo	0 mg
Week 108 - EXT	24JAN2011	764	14	Placebo	0 mg
Week 112 - EXT	21FEB2011	792	15	Placebo	0 mg
Week 112 - EXT	21FEB2011	792	15	Placebo	0 mg
Week 116 - EXT	21MAR2011	820	16	Placebo	0 mg
Week 116 - EXT	21MAR2011	820	16	Placebo	0 mg
Week 120 - EXT	18APR2011	848	17	Placebo	0 mg
Week 120 - EXT	18APR2011	848	17	Placebo	0 mg
Week 124 - EXT	16MAY2011	876	18	Placebo	0 mg
Week 124 - EXT	16MAY2011	876	18	Placebo	0 mg
Week 128 - EXT	13JUN2011	904	19	Placebo	0 mg
Week 128 - EXT	13JUN2011	904	19	Placebo	0 mg
Week 132 - EXT	11JUL2011	932	20	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 132 - EXT	11JUL2011	932	20	Placebo	0 mg
Week 136 - EXT	08AUG2011	960	21	Placebo	0 mg
Week 136 - EXT	08AUG2011	960	21	Placebo	0 mg
Week 140 - EXT	07SEP2011	990	22	Placebo	0 mg
Week 140 - EXT	07SEP2011	990	22	Placebo	0 mg
Week 144 - EXT	03OCT2011	1016	1	Placebo	0 mg
Week 144 - EXT	03OCT2011	1016	1	Golimumab	100 mg
Week 148 - EXT	31OCT2011	1044	2	Placebo	0 mg
Week 148 - EXT	31OCT2011	1044	2	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
RIFAMPICIN,Oral	01DEC2011	Ongoing
ISONIAZID,Oral	01DEC2011	18AUG2012
PREDNISOLONE,Oral	14MAR2012	21MAR2012

被験者識別コード：7213-00003

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
01OCT2011 (844)	潰瘍性大腸炎 (UC FLARE)	Yes	Severe/ Not related	No/ NA	Permanent discontinuation of study agent	17OCT2011 (860)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
--APR2011 -	脱毛症 (HAIRLOSS DUE TO SITE EFFECTS OF PREDNISOLON)	Moderate/ Unlikely	No/ NA	None/not applicable	--JUN2011 -
--FEB2011 -	潰瘍性大腸炎 (WORSENING OF ULCERATIVE COLITIS)	Moderate/ Not related	No/ NA	Temporary interruption/dose modification	--APR2011 -
30JUL2011 (781)	潰瘍性大腸炎 (WORSENING OF ULCERATIVE COLITIS)	Moderate/ Not related	No/ NA	None/not applicable	Ongoing -
30AUG2011 (812)	アラニンアミノトランスフェラーゼ増加 (HIGH ALT RESULT)	Moderate/ Unlikely	No/ NA	None/not applicable	08NOV2011 (882)
30AUG2011 (812)	アスパラギン酸アミノトランスフェラーゼ増加 (HIGH AST RESULT)	Moderate/ Unlikely	No/ NA	None/not applicable	08NOV2011 (882)

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
01OCT2011 (844)	腹部圧痛 (DIFFUSE TENDERNESS ON ABDOMINAL PALPATION)	Moderate/ Not related	No/ NA	None/not applicable	17OCT2011 (860)
01OCT2011 (844)	悪液質 (CACHEXIA)	Moderate/ Not related	No/ NA	None/not applicable	Ongoing -
01OCT2011 (844)	胃腸音異常 (VIVID ABDOMINAL SOUNDS)	Moderate/ Not related	No/ NA	None/not applicable	17OCT2011 (860)
01OCT2011 (844)	蒼白 (PALLOR)	Moderate/ Not related	No/ NA	None/not applicable	Ongoing -

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 2[redacted]
□ Sex: Female
□ Date of birth: 01AUG[redacted]
□ Height (cm): 160
□ Weight (kg): 37.9
□ Date of UC diagnosis: --SEP2006
□ UC disease duration (years): 2.6
□ Relevant medical history at baseline: 関節痛

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: Placebo SC

□ Treatment group in maintenance: Non-randomized subject/responder to placebo induction dosing/placebo in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Placebo

□ Dose adjusted during LTE: Yes

□ Adjusted treatment group during LTE: Golimumab 100 mg

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	07JUL2010	393	1	Placebo	0 mg
Week 56 - EXT	07JUL2010	393	1	Placebo	0 mg
Week 60 - EXT	04AUG2010	421	2	Placebo	0 mg
Week 60 - EXT	04AUG2010	421	2	Placebo	0 mg
Week 64 - EXT	08SEP2010	456	3	Placebo	0 mg
Week 64 - EXT	08SEP2010	456	3	Placebo	0 mg
Week 68 - EXT	04OCT2010	482	4	Placebo	0 mg
Week 68 - EXT	04OCT2010	482	4	Placebo	0 mg
Week 72 - EXT	27OCT2010	505	5	Placebo	0 mg
Week 72 - EXT	27OCT2010	505	5	Placebo	0 mg
Week 76 - EXT	24NOV2010	533	6	Placebo	0 mg
Week 76 - EXT	24NOV2010	533	6	Placebo	0 mg
Week 80 - EXT	20DEC2010	559	7	Placebo	0 mg
Week 80 - EXT	20DEC2010	559	7	Placebo	0 mg
Week 84 - EXT	26JAN2011	596	8	Placebo	0 mg
Week 84 - EXT	26JAN2011	596	8	Placebo	0 mg
Week 88 - EXT	18FEB2011	619	9	Placebo	0 mg
Week 88 - EXT	18FEB2011	619	9	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 92 - EXT	10MAR2011	639	1	Golimumab	100 mg
Week 92 - EXT	10MAR2011	639	1	Placebo	0 mg
Week 96 - EXT	19APR2011	679	2	Golimumab	100 mg
Week 96 - EXT	19APR2011	679	2	Placebo	0 mg
Week 100 - EXT	16MAY2011	706	3	Golimumab	100 mg
Week 100 - EXT	16MAY2011	706	3	Placebo	0 mg
Week 104 - EXT	06JUN2011	727	4	Golimumab	100 mg
Week 104 - EXT	06JUN2011	727	4	Placebo	0 mg
Week 108 - EXT	05JUL2011	756	5	Placebo	0 mg
Week 108 - EXT	05JUL2011	756	5	Golimumab	100 mg
Week 112 - EXT	04AUG2011	786	6	Golimumab	100 mg
Week 112 - EXT	04AUG2011	786	6	Placebo	0 mg
Week 116 - EXT	30AUG2011	812	7	Placebo	0 mg
Week 116 - EXT	30AUG2011	812	7	Golimumab	100 mg
Week 120 - EXT	27SEP2011	840	8	Golimumab	100 mg
Week 120 - EXT	27SEP2011	840	8	Placebo	0 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
PREDNISOLONE,Oral	02MAR2011	24APR2011
MIDAZOLAM,Intravenous	02MAR2011	02MAR2011
PROPOFOL,Intravenous	02MAR2011	02MAR2011
PREDNISOLONE,Oral	02AUG2011	04AUG2011
METHOTREXATE,Subcutaneous	12AUG2011	Ongoing
FOLIC ACID,Oral	13AUG2011	Ongoing
PREDNISOLONE,Oral	30AUG2011	01SEP2011
TRAMADOL,Oral	31AUG2011	Ongoing
MESALAZINE,Oral	31AUG2011	Ongoing
MESALAZINE,Oral	01OCT2011	Ongoing
OMEPRAZOLE,Oral	01OCT2011	--NOV2011
CICLOSPORIN,Intravenous	05OCT2011	16OCT2011
INFLIXIMAB,Intravenous	25OCT2011	Ongoing

被験者識別コード：7401-00006

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
02MAR2011 (785)	胸椎骨折 (THORACIC VERTEBRAL FRACTURE)	Yes	Severe/ Not related	No/ NA	Permanent discontinuation of study agent	Ongoing -

■ **Other Adverse Events**

No Other Adverse Events reported

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 3[redacted]
□ Sex: Male
□ Date of birth: 26MAR[redacted]
□ Height (cm): 181
□ Weight (kg): 71.0
□ Date of UC diagnosis: 26MAY2006
□ UC disease duration (years): 2.5
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: Placebo SC

□ Treatment group in maintenance: Non-randomized subject/responder to placebo induction dosing/placebo in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Placebo

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	10FEB2010	400	1	Placebo	0 mg
Week 56 - EXT	10FEB2010	400	1	Placebo	0 mg
Week 56 - EXT	10FEB2010	400	1	Placebo	0 mg
Week 60 - EXT	03MAR2010	421	2	Placebo	0 mg
Week 60 - EXT	03MAR2010	421	2	Placebo	0 mg
Week 64 - EXT	31MAR2010	449	3	Placebo	0 mg
Week 64 - EXT	31MAR2010	449	3	Placebo	0 mg
Week 68 - EXT	28APR2010	477	4	Placebo	0 mg
Week 68 - EXT	28APR2010	477	4	Placebo	0 mg
Week 72 - EXT	26MAY2010	505	5	Placebo	0 mg
Week 72 - EXT	26MAY2010	505	5	Placebo	0 mg
Week 76 - EXT	23JUN2010	533	6	Placebo	0 mg
Week 76 - EXT	23JUN2010	533	6	Placebo	0 mg
Week 80 - EXT	21JUL2010	561	7	Placebo	0 mg
Week 80 - EXT	21JUL2010	561	7	Placebo	0 mg
Week 84 - EXT	18AUG2010	589	8	Placebo	0 mg
Week 84 - EXT	18AUG2010	589	8	Placebo	0 mg
Week 88 - EXT	08SEP2010	610	9	Placebo	0 mg
Week 88 - EXT	08SEP2010	610	9	Placebo	0 mg
Week 92 - EXT	13OCT2010	645	10	Placebo	0 mg
Week 92 - EXT	13OCT2010	645	10	Placebo	0 mg
Week 96 - EXT	09NOV2010	672	11	Placebo	0 mg
Week 96 - EXT	09NOV2010	672	11	Placebo	0 mg
Week 100 - EXT	08DEC2010	701	12	Placebo	0 mg
Week 100 - EXT	08DEC2010	701	12	Placebo	0 mg
Week 104 - EXT	05JAN2011	729	13	Placebo	0 mg
Week 104 - EXT	05JAN2011	729	13	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 108 - EXT	02FEB2011	757	14	Placebo	0 mg
Week 108 - EXT	02FEB2011	757	14	Placebo	0 mg

■ **Treatment and Study Status**

□ Date of study discontinuation: 02MAR2011

□ Reason for noncompletion: Withdrawal of consent

□ Other reason for noncompletion/details: -

□ Date of disposition status: 02Mar2011

■ **Concomitant Medications**

No Concomitant Medications reported.

被験者識別コード：7407-00010

■ **REASON FOR NARRATIVE SELECTION**

Death

SAE

Discontinuation of study agent due to AE

Event of interest: Serious infection

Event of interest: Heart failure

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
11MAR2011 (731)	心筋梗塞 (CARDIAC INFARCT)	Yes	Moderate/ Not related	No/ NA	Permanent discontinuation of study agent	18MAR2011 (738)
23MAR2011 (743)	心不全 (HEART FAILURE)	Yes	Severe/ Not related	No/ NA	Permanent discontinuation of study agent	27MAR2011 (747)
23MAR2011 (743)	肺炎 (PNEUMONIA)	Yes	Severe/ Not related	Yes/ Yes	Permanent discontinuation of study agent	27MAR2011 (747)

■ **Other Adverse Events**

No Other Adverse Events reported

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 5[redacted]
□ Sex: Male
□ Date of birth: 01NOV[redacted]
□ Height (cm): 175
□ Weight (kg): 95.0
□ Date of UC diagnosis: 07MAR2000
□ UC disease duration (years): 8.9
□ Relevant medical history at baseline: 喫煙（過去/現在）

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: Placebo SC

□ Treatment group in maintenance: Non-randomized subject/responder to placebo induction dosing/placebo in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Placebo

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	07APR2010	393	1	Placebo	0 mg
Week 56 - EXT	07APR2010	393	1	Placebo	0 mg
Week 60 - EXT	06MAY2010	422	2	Placebo	0 mg
Week 60 - EXT	06MAY2010	422	2	Placebo	0 mg
Week 64 - EXT	02JUN2010	449	3	Placebo	0 mg
Week 64 - EXT	02JUN2010	449	3	Placebo	0 mg
Week 68 - EXT	30JUN2010	477	4	Placebo	0 mg
Week 68 - EXT	30JUN2010	477	4	Placebo	0 mg
Week 72 - EXT	27JUL2010	504	5	Placebo	0 mg
Week 72 - EXT	27JUL2010	504	5	Placebo	0 mg
Week 76 - EXT	25AUG2010	533	6	Placebo	0 mg
Week 76 - EXT	25AUG2010	533	6	Placebo	0 mg
Week 80 - EXT	22SEP2010	561	7	Placebo	0 mg
Week 80 - EXT	22SEP2010	561	7	Placebo	0 mg
Week 84 - EXT	20OCT2010	589	8	Placebo	0 mg
Week 84 - EXT	20OCT2010	589	8	Placebo	0 mg
Week 88 - EXT	17NOV2010	617	9	Placebo	0 mg
Week 88 - EXT	17NOV2010	617	9	Placebo	0 mg
Week 92 - EXT	15DEC2010	645	10	Placebo	0 mg
Week 92 - EXT	15DEC2010	645	10	Placebo	0 mg
Week 96 - EXT	12JAN2011	673	11	Placebo	0 mg
Week 96 - EXT	12JAN2011	673	11	Placebo	0 mg
Week 100 - EXT	09FEB2011	701	12	Placebo	0 mg
Week 100 - EXT	09FEB2011	701	12	Placebo	0 mg
Week 104 - EXT	09MAR2011	729	13	Placebo	0 mg
Week 104 - EXT	09MAR2011	729	13	Placebo	0 mg

■ **Treatment and Study Status**

□ Date of study discontinuation: 27Mar2011

□ Reason for noncompletion: Death

□ Other reason for noncompletion/details: -

□ Date of disposition status: 27Mar2011

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
SPIRONOLACTONE,Oral	11MAR2011	27MAR2011
GLYCERYL TRINITRATE,Intravenous	11MAR2011	14MAR2011
ACETYLSALICYLIC ACID,Oral	11MAR2011	27MAR2011
WARFARIN,Oral	11MAR2011	27MAR2011
ACETYLCYSTEINE,Oral	11MAR2011	18MAR2011
FUROSEMIDE,Intravenous	11MAR2011	18MAR2011
METOPROLOL,Oral	11MAR2011	27MAR2011
GLICLAZIDE,Oral	11MAR2011	27MAR2011

Prior/Concomitant Therapy, Route	Start Date	End Date
AUGMENTIN /00756801/,Intravenous	11MAR2011	18MAR2011
RAMIPRIL,Oral	11MAR2011	27MAR2011
SIMVASTATIN,Oral	11MAR2011	18MAR2011
CLOPIDOGREL,Oral	11MAR2011	27MAR2011
GLYCERYL TRINITRATE,Sublingual	19MAR2011	27MAR2011
FUROSEMIDE,Oral	19MAR2011	27MAR2011
AUGMENTIN /00756801/,Oral	19MAR2011	22MAR2011
ATORVASTATIN,Oral	19MAR2011	27MAR2011

被験者識別コード：7732-00005

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
03MAY2011 (581)	胸膜炎 (COUGH WITH PLEURITC CHEST PAIN)	No	Moderate/ Possible	Yes/ No	Permanent discontinuation of study agent	23MAY2012 (967)
03MAY2011 (581)	肺炎 (MULTIFOCAL CAVITARY PNEUMONIA)	Yes	Moderate/ Possible	Yes/ Yes	Permanent discontinuation of study agent	25MAY2012 (969)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
15DEC2010 (442)	背部痛 (BACK PAIN)	Moderate/ Not related	No/ NA	None/not applicable	01MAR2011 (518)
01MAR2011 (518)	発熱 (FEVER)	Mild/ Possible	Yes/ No	None/not applicable	08MAR2011 (525)
01MAR2011 (518)	副鼻腔炎 (SINUS INFECTION)	Mild/ Possible	Yes/ Yes	None/not applicable	08MAR2011 (525)
21APR2011 (569)	咳嗽 (NON-PRODUCTIVE COUGH)	Moderate/ Possible	Yes/ No	None/not applicable	Ongoing -
21APR2011 (569)	深部静脈血栓症 (RIGHT LOWER EXTREMITY DEEP VENOUS THROMBOSIS)	Moderate/ Unlikely	No/ NA	None/not applicable	21APR2011 (569)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 4[redacted]
□ Sex: Female
□ Date of birth: 05APR[redacted]
□ Height (cm): 163
□ Weight (kg): 49.5
□ Date of UC diagnosis: -----1997
□ UC disease duration (years): 11.6
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: Placebo SC

□ Treatment group in maintenance: Non-randomized subject/responder to placebo induction dosing/placebo in maintenance

□ Dose adjusted?: Yes

□ Adjusted treatment group: Golimumab 100 mg

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	28OCT2010	394	1	Golimumab	100 mg
Week 56 - EXT	28OCT2010	394	1	Placebo	0 mg
Week 60 - EXT	23NOV2010	420	2	Placebo	0 mg
Week 60 - EXT	23NOV2010	420	2	Golimumab	100 mg
Week 64 - EXT	29DEC2010	456	3	Placebo	0 mg
Week 64 - EXT	29DEC2010	456	3	Golimumab	100 mg
Week 68 - EXT	27JAN2011	485	4	Placebo	0 mg
Week 68 - EXT	27JAN2011	485	4	Golimumab	100 mg
Week 72 - EXT	24FEB2011	513	5	Golimumab	100 mg
Week 72 - EXT	24FEB2011	513	5	Placebo	0 mg
Week 76 - EXT	24MAR2011	541	6	Golimumab	100 mg
Week 76 - EXT	24MAR2011	541	6	Placebo	0 mg
Week 80 - EXT	21APR2011	569	7	Placebo	0 mg
Week 80 - EXT	21APR2011	569	7	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
CYCLOBENZAPRINE,Oral	29DEC2010	04JAN2011
TRAMADOL,Oral	04JAN2011	15JAN2011
PARACETAMOL,Oral	01MAR2011	06MAR2011
IBUPROFEN,Oral	02MAR2011	07MAR2011
PENICILLIN NOS,Oral	05MAR2011	07MAR2011
WARFARIN,Oral	22APR2011	Ongoing
FONDAPARINUX,Subcutaneous	26MAY2011	02JUN2011
VORICONAZOLE,Oral	18JUN2011	14JUL2011
DOXYCYCLINE,Oral	31JUL2011	05AUG2011
POSACONAZOLE,Oral	06AUG2011	Ongoing

b) プラセボ寛解導入 non-responder

被験者識別コード：6078-00002

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: Serious infection

Event of interest: Liver function test (LFT) related

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
09NOV2011 (994)	A型肝炎 (ACUTE HEPATITIS A.)	Yes	Severe/ Not related	Yes/ No	Permanent discontinuation of study agent	21NOV2011 (1006)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
15OCT2010 (604)	ウイルス感染 (VIRAL INFECTION)	Mild/ Not related	Yes/ No	None/not applicable	01NOV2010 (621)

■ **Demographics and Baseline Characteristics**

- □ Race: Caucasian
- □ Age (yrs): 4[redacted]
- □ Sex: Male
- □ Date of birth: 03JUL[redacted]
- □ Height (cm): 168
- □ Weight (kg): 80.5
- □ Date of UC diagnosis: 03MAR2000
- □ UC disease duration (years): 8.8
- □ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T16

□ Treatment group in induction: Placebo IV

□ Treatment group in maintenance: Non-randomized subject/non-responder to placebo induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	09MAR2010	384	1	Placebo	0 mg
Week 56 - EXT	09MAR2010	384	1	Golimumab	100 mg
Week 60 - EXT	07APR2010	413	2	Placebo	0 mg
Week 60 - EXT	07APR2010	413	2	Golimumab	100 mg
Week 64 - EXT	04MAY2010	440	3	Placebo	0 mg
Week 64 - EXT	04MAY2010	440	3	Golimumab	100 mg
Week 68 - EXT	03JUN2010	470	4	Golimumab	100 mg
Week 68 - EXT	03JUN2010	470	4	Placebo	0 mg
Week 72 - EXT	29JUN2010	496	5	Golimumab	100 mg
Week 72 - EXT	29JUN2010	496	5	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 76 - EXT	28JUL2010	525	6	Golimumab	100 mg
Week 76 - EXT	28JUL2010	525	6	Placebo	0 mg
Week 80 - EXT	20AUG2010	548	7	Placebo	0 mg
Week 80 - EXT	20AUG2010	548	7	Golimumab	100 mg
Week 84 - EXT	17SEP2010	576	8	Placebo	0 mg
Week 84 - EXT	17SEP2010	576	8	Golimumab	100 mg
Week 88 - EXT	01NOV2010	621	9	Placebo	0 mg
Week 88 - EXT	01NOV2010	621	9	Golimumab	100 mg
Week 92 - EXT	26NOV2010	646	10	Golimumab	100 mg
Week 92 - EXT	26NOV2010	646	10	Placebo	0 mg
Week 96 - EXT	27DEC2010	677	11	Golimumab	100 mg
Week 96 - EXT	27DEC2010	677	11	Placebo	0 mg
Week 100 - EXT	21JAN2011	702	12	Golimumab	100 mg
Week 100 - EXT	21JAN2011	702	12	Placebo	0 mg
Week 104 - EXT	01MAR2011	741	13	Golimumab	100 mg
Week 104 - EXT	01MAR2011	741	13	Placebo	0 mg
Week 108 - EXT	18MAR2011	758	14	Golimumab	100 mg
Week 108 - EXT	18MAR2011	758	14	Placebo	0 mg
Week 112 - EXT	18APR2011	789	15	Golimumab	100 mg
Week 112 - EXT	18APR2011	789	15	Placebo	0 mg
Week 116 - EXT	20MAY2011	821	16	Golimumab	100 mg
Week 116 - EXT	20MAY2011	821	16	Placebo	0 mg
Week 120 - EXT	20JUN2011	852	17	Placebo	0 mg
Week 120 - EXT	20JUN2011	852	17	Golimumab	100 mg
Week 124 - EXT	18JUL2011	880	18	Placebo	0 mg
Week 124 - EXT	18JUL2011	880	18	Golimumab	100 mg
Week 128 - EXT	15AUG2011	908	19	Golimumab	100 mg
Week 128 - EXT	15AUG2011	908	19	Placebo	0 mg
Week 132 - EXT	15SEP2011	939	20	Golimumab	100 mg
Week 132 - EXT	15SEP2011	939	20	Placebo	0 mg
Week 136 - EXT	06OCT2011	960	21	Golimumab	100 mg
Week 136 - EXT	06OCT2011	960	21	Placebo	0 mg
Week 140 - EXT	07NOV2011	992	22	Golimumab	100 mg
Week 140 - EXT	07NOV2011	992	22	Placebo	0 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
SILYBUM MARIANUM,Oral	11NOV2011	Ongoing

■ **Liver Function Test Results**

Visit	Visit Date	ALT (IU/L)	AST (IU/L)	Total Bilirubin (mg/dL)
Week 56 - EXT	09MAR2010	21.00	22.00	0.70
Week 68 - EXT	03JUN2010	28.00	22.00	0.50
Week 80 - EXT	20AUG2010	19.00	20.00	0.60
Unscheduled - MAIN	15OCT2010	22.00	19.00	0.40
Week 92 - EXT	26NOV2010	20.00	19.00	0.70
Week 104 - EXT	01MAR2011	41.00	26.00	0.60
Week 116 - EXT	20MAY2011	19.00	23.00	0.30
Week 128 - EXT	15AUG2011	16.00	19.00	0.40

Visit	Visit Date	ALT (IU/L)	AST (IU/L)	Total Bilirubin (mg/dL)
Week 140 - EXT	07NOV2011	1493.0	682.00	0.90
Week 140 - EXT	11NOV2011	3910.0	1977.0	5.80
Unscheduled - MAIN	20DEC2011	27.00	22.00	0.70

被験者識別コード：6106-00008

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
14JUL2013 (1103)	クローン病 (CROHN'S DISEASE)	Yes	Severe/ Not related	No/ NA	Permanent discontinuation of study agent	22JUL2013 (1111)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
29NOV2011 (510)	潰瘍性大腸炎 (WORSENING OF ULCERATIVE COLITIS)	Moderate/ Not related	No/ NA	None/not applicable	20DEC2011 (531)
01DEC2011 (512)	鼻咽頭炎 (COMMON HEAD COLD)	Mild/ Not related	No/ NA	None/not applicable	23DEC2011 (534)
07JAN2013 (915)	鼻咽頭炎 (COMMON HEAD COLD)	Mild/ Not related	Yes/ No	None/not applicable	11JAN2013 (919)
20FEB2013 (959)	鼻咽頭炎 (COMMON HEAD CLOD)	Mild/ Not related	Yes/ No	None/not applicable	20MAR2013 (987)
05JUN2013 (1064)	嘔吐 (VOMITTING)	Moderate/ Not related	No/ NA	None/not applicable	07JUN2013 (1066)
23JUL2013 (1112)	クローン病 (CROHN'S DISEASE)	Moderate/ Unlikely	No/ NA	None/not applicable	Ongoing -

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 3[redacted]
□ Sex: Female
□ Date of birth: 12SEP[redacted]
□ Height (cm): 150
□ Weight (kg): 73.4
□ Date of UC diagnosis: 01JAN1995
□ UC disease duration (years): 15.4
□ Relevant medical history at baseline: 喫煙（過去/現在），関節炎

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: Placebo SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to placebo induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	27JUL2011	385	1	Golimumab	100 mg
Week 56 - EXT	27JUL2011	385	1	Placebo	0 mg
Week 60 - EXT	24AUG2011	413	2	Golimumab	100 mg
Week 60 - EXT	24AUG2011	413	2	Placebo	0 mg
Week 64 - EXT	27SEP2011	447	3	Placebo	0 mg
Week 64 - EXT	27SEP2011	447	3	Golimumab	100 mg
Week 68 - EXT	02NOV2011	483	4	Placebo	0 mg
Week 68 - EXT	02NOV2011	483	4	Golimumab	100 mg
Week 72 - EXT	29NOV2011	510	5	Golimumab	100 mg
Week 72 - EXT	29NOV2011	510	5	Placebo	0 mg
Week 76 - EXT	20DEC2011	531	6	Placebo	0 mg
Week 76 - EXT	20DEC2011	531	6	Golimumab	100 mg
Week 80 - EXT	17JAN2012	559	7	Golimumab	100 mg
Week 84 - EXT	14FEB2012	587	8	Golimumab	100 mg
Week 88 - EXT	13MAR2012	615	9	Golimumab	100 mg
Week 92 - EXT	10APR2012	643	10	Golimumab	100 mg
Week 96 - EXT	08MAY2012	671	11	Golimumab	100 mg
Week 100 - EXT	05JUN2012	699	12	Golimumab	100 mg
Week 104 - EXT	26JUN2012	720	13	Golimumab	100 mg
Week 108 - EXT	31JUL2012	755	14	Golimumab	100 mg
Week 112 - EXT	28AUG2012	783	15	Golimumab	100 mg
Week 116 - EXT	25SEP2012	811	16	Golimumab	100 mg
Week 120 - EXT	31OCT2012	847	17	Golimumab	100 mg
Week 124 - EXT	21NOV2012	868	18	Golimumab	100 mg
Week 128 - EXT	18DEC2012	895	19	Golimumab	100 mg
Week 132 - EXT	15JAN2013	923	20	Golimumab	100 mg
Week 136 - EXT	12FEB2013	951	21	Golimumab	100 mg
Week 140 - EXT	26MAR2013	993	22	Golimumab	100 mg
Week 144 - EXT	16APR2013	1014	23	Golimumab	100 mg
Week 148 - EXT	08MAY2013	1036	24	Golimumab	100 mg
Week 152 - EXT	12JUN2013	1071	25	Golimumab	100 mg
Week 156 - EXT	03JUL2013	1092	26	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
MESALAZINE,Oral	28JUL2011	Ongoing
MESALAZINE,Rectal	29NOV2011	Ongoing
MESALAZINE,Topical	31OCT2012	Ongoing
METOPROLOL,Oral	26FEB2013	Ongoing
METRONIDAZOLE,Oral	14JUL2013	Ongoing
LORAZEPAM,Oral	14JUL2013	Ongoing
SOLPADEINE /00154101/,Oral	14JUL2013	Ongoing
ZOPICLONE,Oral	14JUL2013	Ongoing
CIPROFLOXACIN,Oral	14JUL2013	Ongoing
PREDNISONE,Oral	21JUL2013	Ongoing

被験者識別コード：7003-00003

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
28OCT2010 (844)	皮下組織膿瘍 (ABSCESS LEFT BUTTOCK)	Yes	Severe/ Possible	Yes/ Yes	None/not applicable	03DEC2010 (880)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
30OCT2009 (481)	血性下痢 (DIARRHOEA BLEEDING)	Moderate/ Not related	No/ NA	None/not applicable	31OCT2009 (482)
13DEC2009 (525)	潰瘍性大腸炎 (WORSENING UC)	Moderate/ Not related	No/ NA	None/not applicable	27APR2010 (660)
01JUL2010 (725)	気管支炎 (BRONCHITIS)	Mild/ Unlikely	Yes/ Yes	None/not applicable	15JUL2010 (739)
18AUG2010 (773)	上気道感染 (URTI)	Mild/ Not related	Yes/ No	None/not applicable	25AUG2010 (780)
11FEB2011 (950)	ざ瘡 (SMALL 'PIMPLE' - REDDENED AREAON ABDO)	Mild/ Possible	Yes/ Yes	None/not applicable	20MAR2011 (987)
25JUN2011 (1084)	口腔咽頭痛 (SORE THROAT)	Mild/ Not related	Yes/ Yes	None/not applicable	01JUL2011 (1090)

■ **Demographics and Baseline Characteristics**

- □ Race: Caucasian
- □ Age (yrs): 3[redacted]
- □ Sex: Female
- □ Date of birth: 20OCT[redacted]
- □ Height (cm): 165
- □ Weight (kg): 78.0
- □ Date of UC diagnosis: 13SEP2000
- □ UC disease duration (years): 7.7
- □ Relevant medical history at baseline: なし

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: Placebo SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to placebo induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: Not applicable or N/A

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: Not Applicable or N/A

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	20AUG2009	410	1	Golimumab	100 mg
Week 56 - EXT	20AUG2009	410	1	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	20AUG2009	410	1	Placebo	0 mg
Week 60 - EXT	18SEP2009	439	2	Placebo	0 mg
Week 60 - EXT	18SEP2009	439	2	Placebo	0 mg
Week 60 - EXT	18SEP2009	439	2	Golimumab	100 mg
Week 64 - EXT	16OCT2009	467	3	Golimumab	100 mg
Week 64 - EXT	16OCT2009	467	3	Placebo	0 mg
Week 64 - EXT	16OCT2009	467	3	Placebo	0 mg
Week 68 - EXT	09NOV2009	491	4	Placebo	0 mg
Week 68 - EXT	09NOV2009	491	4	Golimumab	100 mg
Week 68 - EXT	09NOV2009	491	4	Placebo	0 mg
Week 72 - EXT	07DEC2009	519	5	Golimumab	100 mg
Week 72 - EXT	07DEC2009	519	5	Placebo	0 mg
Week 72 - EXT	07DEC2009	519	5	Placebo	0 mg
Week 76 - EXT	06JAN2010	549	6	Placebo	0 mg
Week 76 - EXT	06JAN2010	549	6	Golimumab	100 mg
Week 76 - EXT	06JAN2010	549	6	Placebo	0 mg
Week 80 - EXT	04FEB2010	578	7	Placebo	0 mg
Week 80 - EXT	04FEB2010	578	7	Golimumab	100 mg
Week 80 - EXT	04FEB2010	578	7	Placebo	0 mg
Week 84 - EXT	04MAR2010	606	8	Golimumab	100 mg
Week 84 - EXT	04MAR2010	606	8	Placebo	0 mg
Week 88 - EXT	31MAR2010	633	9	Golimumab	100 mg
Week 88 - EXT	31MAR2010	633	9	Placebo	0 mg
Week 92 - EXT	27APR2010	660	10	Golimumab	100 mg
Week 92 - EXT	27APR2010	660	10	Placebo	0 mg
Week 96 - EXT	25MAY2010	688	11	Placebo	0 mg
Week 96 - EXT	25MAY2010	688	11	Golimumab	100 mg
Week 100 - EXT	17JUN2010	711	12	Placebo	0 mg
Week 100 - EXT	17JUN2010	711	12	Golimumab	100 mg
Week 104 - EXT	08JUL2010	732	13	Placebo	0 mg
Week 104 - EXT	08JUL2010	732	13	Golimumab	100 mg
Week 108 - EXT	02AUG2010	757	14	Golimumab	100 mg
Week 108 - EXT	02AUG2010	757	14	Placebo	0 mg
Week 112 - EXT	30AUG2010	785	15	Placebo	0 mg
Week 112 - EXT	30AUG2010	785	15	Golimumab	100 mg
Week 116 - EXT	24SEP2010	810	16	Golimumab	100 mg
Week 116 - EXT	24SEP2010	810	16	Placebo	0 mg
Week 120 - EXT	26OCT2010	842	17	Placebo	0 mg
Week 120 - EXT	26OCT2010	842	17	Golimumab	100 mg
Week 124 - EXT	23NOV2010	870	18	Placebo	0 mg
Week 124 - EXT	23NOV2010	870	18	Golimumab	100 mg
Week 128 - EXT	20DEC2010	897	19	Placebo	0 mg
Week 128 - EXT	20DEC2010	897	19	Golimumab	100 mg
Week 132 - EXT	14JAN2011	922	20	Golimumab	100 mg
Week 132 - EXT	14JAN2011	922	20	Placebo	0 mg
Week 136 - EXT	14FEB2011	953	21	Golimumab	100 mg
Week 136 - EXT	14FEB2011	953	21	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 140 - EXT	17MAR2011	984	22	Placebo	0 mg
Week 140 - EXT	17MAR2011	984	22	Golimumab	100 mg
Week 144 - EXT	12APR2011	1010	23	Placebo	0 mg
Week 144 - EXT	12APR2011	1010	23	Golimumab	100 mg
Week 148 - EXT	10MAY2011	1038	24	Placebo	0 mg
Week 148 - EXT	10MAY2011	1038	24	Golimumab	100 mg
Week 152 - EXT	07JUN2011	1066	25	Placebo	0 mg
Week 152 - EXT	07JUN2011	1066	25	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
MESALAZINE,Rectal	07JAN2010	08MAR2010
ROXITHROMYCIN,Oral	08JUL2010	12JUL2010
CODRAL COLD & FLU,Oral	18AUG2010	25AUG2010
CEFALEXIN,Oral	27OCT2010	28OCT2010
FLUCLOXACILLIN,Intravenous	28OCT2010	29OCT2010
CLINDAMYCIN,Intravenous	28OCT2010	29OCT2010
PANADEINE CO,Oral	29OCT2010	03DEC2010
OXYCODONE,Oral	29OCT2010	31OCT2010
CEFALEXIN,Oral	30OCT2010	10NOV2010
PARACETAMOL,Oral	01NOV2010	Ongoing
MESALAZINE,Oral	15JAN2011	14FEB2011
FLUCLOXACILLIN,Oral	14FEB2011	21FEB2011
BALSALAZIDE,Oral	15FEB2011	Ongoing
MESALAZINE,Rectal	28FEB2011	22JUN2011
CEFACLOR,Oral	27JUN2011	01JUL2011

被験者識別コード：7077-00007

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
06JAN2011 (427)	肺炎 (BILATERAL PNEUMONIA)	Yes	Moderate/ Not related	Yes/ Yes	None/not applicable	14JAN2011 (435)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
03JAN2011 (424)	咳嗽 (COUGH)	Mild/ Not related	Yes/ Yes	None/not applicable	31JAN2011 (452)
04JAN2011 (425)	発熱 (FEVER)	Mild/ Not related	Yes/ Yes	None/not applicable	10JAN2011 (431)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 6[redacted]
□ Sex: Male
□ Date of birth: 14DEC[redacted]
□ Height (cm): 170
□ Weight (kg): 74.0
□ Date of UC diagnosis: --NOV2008
□ UC disease duration (years): 0.8
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: Placebo SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to placebo induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	16DEC2010	406	1	Golimumab	100 mg
Week 56 - EXT	16DEC2010	406	1	Placebo	0 mg
Week 60 - EXT	14JAN2011	435	2	Golimumab	100 mg
Week 60 - EXT	14JAN2011	435	2	Placebo	0 mg
Week 64 - EXT	02FEB2011	454	3	Golimumab	100 mg
Week 64 - EXT	02FEB2011	454	3	Placebo	0 mg
Week 68 - EXT	01MAR2011	481	4	Golimumab	100 mg
Week 68 - EXT	01MAR2011	481	4	Placebo	0 mg
Week 72 - EXT	08APR2011	519	5	Placebo	0 mg
Week 72 - EXT	08APR2011	519	5	Golimumab	100 mg
Week 76 - EXT	09MAY2011	550	6	Golimumab	100 mg
Week 76 - EXT	09MAY2011	550	6	Placebo	0 mg
Week 80 - EXT	01JUN2011	573	7	Placebo	0 mg
Week 80 - EXT	01JUN2011	573	7	Golimumab	100 mg
Week 84 - EXT	28JUN2011	600	8	Golimumab	100 mg
Week 84 - EXT	28JUN2011	600	8	Placebo	0 mg
Week 88 - EXT	28JUL2011	630	9	Placebo	0 mg
Week 88 - EXT	28JUL2011	630	9	Golimumab	100 mg
Week 92 - EXT	16AUG2011	649	10	Golimumab	100 mg
Week 92 - EXT	16AUG2011	649	10	Placebo	0 mg
Week 96 - EXT	15SEP2011	679	11	Golimumab	100 mg
Week 96 - EXT	15SEP2011	679	11	Placebo	0 mg
Week 100 - EXT	13OCT2011	707	12	Placebo	0 mg
Week 100 - EXT	13OCT2011	707	12	Golimumab	100 mg
Week 104 - EXT	01NOV2011	726	13	Golimumab	100 mg
Week 104 - EXT	01NOV2011	726	13	Placebo	0 mg
Week 108 - EXT	06DEC2011	761	14	Golimumab	100 mg
Week 108 - EXT	06DEC2011	761	14	Placebo	0 mg
Week 112 - EXT	04JAN2012	790	15	Golimumab	100 mg
Week 116 - EXT	10FEB2012	827	16	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 120 - EXT	08MAR2012	854	17	Golimumab	100 mg
Week 124 - EXT	28MAR2012	874	18	Golimumab	100 mg
Week 128 - EXT	17APR2012	894	19	Golimumab	100 mg
Week 132 - EXT	19MAY2012	926	20	Golimumab	100 mg
Week 136 - EXT	08JUN2012	946	21	Golimumab	100 mg
Week 140 - EXT	26JUL2012	994	22	Golimumab	100 mg
Week 144 - EXT	20AUG2012	1019	23	Golimumab	100 mg
Week 148 - EXT	19SEP2012	1049	24	Golimumab	100 mg
Week 152 - EXT	17OCT2012	1077	25	Golimumab	100 mg
Week 160 - EXT	06DEC2012	1127	26	Golimumab	100 mg
Week 164 - EXT	08JAN2013	1160	27	Golimumab	100 mg
Week 168 - EXT	01FEB2013	1184	28	Golimumab	100 mg
Week 172 - EXT	28FEB2013	1211	29	Golimumab	100 mg
Week 176 - EXT	18MAR2013	1229	30	Golimumab	100 mg
Week 180 - EXT	08APR2013	1250	31	Golimumab	100 mg
Week 184 - EXT	16MAY2013	1288	32	Golimumab	100 mg
Week 188 - EXT	26JUN2013	1329	33	Golimumab	100 mg
Week 192 - EXT	23JUL2013	1356	34	Golimumab	100 mg
Week 196 - EXT	15AUG2013	1379	35	Golimumab	100 mg
Week 200 - EXT	03SEP2013	1398	36	Golimumab	100 mg
Week 204 - EXT	11OCT2013	1436	37	Golimumab	100 mg
Week 208 - EXT	07NOV2013	1463	38	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
METAMIZOLE,Oral	03JAN2011	06JAN2011
DOXYCYCLINE,Oral	03JAN2011	06JAN2011
GLUCOSE,Intravenous	06JAN2011	14JAN2011
CEFAZOLIN,Intravenous	06JAN2011	10JAN2011
BROMHEXINE,Intravenous	06JAN2011	14JAN2011
CIPROFLOXACIN,Intravenous	10JAN2011	14JAN2011
CIPROFLOXACIN,Oral	14JAN2011	19JAN2011

被験者識別コード：7126-00014

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
03AUG2012 (820)	ウイルス性髄膜炎 (VIRAL MENINGITIS)	Yes	Severe/ Possible	Yes/ Yes	Temporary interruption/dose modification	13AUG2012 (830)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
--AUG2012 -	疲労 (FATIQUE)	Mild/ Not related	No/ NA	None/not applicable	03OCT2012 (881)
24AUG2011 (475)	鼻咽頭炎 (COMMON COLD)	Mild/ Unlikely	Yes/ No	None/not applicable	29AUG2011 (480)
02SEP2011 (484)	頭痛 (HEADACHE)	Mild/ Not related	No/ NA	None/not applicable	20OCT2011 (532)
17JAN2012 (621)	高血圧 (HYPERTENSION)	Moderate/ Not related	No/ NA	None/not applicable	Ongoing -
30JUL2012 (816)	頭痛 (HEADACHE)	Severe/ Not related	No/ NA	None/not applicable	13AUG2012 (830)
13AUG2012 (830)	頭痛 (HEADACHE)	Mild/ Not related	No/ NA	None/not applicable	03OCT2012 (881)
27DEC2012 (966)	インフルエンザ (INFLUENZA)	Mild/ Unlikely	Yes/ No	None/not applicable	19JAN2013 (989)
06MAR2013 (1035)	胃腸炎 (GASTROENTERITIS)	Mild/ Not related	Yes/ No	None/not applicable	08MAR2013 (1037)
14OCT2013 (1257)	腱鞘炎 (LEFT HAND TENDOVAGINITIS)	Mild/ Not related	No/ NA	None/not applicable	21OCT2013 (1264)
02NOV2013 (1276)	筋骨格痛 (LEFT SHOULDER PAIN)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
13MAY2014 (1468)	頭痛 (HEADACHE)	Mild/ Unlikely	No/ NA	None/not applicable	26JUN2014 (1512)
10SEP2014 (1588)	鼻咽頭炎 (COMMON COLD)	Mild/ Unlikely	Yes/ No	None/not applicable	Ongoing -

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 4[redacted]
□ Sex: Male
□ Date of birth: 09APR[redacted]
□ Height (cm): 183
□ Weight (kg): 87.0
□ Date of UC diagnosis: 19JAN1996
□ UC disease duration (years): 14.2
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: Placebo SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to placebo induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	07JUN2011	397	1	Placebo	0 mg
Week 56 - EXT	07JUN2011	397	1	Golimumab	100 mg
Week 60 - EXT	01JUL2011	421	2	Golimumab	100 mg
Week 60 - EXT	01JUL2011	421	2	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 64 - EXT	02AUG2011	453	3	Placebo	0 mg
Week 64 - EXT	02AUG2011	453	3	Golimumab	100 mg
Week 68 - EXT	26AUG2011	477	4	Golimumab	100 mg
Week 68 - EXT	26AUG2011	477	4	Placebo	0 mg
Week 72 - EXT	27SEP2011	509	5	Placebo	0 mg
Week 72 - EXT	27SEP2011	509	5	Golimumab	100 mg
Week 76 - EXT	21OCT2011	533	6	Golimumab	100 mg
Week 76 - EXT	21OCT2011	533	6	Placebo	0 mg
Week 80 - EXT	18NOV2011	561	7	Golimumab	100 mg
Week 80 - EXT	18NOV2011	561	7	Placebo	0 mg
Week 84 - EXT	16DEC2011	589	8	Placebo	0 mg
Week 84 - EXT	16DEC2011	589	8	Golimumab	100 mg
Week 88 - EXT	17JAN2012	621	9	Golimumab	100 mg
Week 92 - EXT	13FEB2012	648	10	Golimumab	100 mg
Week 96 - EXT	12MAR2012	676	11	Golimumab	100 mg
Week 100 - EXT	10APR2012	705	12	Golimumab	100 mg
Week 104 - EXT	02MAY2012	727	13	Golimumab	100 mg
Week 108 - EXT	01JUN2012	757	14	Golimumab	100 mg
Week 112 - EXT	29JUN2012	785	15	Golimumab	100 mg
Week 116 - EXT	03AUG2012	820	16	Golimumab	100 mg
Week 124 - EXT	17SEP2012	865	17	Golimumab	100 mg
Week 128 - EXT	17OCT2012	895	18	Golimumab	100 mg
Week 132 - EXT	16NOV2012	925	19	Golimumab	100 mg
Week 136 - EXT	14DEC2012	953	20	Golimumab	100 mg
Week 140 - EXT	21JAN2013	991	21	Golimumab	100 mg
Week 144 - EXT	12FEB2013	1013	22	Golimumab	100 mg
Week 148 - EXT	14MAR2013	1043	23	Golimumab	100 mg
Week 152 - EXT	11APR2013	1071	24	Golimumab	100 mg
Week 156 - EXT	03MAY2013	1093	25	Golimumab	100 mg
Week 160 - EXT	04JUN2013	1125	26	Golimumab	100 mg
Week 164 - EXT	28JUN2013	1149	27	Golimumab	100 mg
Week 168 - EXT	02AUG2013	1184	28	Golimumab	100 mg
Week 172 - EXT	30AUG2013	1212	29	Golimumab	100 mg
Week 176 - EXT	20SEP2013	1233	30	Golimumab	100 mg
Week 180 - EXT	18OCT2013	1261	31	Golimumab	100 mg
Week 184 - EXT	15NOV2013	1289	32	Golimumab	100 mg
Week 188 - EXT	18DEC2013	1322	33	Golimumab	100 mg
Week 192 - EXT	10JAN2014	1345	34	Golimumab	100 mg
Week 196 - EXT	11FEB2014	1377	35	Golimumab	100 mg
Week 200 - EXT	11MAR2014	1405	36	Golimumab	100 mg
Week 204 - EXT	11APR2014	1436	37	Golimumab	100 mg
Week 208 - EXT	02MAY2014	1457	38	Golimumab	100 mg
Week 212 - EXT	03JUN2014	1489	39	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
RAMIPRIL,Oral	-----2014	09JUN2014
RAMIPRIL,Oral	13OCT2011	-----2014

Prior/Concomitant Therapy, Route	Start Date	End Date
PARACETAMOL,Oral	31JUL2012	Ongoing
IBUPROFEN,Oral	31JUL2012	Ongoing
TRAMADOL,Oral	03AUG2012	03OCT2012
ACICLOVIR,Intravenous	03AUG2012	06AUG2012
CEFTRIAXONE,Intravenous	04AUG2012	06AUG2012
RAMIPRIL,Oral	10JUN2014	Ongoing
GOLIMUMAB,Subcutaneous	03JUL2014	Ongoing

被験者識別コード：7378-00010

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
16MAY2011 (463)	大腸菌性腎盂腎炎 (E-COLI PYELONEPHRITIS)	Yes	Severe/ Possible	Yes/ Yes	Permanent discontinuation of study agent	05JUN2011 (483)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
14JUN2011 (492)	潰瘍性大腸炎 (FLARE OF ULCERATIVE COLITIS)	Severe/ Not related	No/ NA	None/not applicable	Ongoing -

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 4[redacted]
□ Sex: Female
□ Date of birth: 04JUL[redacted]
□ Height (cm): 167
□ Weight (kg): 59.3
□ Date of UC diagnosis: --AUG1991
□ UC disease duration (years): 18.3
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: Placebo SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to placebo induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	03MAR2011	389	1	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	03MAR2011	389	1	Placebo	0 mg
Week 60 - EXT	06APR2011	423	2	Placebo	0 mg
Week 60 - EXT	06APR2011	423	2	Golimumab	100 mg
Week 64 - EXT	26APR2011	443	3	Golimumab	100 mg
Week 64 - EXT	26APR2011	443	3	Placebo	0 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
GENTAMICIN,Intravenous	18MAY2011	25MAY2011
CEFTRIAXONE,Intravenous	18MAY2011	25MAY2011
AUGMENTIN /00756801/,Oral	25MAY2011	08JUN2011
CIPROFLOXACIN,Oral	25MAY2011	08JUN2011
FENTANYL,Intravenous	14JUN2011	14JUN2011
MIDAZOLAM,Intravenous	14JUN2011	14JUN2011
HYOSCINE,Intravenous	14JUN2011	14JUN2011
MESALAZINE,Rectal	15JUN2011	12JUL2011
PREDNISONE,Oral	15AUG2011	Ongoing
CALCIUM,Oral	15AUG2011	Ongoing
VITAMIN D NOS,Oral	15AUG2011	Ongoing

被験者識別コード：7427-00003

■ **REASON FOR NARRATIVE SELECTION**

Death

SAE

Discontinuation of study agent due to AE

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
23JAN2012 (1111)	心筋梗塞 (MIOCARDIAL INFARCTION)	Yes	Severe/ Unlikely	No/ NA	Permanent discontinuation of study agent	23JAN2012 (1111)

■ **Other Adverse Events**

No Other Adverse Events reported

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian □ Date of birth: 25JUL[redacted] □ Date of UC diagnosis: 21JUL2002
□ Age (yrs): 5[redacted] □ Height (cm): 179 □ UC disease duration (years): 6.4
□ Sex: Male □ Weight (kg): 92.0 □ Relevant medical history at baseline: 喫煙（過去/現在）

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: Placebo SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to placebo induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	05FEB2010	394	1	Placebo	0 mg
Week 56 - EXT	05FEB2010	394	1	Placebo	0 mg
Week 56 - EXT	05FEB2010	394	1	Golimumab	100 mg
Week 60 - EXT	09MAR2010	426	2	Placebo	0 mg
Week 60 - EXT	09MAR2010	426	2	Golimumab	100 mg
Week 64 - EXT	12APR2010	460	3	Placebo	0 mg
Week 64 - EXT	12APR2010	460	3	Golimumab	100 mg
Week 68 - EXT	05MAY2010	483	4	Golimumab	100 mg
Week 68 - EXT	05MAY2010	483	4	Placebo	0 mg
Week 72 - EXT	07JUN2010	516	5	Placebo	0 mg
Week 72 - EXT	07JUN2010	516	5	Golimumab	100 mg
Week 76 - EXT	30JUN2010	539	6	Placebo	0 mg
Week 76 - EXT	30JUN2010	539	6	Golimumab	100 mg
Week 80 - EXT	22JUL2010	561	7	Placebo	0 mg
Week 80 - EXT	22JUL2010	561	7	Golimumab	100 mg
Week 84 - EXT	23AUG2010	593	8	Golimumab	100 mg
Week 84 - EXT	23AUG2010	593	8	Placebo	0 mg
Week 88 - EXT	20SEP2010	621	9	Placebo	0 mg
Week 88 - EXT	20SEP2010	621	9	Golimumab	100 mg
Week 92 - EXT	22OCT2010	653	10	Placebo	0 mg
Week 92 - EXT	22OCT2010	653	10	Golimumab	100 mg
Week 96 - EXT	23NOV2010	685	11	Golimumab	100 mg
Week 96 - EXT	23NOV2010	685	11	Placebo	0 mg
Week 100 - EXT	17DEC2010	709	12	Golimumab	100 mg
Week 100 - EXT	17DEC2010	709	12	Placebo	0 mg
Week 104 - EXT	12JAN2011	735	13	Golimumab	100 mg
Week 104 - EXT	12JAN2011	735	13	Placebo	0 mg
Week 108 - EXT	09FEB2011	763	14	Golimumab	100 mg
Week 108 - EXT	09FEB2011	763	14	Placebo	0 mg
Week 112 - EXT	11MAR2011	793	15	Golimumab	100 mg
Week 112 - EXT	11MAR2011	793	15	Placebo	0 mg
Week 116 - EXT	11APR2011	824	16	Golimumab	100 mg
Week 116 - EXT	11APR2011	824	16	Placebo	0 mg
Week 120 - EXT	09MAY2011	852	17	Placebo	0 mg
Week 120 - EXT	09MAY2011	852	17	Golimumab	100 mg
Week 124 - EXT	01JUN2011	875	18	Placebo	0 mg
Week 124 - EXT	01JUN2011	875	18	Golimumab	100 mg
Week 128 - EXT	29JUN2011	903	19	Placebo	0 mg
Week 128 - EXT	29JUN2011	903	19	Golimumab	100 mg
Week 132 - EXT	28JUL2011	932	20	Golimumab	100 mg
Week 132 - EXT	28JUL2011	932	20	Placebo	0 mg
Week 136 - EXT	23AUG2011	958	21	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 136 - EXT	23AUG2011	958	21	Placebo	0 mg
Week 140 - EXT	30SEP2011	996	22	Placebo	0 mg
Week 140 - EXT	30SEP2011	996	22	Golimumab	100 mg
Week 144 - EXT	21OCT2011	1017	23	Placebo	0 mg
Week 144 - EXT	21OCT2011	1017	23	Golimumab	100 mg
Week 148 - EXT	11NOV2011	1038	24	Golimumab	100 mg
Week 148 - EXT	11NOV2011	1038	24	Placebo	0 mg
Week 152 - EXT	14DEC2011	1071	25	Golimumab	100 mg
Week 152 - EXT	14DEC2011	1071	25	Placebo	0 mg
Week 156 - EXT	10JAN2012	1098	26	Golimumab	100 mg

■ **Treatment and Study Status**

□ Date of study discontinuation: 23Jan2012

□ Reason for noncompletion: Death

□ Other reason for noncompletion/details:

■ **Concomitant Medications**

No Concomitant Medications reported.

被験者識別コード：7738-00017

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
26DEC2014 (1570)	肺炎 (PNEUMONIA (LEFT LUNG))	Yes	Mild/ Not related	Yes/ Yes	None/not applicable	24JAN2015 (1599)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
--NOV2011 -	うつ病 (DEPRESSION)	Moderate/ Unlikely	No/ NA	None/not applicable	Ongoing -
-----2012 -	消化不良 (HEARTBURN)	Moderate/ Unlikely	No/ NA	None/not applicable	Ongoing -
03DEC2011 (451)	月経過多 (MENORRHAGIA)	Mild/ Unlikely	No/ NA	None/not applicable	14JAN2012 (493)
27DEC2011 (475)	節足動物咬傷 (MULTIPLE INSECT BITES ON NECK)	Moderate/ Not related	No/ NA	None/not applicable	07MAR2012 (546)
27JUN2012 (658)	季節性アレルギー (WORSENING OF SEASONAL ALLERGIES)	Moderate/ Unlikely	No/ NA	None/not applicable	10SEP2012 (733)
10SEP2012 (733)	アトピー性皮膚炎 (RASH FACE (ATOPIC DERMATITIS))	Moderate/ Possible	No/ NA	None/not applicable	Ongoing -

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
10APR2013 (945)	大腸ポリープ (8MM INFLAMMATORY POLYP SIGMOID (BENIGN))	Moderate/ Not related	No/ NA	None/not applicable	10APR2013 (945)
10APR2013 (945)	処置後出血 (POST-PROCEDURAL RECTAL BLEEDING (BLEEDING FROM POLYP EXCISION))	Moderate/ Not related	No/ NA	None/not applicable	17APR2013 (952)
10APR2013 (945)	偽性ポリポーシス (THREE PSEUDOPOLYPS (COLONIC))	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
10APR2013 (945)	直腸ポリープ (RECTAL INFLAMMATORY POLYP (BENIGN))	Moderate/ Not related	No/ NA	None/not applicable	10APR2013 (945)
25JAN2014 (1235)	上気道感染 (UPPER RESPIRATORY INFECTION)	Moderate/ Not related	Yes/ No	None/not applicable	13FEB2014 (1254)
24JUN2014 (1385)	鼻咽頭炎 (HEAD COLD)	Moderate/ Not related	No/ NA	None/not applicable	23JUL2014 (1414)
01DEC2014 (1545)	頚部痛 (NECK PAIN)	Moderate/ Not related	No/ NA	None/not applicable	Ongoing -
16DEC2014 (1560)	呼吸困難 (DIFFICULTY BREATHING)	Mild/ Not related	No/ NA	None/not applicable	24JAN2015 (1599)
16DEC2014 (1560)	副鼻腔うっ血 (SINUS CONGESTION)	Moderate/ Not related	No/ NA	None/not applicable	30JAN2015 (1605)
21DEC2014 (1565)	肺感染 (LUNG INFECTION)	Mild/ Not related	Yes/ Yes	None/not applicable	26DEC2014 (1570)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 4[redacted]
□ Sex: Female
□ Date of birth: 16APR[redacted]
□ Height (cm): 163
□ Weight (kg): 72.6
□ Date of UC diagnosis: --NOV2008
□ UC disease duration (years): 1.7
□ Relevant medical history at baseline: 喫煙（過去/現在）

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: Placebo SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to placebo induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	03OCT2011	390	1	Golimumab	100 mg
Week 56 - EXT	03OCT2011	390	1	Placebo	0 mg
Week 60 - EXT	02NOV2011	420	2	Golimumab	100 mg
Week 60 - EXT	02NOV2011	420	2	Placebo	0 mg
Week 64 - EXT	30NOV2011	448	3	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 64 - EXT	30NOV2011	448	3	Placebo	0 mg
Week 68 - EXT	30DEC2011	478	4	Golimumab	100 mg
Week 72 - EXT	25JAN2012	504	5	Golimumab	100 mg
Week 76 - EXT	22FEB2012	532	6	Golimumab	100 mg
Week 80 - EXT	28MAR2012	567	7	Golimumab	100 mg
Week 84 - EXT	26APR2012	596	8	Golimumab	100 mg
Week 88 - EXT	17MAY2012	617	9	Golimumab	100 mg
Week 92 - EXT	14JUN2012	645	10	Golimumab	100 mg
Week 96 - EXT	11JUL2012	672	11	Golimumab	100 mg
Week 100 - EXT	07AUG2012	699	12	Golimumab	100 mg
Week 104 - EXT	07SEP2012	730	13	Golimumab	100 mg
Week 108 - EXT	09OCT2012	762	14	Golimumab	100 mg
Week 112 - EXT	07NOV2012	791	15	Golimumab	100 mg
Week 116 - EXT	05DEC2012	819	16	Golimumab	100 mg
Week 120 - EXT	31DEC2012	845	17	Golimumab	100 mg
Week 124 - EXT	28JAN2013	873	18	Golimumab	100 mg
Week 128 - EXT	21FEB2013	897	19	Golimumab	100 mg
Week 132 - EXT	20MAR2013	924	20	Golimumab	100 mg
Week 136 - EXT	17APR2013	952	21	Golimumab	100 mg
Week 140 - EXT	14MAY2013	979	22	Golimumab	100 mg
Week 144 - EXT	13JUN2013	1009	23	Golimumab	100 mg
Week 148 - EXT	15JUL2013	1041	24	Golimumab	100 mg
Week 152 - EXT	07AUG2013	1064	25	Golimumab	100 mg
Week 156 - EXT	04SEP2013	1092	26	Golimumab	100 mg
Week 160 - EXT	08OCT2013	1126	27	Golimumab	100 mg
Week 164 - EXT	30OCT2013	1148	28	Golimumab	100 mg
Week 168 - EXT	05DEC2013	1184	29	Golimumab	100 mg
Week 172 - EXT	03JAN2014	1213	30	Golimumab	100 mg
Week 176 - EXT	30JAN2014	1240	31	Golimumab	100 mg
Week 180 - EXT	20FEB2014	1261	32	Golimumab	100 mg
Week 184 - EXT	20MAR2014	1289	33	Golimumab	100 mg
Week 188 - EXT	24APR2014	1324	34	Golimumab	100 mg
Week 192 - EXT	23MAY2014	1353	35	Golimumab	100 mg
Week 196 - EXT	12JUN2014	1373	36	Golimumab	100 mg
Week 200 - EXT	14JUL2014	1405	37	Golimumab	100 mg
Week 204 - EXT	07AUG2014	1429	38	Golimumab	100 mg
Week 208 - EXT	04SEP2014	1457	39	Golimumab	100 mg
Week 212 - EXT	09OCT2014	1492	40	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
RANITIDINE,Oral	--AUG2013	Ongoing
HYDROCORTISONE,Topical	--DEC2012	Ongoing
CITALOPRAM,Oral	01DEC2011	15APR2012
CORTISONE,Topical	28DEC2011	21MAR2012
NEOTRACIN /00038301/,Topical	22JAN2012	21MAR2012
MINERALS NOS W/VITAMINS NOS,Oral	16APR2012	09MAY2012
CITALOPRAM,Oral	16APR2012	06JUL2012

Prior/Concomitant Therapy, Route	Start Date	End Date
WOMEN'S MULTI /02225001/,Oral	10MAY2012	Ongoing
CITALOPRAM,Oral	07JUL2012	11JUL2012
CITALOPRAM,Oral	12JUL2012	--OCT2012
IRON,Oral	12JUL2012	Ongoing
CEFALEXIN,Oral	25OCT2012	01NOV2012
METHYLPREDNISOLONE,Oral	26OCT2012	31OCT2012
OLOPATADINE,Ophthalmic	09NOV2012	Ongoing
CEFALEXIN,Oral	09NOV2012	23NOV2012
PREDNISONE,Oral	09NOV2012	16NOV2012
HYDROCORTISONE,Topical	09NOV2012	30NOV2012
MINOCYCLINE,Oral	15JAN2013	Ongoing
MACROGOL,Oral	09APR2013	09APR2013
BISACODYL,Oral	09APR2013	09APR2013
PROPOFOL,Intravenous	10APR2013	10APR2013
PARAFFIN, LIQUID,Rectal	10APR2013	10APR2013
PETHIDINE,Intravenous	10APR2013	10APR2013
MACROGOL,Oral	16APR2013	16APR2013
BISACODYL,Oral	16APR2013	16APR2013
PROPOFOL,Intravenous	17APR2013	17APR2013
PARAFFIN, LIQUID,Rectal	17APR2013	17APR2013
DIPHENHYDRAMINE,Oral	02SEP2013	--OCT2013
HYPERICUM PERFORATUM,Oral	31JAN2014	--FEB2014
METHOCARBAMOL,Oral	04DEC2014	Ongoing
AZATHIOPRINE,Oral	17DEC2014	Ongoing
AZITHROMYCIN,Oral	21DEC2014	26DEC2014
PROMETHAZINE,Oral	22DEC2014	26DEC2014
ALL OTHER THERAPEUTIC PRODUCTS,Inhalation	26DEC2014	28DEC2014
POTASSIUM W/SODIUM CHLORIDE,Intravenous	26DEC2014	28DEC2014
LEVOFLOXACIN,Oral	28DEC2014	01JAN2015
PROMETHAZINE W/CODEINE,Oral	28DEC2014	22JAN2015
SALBUTAMOL,Inhalation	28DEC2014	24JAN2015
DOXYCYCLINE,Oral	28DEC2014	06JAN2015
AMOXI-CLAVULANICO,Oral	15JAN2015	24JAN2015
DIPHENHYDRAMINE W/PARACETAMOL/PHENYLEPHRINE,Oral	15JAN2015	30JAN2015

被験者識別コード：7816-00003

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
22AUG2011 (617)	再生不良性貧血 (APLASTIC ANAEMIA)	Yes	Severe/ Unlikely	No/ NA	Permanent discontinuation of study agent	Ongoing -

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
30AUG2011 (625)	偽膜性大腸炎 (ENTERITIS PSEUDOMEMBRANOUS)	Mild/ Not related	Yes/ Yes	None/not applicable	28SEP2011 (654)
08SEP2011 (634)	不眠症 (INSOMNIA)	Mild/ Not related	No/ NA	None/not applicable	13SEP2011 (639)
16OCT2011 (672)	上気道の炎症 (ACUTE UPPER RESPIRATORY INFLAMMATION)	Mild/ Not related	Yes/ Yes	None/not applicable	18OCT2011 (674)
23OCT2011 (679)	頭痛 (HEADACHES)	Mild/ Not related	No/ NA	None/not applicable	23OCT2011 (679)

■ **Demographics and Baseline Characteristics**

□ Race: Asian □ Date of birth:
□ Age (yrs): 29JUN[redacted]
4[redacted] □ Height (cm): 155
□ Sex: Female □ Weight (kg): 48.5

□ Date of UC diagnosis: 11MAY2005
□ UC disease duration (years): 4.5
□ Relevant medical history at baseline: 結節性紅斑，アフタ性口内炎

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: Placebo SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to placebo induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	17JAN2011	400	1	Golimumab	100 mg
Week 56 - EXT	17JAN2011	400	1	Placebo	0 mg
Week 60 - EXT	07FEB2011	421	2	Golimumab	100 mg
Week 60 - EXT	07FEB2011	421	2	Placebo	0 mg
Week 64 - EXT	07MAR2011	449	3	Golimumab	100 mg
Week 64 - EXT	07MAR2011	449	3	Placebo	0 mg
Week 68 - EXT	04APR2011	477	4	Golimumab	100 mg
Week 68 - EXT	04APR2011	477	4	Placebo	0 mg
Week 72 - EXT	09MAY2011	512	5	Golimumab	100 mg
Week 72 - EXT	09MAY2011	512	5	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 76 - EXT	06JUN2011	540	6	Golimumab	100 mg
Week 76 - EXT	06JUN2011	540	6	Placebo	0 mg
Week 80 - EXT	04JUL2011	568	7	Placebo	0 mg
Week 80 - EXT	04JUL2011	568	7	Golimumab	100 mg
Week 84 - EXT	01AUG2011	596	8	Placebo	0 mg
Week 84 - EXT	01AUG2011	596	8	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
PARACETAMOL,Oral	22AUG2011	22AUG2011
LOXOPROFEN,Oral	23AUG2011	24AUG2011
FLOMOXEF,Intravenous	23AUG2011	24AUG2011
ACMAIN,Intravenous	23AUG2011	24AUG2011
CEFEPIME,Intravenous	24AUG2011	27AUG2011
MEROPENEM,Intravenous	27AUG2011	28AUG2011
MICAFUNGIN,Intravenous	27AUG2011	31AUG2011
FILGRASTIM,Subcutaneous	27AUG2011	03SEP2011
CEFEPIME,Intravenous	29AUG2011	31AUG2011
VANCOMYCIN,Oral	30AUG2011	28SEP2011
MESALAZINE,Oral	31AUG2011	27SEP2011
LANSOPRAZOLE,Oral	31AUG2011	Ongoing
MOSAPRIDE,Oral	31AUG2011	Ongoing
ITRACONAZOLE,Oral	01SEP2011	Ongoing
GARENOXACIN,Oral	01SEP2011	07SEP2011
METHYLPREDNISOLONE,Intravenous	02SEP2011	02SEP2011
PREDNISOLONE,Oral	03SEP2011	15OCT2011
POTASSIUM ASPARTATE,Oral	03SEP2011	21SEP2011
OMEPRAZOLE,Intravenous	04SEP2011	09SEP2011
MICAFUNGIN,Intravenous	05SEP2011	13SEP2011
MICONAZOLE,Oral	06SEP2011	Ongoing
CEFEPIME,Intravenous	06SEP2011	20SEP2011
VALACICLOVIR,Oral	07SEP2011	Ongoing
ETIZOLAM,Oral	08SEP2011	13SEP2011
CICLOSPORIN,Oral	09SEP2011	Ongoing
FILGRASTIM,Subcutaneous	09SEP2011	Ongoing
SULFAMETHOXAZOLE,Oral	11SEP2011	Ongoing
CEFTAZIDIME,Intravenous	20SEP2011	26SEP2011
RISEDRONIC ACID,Oral	03OCT2011	Ongoing
CLARITHROMYCIN,Oral	16OCT2011	18OCT2011

c) ゴリムマブ寛解導入 non-responder

被験者識別コード：6051-00002

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: Malignancy

Event of interest: Heart failure

Event of interest: Interstitial lung disease

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
--OCT2009 -	基底細胞癌 (BASOCELLULAR CARCINOMA ON EAR)	No	Moderate/ Possible	No/ NA	None/not applicable	02DEC2009 (513)
--OCT2009 -	皮膚有棘細胞癌 (INVASIVE SPINOCELLULAR CARCINOMA ON EAR)	No	Moderate/ Possible	No/ NA	None/not applicable	02DEC2009 (513)
27OCT2010 (842)	基底細胞癌 (INFILTRATED BASOCELLULAR CARCINOMA PRE AURICULAR ON RIGHT SIDE)	No	Moderate/ Possible	No/ NA	None/not applicable	02DEC2010 (878)
27OCT2010 (842)	基底細胞癌 (NODULAR BASOCELLULAR CARCINOMA RETROAURICULAR LEFT SIDE)	No	Moderate/ Possible	No/ NA	None/not applicable	22NOV2010 (868)
23MAY2012 (1416)	間質性肺疾患 (INTERSTITIAL LUNG DISEASE)	Yes	Moderate/ Possible	No/ NA	Permanent discontinuation of study agent	04DEC2012 (1611)
01JUN2012 (1425)	心不全 (SECONDARY CARDIAC FAILURE)	No	Moderate/ Not related	No/ NA	None/not applicable	19JUN2012 (1443)
01JUN2012 (1425)	間質性肺疾患 (ACUTE FLARE OF INTERSTITIAL LUNG DISEASE)	Yes	Severe/ Possible	No/ NA	None/not applicable	19JUN2012 (1443)
27JUN2012 (1451)	間質性肺疾患 (ACUTE FLARE INTERSTITIAL LUNGDISEAE)	Yes	Severe/ Possible	No/ NA	None/not applicable	06JUL2012 (1460)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
--DEC2011 -	薬疹 (RASH ON LOWER ARMSS DUE TO EFFUDIX OINTMENT)	Moderate/ Not related	No/ NA	None/not applicable	--DEC2011 -

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
--MAR2012 -	呼吸困難 (DYSPNEA)	Moderate/ Possible	No/ NA	None/not applicable	29MAY2012 (1422)
--NOV2009 -	筋骨格痛 (PAIN LEFT SHOULDER)	Moderate/ Not related	No/ NA	None/not applicable	--DEC2009 -
--AUG2009 -	そう痒症 (ITCHING)	Moderate/ Possible	No/ NA	None/not applicable	--OCT2009 -
23NOV2009 (504)	鼻咽頭炎 (COMMON COLD)	Mild/ Unlikely	Yes/ No	None/not applicable	28NOV2009 (509)
12JAN2010 (554)	上気道感染 (UPPER RESPIRATORY TRACT INFECTION)	Moderate/ Unlikely	Yes/ Yes	None/not applicable	17JAN2010 (559)
12FEB2010 (585)	鼻咽頭炎 (COMMON COLD)	Mild/ Unlikely	Yes/ No	None/not applicable	20FEB2010 (593)
24MAR2010 (625)	上気道感染 (UPPER RESPIRATORY TRACT INFECTION)	Moderate/ Unlikely	Yes/ Yes	None/not applicable	28MAR2010 (629)
25SEP2010 (810)	創傷 (FALL WITH WOUND ON LEFT LEG)	Moderate/ Not related	No/ NA	None/not applicable	--OCT2010 -
08NOV2010 (854)	気管支炎 (BRONCHITIS)	Moderate/ Not related	Yes/ Yes	None/not applicable	30JAN2011 (937)
08NOV2010 (854)	咽頭の炎症 (THROAT INFLAMMATION)	Moderate/ Not related	Yes/ Yes	None/not applicable	--NOV2010 -
22APR2011 (1019)	骨挫傷 (BRUISED RIBS DUE TO FALL)	Moderate/ Not related	No/ NA	None/not applicable	--JUN2011 -
06FEB2012 (1309)	咳嗽 (COUGH)	Moderate/ Possible	Yes/ Yes	None/not applicable	22MAY2012 (1415)
07APR2012 (1370)	悪心 (NAUSEA)	Moderate/ Possible	No/ NA	None/not applicable	--AUG2012 -
09APR2012 (1372)	胃炎 (MILD ACTIVE MILD CHRONIC PANGASTRITIS)	Moderate/ Possible	No/ NA	None/not applicable	Ongoing -
11APR2012 (1374)	びらん性十二指腸炎 (DUODENOPATHY: EROSIONS IN SECOND PART OF THE DUODENUM)	Moderate/ Possible	No/ NA	None/not applicable	Ongoing -
11APR2012 (1374)	胃障害 (GASTROPATHY)	Moderate/ Possible	No/ NA	None/not applicable	Ongoing -
30MAY2012 (1423)	呼吸困難 (INCREASED DYSPNEA)	Moderate/ Possible	No/ NA	None/not applicable	31MAY2012 (1424)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian □ Date of birth: 06SEP[redacted] □ Date of UC diagnosis: --SEP1996
□ Age (yrs): 7[redacted] □ Height (cm): 160 □ UC disease duration (years): 11.7
□ Sex: Male □ Weight (kg): 74.0 □ Relevant medical history at baseline: 喫煙（過去/現在）

■ **Treatment Groups**

□ Induction study: C0524T16

□ Treatment group in induction: 1 mg/kg IV

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	04AUG2009	393	1	Placebo	0 mg
Week 56 - EXT	04AUG2009	393	1	Placebo	0 mg
Week 56 - EXT	04AUG2009	393	1	Golimumab	100 mg
Week 60 - EXT	02SEP2009	422	2	Placebo	0 mg
Week 60 - EXT	02SEP2009	422	2	Golimumab	100 mg
Week 60 - EXT	02SEP2009	422	2	Placebo	0 mg
Week 64 - EXT	30SEP2009	450	3	Placebo	0 mg
Week 64 - EXT	30SEP2009	450	3	Golimumab	100 mg
Week 64 - EXT	30SEP2009	450	3	Placebo	0 mg
Week 68 - EXT	28OCT2009	478	4	Placebo	0 mg
Week 68 - EXT	28OCT2009	478	4	Placebo	0 mg
Week 68 - EXT	28OCT2009	478	4	Golimumab	100 mg
Week 72 - EXT	02DEC2009	513	5	Placebo	0 mg
Week 72 - EXT	02DEC2009	513	5	Placebo	0 mg
Week 72 - EXT	02DEC2009	513	5	Golimumab	100 mg
Week 76 - EXT	29DEC2009	540	6	Placebo	0 mg
Week 76 - EXT	29DEC2009	540	6	Golimumab	100 mg
Week 76 - EXT	29DEC2009	540	6	Placebo	0 mg
Week 80 - EXT	20JAN2010	562	7	Golimumab	100 mg
Week 80 - EXT	20JAN2010	562	7	Placebo	0 mg
Week 80 - EXT	20JAN2010	562	7	Placebo	0 mg
Week 84 - EXT	17FEB2010	590	8	Golimumab	100 mg
Week 84 - EXT	17FEB2010	590	8	Placebo	0 mg
Week 84 - EXT	17FEB2010	590	8	Placebo	0 mg
Week 88 - EXT	17MAR2010	618	9	Placebo	0 mg
Week 88 - EXT	17MAR2010	618	9	Golimumab	100 mg
Week 92 - EXT	14APR2010	646	10	Placebo	0 mg
Week 92 - EXT	14APR2010	646	10	Golimumab	100 mg
Week 96 - EXT	12MAY2010	674	11	Golimumab	100 mg
Week 96 - EXT	12MAY2010	674	11	Placebo	0 mg
Week 100 - EXT	09JUN2010	702	12	Golimumab	100 mg
Week 100 - EXT	09JUN2010	702	12	Placebo	0 mg
Week 104 - EXT	07JUL2010	730	13	Golimumab	100 mg
Week 104 - EXT	07JUL2010	730	13	Placebo	0 mg
Week 108 - EXT	04AUG2010	758	14	Placebo	0 mg
Week 108 - EXT	04AUG2010	758	14	Golimumab	100 mg
Week 112 - EXT	01SEP2010	786	15	Placebo	0 mg
Week 112 - EXT	01SEP2010	786	15	Golimumab	100 mg
Week 116 - EXT	29SEP2010	814	16	Placebo	0 mg
Week 116 - EXT	29SEP2010	814	16	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 120 - EXT	27OCT2010	842	17	Golimumab	100 mg
Week 120 - EXT	27OCT2010	842	17	Placebo	0 mg
Week 124 - EXT	22NOV2010	868	18	Placebo	0 mg
Week 124 - EXT	22NOV2010	868	18	Golimumab	100 mg
Week 128 - EXT	22DEC2010	898	19	Golimumab	100 mg
Week 128 - EXT	22DEC2010	898	19	Placebo	0 mg
Week 132 - EXT	19JAN2011	926	20	Placebo	0 mg
Week 132 - EXT	19JAN2011	926	20	Golimumab	100 mg
Week 136 - EXT	21FEB2011	959	21	Golimumab	100 mg
Week 136 - EXT	21FEB2011	959	21	Placebo	0 mg
Week 140 - EXT	16MAR2011	982	22	Placebo	0 mg
Week 140 - EXT	16MAR2011	982	22	Golimumab	100 mg
Week 144 - EXT	13APR2011	1010	23	Golimumab	100 mg
Week 144 - EXT	13APR2011	1010	23	Placebo	0 mg
Week 148 - EXT	11MAY2011	1038	24	Golimumab	100 mg
Week 148 - EXT	11MAY2011	1038	24	Placebo	0 mg
Week 152 - EXT	08JUN2011	1066	25	Placebo	0 mg
Week 152 - EXT	08JUN2011	1066	25	Golimumab	100 mg
Week 156 - EXT	13JUL2011	1101	26	Golimumab	100 mg
Week 156 - EXT	13JUL2011	1101	26	Placebo	0 mg
Week 160 - EXT	03AUG2011	1122	27	Golimumab	100 mg
Week 160 - EXT	03AUG2011	1122	27	Placebo	0 mg
Week 164 - EXT	31AUG2011	1150	28	Golimumab	100 mg
Week 164 - EXT	31AUG2011	1150	28	Placebo	0 mg
Week 168 - EXT	28SEP2011	1178	29	Placebo	0 mg
Week 168 - EXT	28SEP2011	1178	29	Golimumab	100 mg
Week 172 - EXT	26OCT2011	1206	30	Golimumab	100 mg
Week 172 - EXT	26OCT2011	1206	30	Placebo	0 mg
Week 176 - EXT	23NOV2011	1234	31	Placebo	0 mg
Week 176 - EXT	23NOV2011	1234	31	Golimumab	100 mg
Week 180 - EXT	21DEC2011	1262	32	Golimumab	100 mg
Week 184 - EXT	18JAN2012	1290	33	Golimumab	100 mg
Week 188 - EXT	15FEB2012	1318	34	Golimumab	100 mg
Week 192 - EXT	14MAR2012	1346	35	Golimumab	100 mg
Week 196 - EXT	11APR2012	1374	36	Golimumab	100 mg
Week 200 - EXT	09MAY2012	1402	37	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
BISOPROLOL,Oral	--JAN2010	Ongoing
LOSARTAN,Oral	--MAY2012	Ongoing
CLARITHROMYCIN,Oral	--FEB2012	--FEB2012
PANTOPRAZOLE,Oral	--APR2012	Ongoing
INFLUENZA VACCINE,Intramuscular	--OCT2009	--OCT2009
GLICLAZIDE,Oral	-----2012	Ongoing
BUMETANIDE,Oral	--JUL2012	Ongoing
A/H1N1 INFLUENZA PANDEMIC VACCINE,Intramuscular	11NOV2009	11NOV2009
AMOXICILLIN,Oral	13JAN2010	17JAN2010

Prior/Concomitant Therapy, Route	Start Date	End Date
AMOXICILLIN,Oral	24MAR2010	28MAR2010
DITEMER,Intramuscular	25SEP2010	25SEP2010
AMOXICILLIN,Oral	08NOV2010	12NOV2010
AMOXI-CLAVULANICO,Oral	15NOV2010	18NOV2010
ACETYLCYSTEINE,Oral	15NOV2010	--DEC2010
CLARITHROMYCIN,Oral	23NOV2010	27NOV2010
CLARITHROMYCIN,Oral	20JAN2011	29JAN2011
FLUOROURACIL,Topical	21FEB2011	--MAY2011
PARACETAMOL,Oral	22APR2011	--APR2011
FLUOROURACIL,Topical	23NOV2011	21DEC2011
CETRIMIDE,Topical	21DEC2011	15JAN2012
DEXTROMETHORPHAN,Oral	08FEB2012	--FEB2012
FUCICORT,Topical	16MAR2012	21MAR2012
FLUCLOXACILLIN,Oral	16MAR2012	--MAR2012
BETAMETHASONE,Topical	21MAR2012	21APR2012
LEVODROPROPIZINE,Oral	30MAR2012	03APR2012
AMOXICILLIN,Oral	30MAR2012	03APR2012
METHYLPREDNISOLONE,Oral	25MAY2012	01JUN2012
INSULIN HUMAN,Intravenous	01JUN2012	--JUN2012
ENOXAPARIN,Subcutaneous	01JUN2012	05JUL2012
PARACETAMOL,Intravenous	01JUN2012	--JUN2012
METHYLPREDNISOLONE,Intravenous	01JUN2012	07JUN2012
MEROPENEM,Intravenous	08JUN2012	11JUN2012
METHYLPREDNISOLONE,Oral	08JUN2012	Ongoing
FUROSEMIDE,Oral	13JUN2012	15JUN2012
AZITHROMYCIN,Oral	16JUN2012	19JUN2012
FUROSEMIDE,Intravenous	27JUN2012	27JUN2012
DUOVENT	28JUN2012	--OCT2012
BACTRIM,Intravenous	28JUN2012	02JUL2012
AZITHROMYCIN,Oral	29JUN2012	Ongoing
CANRENOIC ACID,Oral	18JUL2012	Ongoing

被験者識別コード：6179-00003

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
20OCT2010 (884)	脱髄 (DEMYELINIISATION)	Yes	Moderate/ Possible	No/ NA	Permanent discontinuation of study agent	04JAN2012 (1325)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
--JUL2009 -	そう痒症 (PRURITUS)	Moderate/ Possible	No/ NA	None/not applicable	--AUG2009 -
--DEC2009 -	視力低下 (DECREASE IN VISUAL ACUITY)	Mild/ Possible	No/ NA	None/not applicable	28APR2010 (709)
06JUN2009 (383)	耳感染 (OTITIS)	Moderate/ Unlikely	No/ NA	None/not applicable	15JUN2009 (392)
29JUL2009 (436)	耳感染 (OTITIS)	Moderate/ Unlikely	Yes/ Yes	None/not applicable	19AUG2009 (457)
17AUG2009 (455)	喉頭炎 (LARYNGITIS)	Moderate/ Possible	Yes/ Yes	None/not applicable	23AUG2009 (461)
02SEP2009 (471)	関節痛 (INTERMITTENT ARTHRALGIA ON HANDS)	Moderate/ Possible	No/ NA	None/not applicable	17NOV2009 (547)
28SEP2009 (497)	そう痒症 (PRURITUS)	Mild/ Possible	No/ NA	None/not applicable	01OCT2009 (500)
10NOV2009 (540)	耳感染 (SUPERINFECTED OTITIS)	Moderate/ Possible	Yes/ Yes	None/not applicable	10NOV2009 (540)
24NOV2009 (554)	腹痛 (ABDOMINAL PAIN)	Moderate/ Possible	No/ NA	None/not applicable	15DEC2009 (575)
24NOV2009 (554)	放屁 (FLATULENCE)	Moderate/ Possible	No/ NA	None/not applicable	15DEC2009 (575)
11DEC2009 (571)	便秘 (CONSTIPATION)	Mild/ Possible	No/ NA	None/not applicable	13DEC2009 (573)
13JAN2010 (604)	胃腸炎 (GASTROENTERITIS)	Moderate/ Unlikely	Yes/ No	None/not applicable	23JAN2010 (614)
14JAN2010 (605)	錯感覚 (TINGLING ON THE RIGHT LEG)	Mild/ Possible	No/ NA	None/not applicable	14JAN2010 (605)
13FEB2010 (635)	錯感覚 (TINGLING ON THE LOWER AND THE UPPER LIMB)	Mild/ Possible	No/ NA	None/not applicable	Ongoing -
10MAY2010 (721)	扁桃炎 (TONSILITIS)	Moderate/ Possible	Yes/ Yes	None/not applicable	15MAY2010 (726)
07JUN2010 (749)	アレルギー性咽頭炎 (ALLERGIC PHARYNGITIS)	Moderate/ Possible	Yes/ Yes	None/not applicable	10JUN2010 (752)
30JUN2010 (772)	穿刺部位疼痛 (LUMBAR PAIN AFTER LUMBAR PONCTURE)	Moderate/ Not related	No/ NA	None/not applicable	14JUL2010 (786)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian □ Date of birth: 20NOV[redacted] □ Date of UC diagnosis: 16FEB2007
□ Age (yrs): 4[redacted] □ Height (cm): 155 □ UC disease duration (years): 1.1
□ Sex: Female □ Weight (kg): 55.0 □ Relevant medical history at baseline: 喫煙（過去/現在）

■ **Treatment Groups**

□ Induction study: C0524T16

□ Treatment group in induction: 1 mg/kg IV

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	30JUN2009	407	1	Golimumab	100 mg
Week 56 - EXT	30JUN2009	407	1	Placebo	0 mg
Week 56 - EXT	30JUN2009	407	1	Placebo	0 mg
Week 60 - EXT	04AUG2009	442	2	Placebo	0 mg
Week 60 - EXT	04AUG2009	442	2	Golimumab	100 mg
Week 60 - EXT	04AUG2009	442	2	Placebo	0 mg
Week 64 - EXT	02SEP2009	471	3	Golimumab	100 mg
Week 64 - EXT	02SEP2009	471	3	Placebo	0 mg
Week 64 - EXT	02SEP2009	471	3	Placebo	0 mg
Week 68 - EXT	29SEP2009	498	4	Placebo	0 mg
Week 68 - EXT	29SEP2009	498	4	Placebo	0 mg
Week 68 - EXT	29SEP2009	498	4	Golimumab	100 mg
Week 72 - EXT	21OCT2009	520	5	Golimumab	100 mg
Week 72 - EXT	21OCT2009	520	5	Placebo	0 mg
Week 72 - EXT	21OCT2009	520	5	Placebo	0 mg
Week 76 - EXT	17NOV2009	547	6	Golimumab	100 mg
Week 76 - EXT	17NOV2009	547	6	Placebo	0 mg
Week 76 - EXT	17NOV2009	547	6	Placebo	0 mg
Week 80 - EXT	15DEC2009	575	7	Placebo	0 mg
Week 80 - EXT	15DEC2009	575	7	Placebo	0 mg
Week 80 - EXT	15DEC2009	575	7	Golimumab	100 mg
Week 84 - EXT	05JAN2010	596	8	Golimumab	100 mg
Week 84 - EXT	05JAN2010	596	8	Placebo	0 mg
Week 84 - EXT	05JAN2010	596	8	Placebo	0 mg
Week 88 - EXT	26JAN2010	617	9	Placebo	0 mg
Week 88 - EXT	26JAN2010	617	9	Placebo	0 mg
Week 88 - EXT	26JAN2010	617	9	Golimumab	100 mg
Week 92 - EXT	23FEB2010	645	10	Golimumab	100 mg
Week 92 - EXT	23FEB2010	645	10	Placebo	0 mg
Week 96 - EXT	25MAR2010	675	11	Golimumab	100 mg
Week 96 - EXT	25MAR2010	675	11	Placebo	0 mg
Week 100 - EXT	28APR2010	709	12	Placebo	0 mg
Week 100 - EXT	28APR2010	709	12	Golimumab	100 mg
Week 104 - EXT	19MAY2010	730	13	Golimumab	100 mg
Week 104 - EXT	19MAY2010	730	13	Placebo	0 mg
Week 108 - EXT	16JUN2010	758	14	Placebo	0 mg
Week 108 - EXT	16JUN2010	758	14	Golimumab	100 mg
Week 112 - EXT	13JUL2010	785	15	Golimumab	100 mg
Week 112 - EXT	13JUL2010	785	15	Placebo	0 mg
Week 116 - EXT	12AUG2010	815	16	Golimumab	100 mg
Week 116 - EXT	12AUG2010	815	16	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 120 - EXT	08SEP2010	842	17	Placebo	0 mg
Week 120 - EXT	08SEP2010	842	17	Golimumab	100 mg
Week 124 - EXT	18OCT2010	882	18	Placebo	0 mg
Week 124 - EXT	18OCT2010	882	18	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
OFLOXACIN,Oral	16JUL2009	27JUL2009
FEXOFENADINE,Oral	22JUL2009	29JUL2009
BETAMETHASONE,AD (Right ear)	30JUL2009	19AUG2009
EBASTINE,Oral	01AUG2009	03AUG2009
TIAPROFENIC ACID,Oral	17AUG2009	23AUG2009
AMOXICILLIN,Oral	17AUG2009	23AUG2009
THIAMPHENICOL,Oral	17AUG2009	23AUG2009
BETAMETHASONE,Topical	30SEP2009	01OCT2009
PARACETAMOL,Oral	11NOV2009	17NOV2009
AMOXI-CLAVULANICO,Oral	11NOV2009	17NOV2009
DEXAMETHASONE W/NEOMYCIN/POLYMYXIN B,Otic	11NOV2009	17NOV2009
INNER HEALTH PLUS DAIRY FREE,Oral	16DEC2009	15JAN2010
METEOSPASMYL /02143701/,Oral	26JAN2010	02FEB2010
BICLOTYMOL,Inhalation	10MAY2010	15MAY2010
CLARITHROMYCIN,Oral	10MAY2010	15MAY2010
CEFUROXIME,Oral	08JUN2010	14JUN2010
BECLOMETASONE,Oral	08JUN2010	07JUL2010
IBUPROFEN,Oral	08JUN2010	13JUN2010
OMEPRAZOLE,Oral	08JUN2010	14JUN2010
MIZOLASTINE,Oral	08JUN2010	07JUL2010
METHOCARBAMOL,Oral	05JUL2010	12JUL2010
PARACETAMOL W/TRAMADOL,Oral	05JUL2010	12JUL2010
MESALAZINE,Oral	10NOV2010	Ongoing

被験者識別コード：6407-00004

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
22AUG2010 (760)	潰瘍性大腸炎 (PROGRESSION OF ULCERATIVE COLITIS)	Yes	Moderate/ Unlikely	No/ NA	Permanent discontinuation of study agent	27AUG2010 (765)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
01APR2010 (617)	潰瘍性大腸炎 (AGGRAVATION OF ULCERATIVE COLITIS)	Moderate/ Possible	No/ NA	None/not applicable	22AUG2010 (760)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 3[redacted]
□ Sex: Male
□ Date of birth: 24OCT[redacted]
□ Height (cm): 182
□ Weight (kg): 64.0
□ Date of UC diagnosis: 16JAN2007
□ UC disease duration (years): 1.4
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T16

□ Treatment group in induction: 1 mg/kg IV

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: Yes

□ Adjusted treatment group during LTE: Golimumab 100 mg

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	20AUG2009	393	1	Placebo	0 mg
Week 56 - EXT	20AUG2009	393	1	Placebo	0 mg
Week 56 - EXT	20AUG2009	393	1	Golimumab	100 mg
Week 60 - EXT	17SEP2009	421	2	Placebo	0 mg
Week 60 - EXT	17SEP2009	421	2	Placebo	0 mg
Week 60 - EXT	17SEP2009	421	2	Golimumab	100 mg
Week 64 - EXT	15OCT2009	449	3	Placebo	0 mg
Week 64 - EXT	15OCT2009	449	3	Placebo	0 mg
Week 64 - EXT	15OCT2009	449	3	Golimumab	100 mg
Week 68 - EXT	12NOV2009	477	4	Placebo	0 mg
Week 68 - EXT	12NOV2009	477	4	Golimumab	100 mg
Week 68 - EXT	12NOV2009	477	4	Placebo	0 mg
Week 72 - EXT	10DEC2009	505	5	Placebo	0 mg
Week 72 - EXT	10DEC2009	505	5	Golimumab	100 mg
Week 72 - EXT	10DEC2009	505	5	Placebo	0 mg
Week 76 - EXT	07JAN2010	533	6	Placebo	0 mg
Week 76 - EXT	07JAN2010	533	6	Golimumab	100 mg
Week 76 - EXT	07JAN2010	533	6	Placebo	0 mg
Week 80 - EXT	04FEB2010	561	7	Placebo	0 mg
Week 80 - EXT	04FEB2010	561	7	Golimumab	100 mg
Week 80 - EXT	04FEB2010	561	7	Placebo	0 mg
Week 84 - EXT	02MAR2010	587	8	Placebo	0 mg
Week 84 - EXT	02MAR2010	587	8	Golimumab	100 mg
Week 88 - EXT	01APR2010	617	9	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 88 - EXT	01APR2010	617	9	Golimumab	100 mg
Week 92 - EXT	29APR2010	645	10	Golimumab	100 mg
Week 92 - EXT	29APR2010	645	10	Placebo	0 mg
Week 96 - EXT	27MAY2010	673	1	Golimumab	100 mg
Week 96 - EXT	27MAY2010	673	1	Placebo	0 mg
Week 100 - EXT	24JUN2010	701	2	Golimumab	100 mg
Week 100 - EXT	24JUN2010	701	2	Placebo	0 mg
Week 104 - EXT	22JUL2010	729	3	Golimumab	100 mg
Week 104 - EXT	22JUL2010	729	3	Placebo	0 mg

■ **Treatment and Study Status**

□ Date of study discontinuation: 22AUG2010

□ Reason for noncompletion: Other

□ Other reason for noncompletion/details: Ae: progression of UC.

□ Date of disposition status: 22Aug2010

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
OMEPRAZOLE,Oral	--AUG2010	--AUG2010
CIPROFLOXACIN,Oral	--AUG2010	--AUG2010
SOLUTIONS FOR PARENTERAL NUTRITION,Intravenous	--AUG2010	--AUG2010
GLUCOSE,Intravenous	--AUG2010	--AUG2010
METHYLPREDNISOLONE,Oral	--AUG2010	--AUG2010
AZATHIOPRINE,Oral	--AUG2010	--AUG2010
COVERAM,Oral	02MAR2010	Ongoing
A + E VITAMINE-,Oral	28AUG2010	Ongoing
FOLIC ACID,Oral	28AUG2010	Ongoing

被験者識別コード：6502-00008

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: TB related

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
02MAR2011 (801)	肺結核 (PULMONARY TUBERCULOSIS)	Yes	Moderate/ Probable	Yes/ Yes	Permanent discontinuation of study agent	06MAY2011 (866)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
01FEB2011 (772)	喉頭炎 (LARYNGITIS CHRONICA HYPERPLASTICA)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 3[redacted]
□ Sex: Female
□ Date of birth: 24JUL[redacted]
□ Height (cm): 168
□ Weight (kg): 59.0
□ Date of UC diagnosis: 31MAR2005
□ UC disease duration (years): 3.6
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T16

□ Treatment group in induction: 1 mg/kg IV

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	19JAN2010	394	1	Placebo	0 mg
Week 56 - EXT	19JAN2010	394	1	Golimumab	100 mg
Week 56 - EXT	19JAN2010	394	1	Placebo	0 mg
Week 60 - EXT	22FEB2010	428	2	Placebo	0 mg
Week 60 - EXT	22FEB2010	428	2	Golimumab	100 mg
Week 60 - EXT	22FEB2010	428	2	Placebo	0 mg
Week 64 - EXT	17MAR2010	451	3	Golimumab	100 mg
Week 64 - EXT	17MAR2010	451	3	Placebo	0 mg
Week 68 - EXT	15APR2010	480	4	Golimumab	100 mg
Week 68 - EXT	15APR2010	480	4	Placebo	0 mg
Week 72 - EXT	12MAY2010	507	5	Golimumab	100 mg
Week 72 - EXT	12MAY2010	507	5	Placebo	0 mg
Week 76 - EXT	09JUN2010	535	6	Golimumab	100 mg
Week 76 - EXT	09JUN2010	535	6	Placebo	0 mg
Week 80 - EXT	06JUL2010	562	7	Golimumab	100 mg
Week 80 - EXT	06JUL2010	562	7	Placebo	0 mg
Week 84 - EXT	09AUG2010	596	8	Golimumab	100 mg
Week 84 - EXT	09AUG2010	596	8	Placebo	0 mg
Week 88 - EXT	03SEP2010	621	9	Golimumab	100 mg
Week 88 - EXT	03SEP2010	621	9	Placebo	0 mg
Week 92 - EXT	30SEP2010	648	10	Placebo	0 mg
Week 92 - EXT	30SEP2010	648	10	Golimumab	100 mg
Week 96 - EXT	28OCT2010	676	11	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 96 - EXT	28OCT2010	676	11	Placebo	0 mg
Week 100 - EXT	25NOV2010	704	12	Golimumab	100 mg
Week 100 - EXT	25NOV2010	704	12	Placebo	0 mg
Week 104 - EXT	21DEC2010	730	13	Golimumab	100 mg
Week 104 - EXT	21DEC2010	730	13	Placebo	0 mg
Week 108 - EXT	17JAN2011	757	14	Golimumab	100 mg
Week 108 - EXT	17JAN2011	757	14	Placebo	0 mg
Week 112 - EXT	21FEB2011	792	15	Golimumab	100 mg
Week 112 - EXT	21FEB2011	792	15	Placebo	0 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
ALLOPURINOL,Oral	02MAR2011	06MAY2011
RIFAMPICIN,Oral	02MAR2011	Ongoing
ISONIAZID,Oral	02MAR2011	Ongoing
PYRAZINAMIDE,Oral	04MAR2011	06MAY2011
ETHAMBUTOL,Oral	08MAR2011	06MAY2011

被験者識別コード：6112-00001

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
10MAR2011 (990)	心膜炎 (PERICARDITIS)	Yes	Moderate/ Unlikely	Yes/ No	None/not applicable	20APR2011 (1031)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
17OCT2009 (481)	帯状疱疹 (SHINGLES, LOWER BACK, DIFFUSE)	Mild/ Possible	Yes/ No	None/not applicable	25OCT2009 (489)
22SEP2010 (821)	消化不良 (INTERMITTENT INDIGESTION)	Mild/ Unlikely	No/ NA	None/not applicable	Ongoing -
31JAN2011 (952)	発疹 (RASH, BACK AND HEAD)	Moderate/ Possible	No/ NA	None/not applicable	23FEB2011 (975)
05MAY2011 (1046)	発疹 (RASH, SCALP)	Moderate/ Possible	No/ NA	None/not applicable	26AUG2011 (1159)
19SEP2011 (1183)	ウイルス性上気道感染 (COLD VIRUS)	Mild/ Unlikely	Yes/ No	None/not applicable	12OCT2011 (1206)
27OCT2011 (1221)	皮膚乳頭腫 (PLANTAR WART)	Moderate/ Unlikely	No/ NA	None/not applicable	03DEC2011 (1258)
30OCT2011 (1224)	処置後感染 (INFECTION AT SITE OF PLANTAR WART EXCISION)	Moderate/ Unlikely	Yes/ Yes	None/not applicable	19NOV2011 (1244)

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
05FEB2012 (1322)	背部痛 (LEFT SIDED BACK PAIN)	Moderate/ Unlikely	No/ NA	None/not applicable	01JUN2012 (1439)

■ **Demographics and Baseline Characteristics**

□ Race:Caucasian
□ Age (yrs):5[redacted]
□ Sex:Male
□ Date of birth:17MAR[redacted]
□ Height (cm):184
□ Weight (kg):75.0
□ Date of UC diagnosis:23MAR1993
□ UC disease duration (years):15.1
□ Relevant medical history at baseline:-

■ **Treatment Groups**

□ Induction study:C0524T16

□ Treatment group in induction:2 mg/kg IV

□ Treatment group in maintenance:Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?:No

□ Adjusted treatment group:-

□ Treatment group during start of LTE:Golimumab 100 mg

□ Dose adjusted during LTE:No

□ Adjusted treatment group during LTE:-

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	21JUL2009	393	1	Placebo	0 mg
Week 56 - EXT	21JUL2009	393	1	Placebo	0 mg
Week 56 - EXT	21JUL2009	393	1	Golimumab	100 mg
Week 60 - EXT	25AUG2009	428	2	Placebo	0 mg
Week 60 - EXT	25AUG2009	428	2	Placebo	0 mg
Week 60 - EXT	25AUG2009	428	2	Golimumab	100 mg
Week 64 - EXT	23SEP2009	457	3	Golimumab	100 mg
Week 64 - EXT	23SEP2009	457	3	Placebo	0 mg
Week 64 - EXT	23SEP2009	457	3	Placebo	0 mg
Week 68 - EXT	13OCT2009	477	4	Placebo	0 mg
Week 68 - EXT	13OCT2009	477	4	Placebo	0 mg
Week 68 - EXT	13OCT2009	477	4	Golimumab	100 mg
Week 72 - EXT	10NOV2009	505	5	Placebo	0 mg
Week 72 - EXT	10NOV2009	505	5	Golimumab	100 mg
Week 72 - EXT	10NOV2009	505	5	Placebo	0 mg
Week 76 - EXT	01DEC2009	526	6	Golimumab	100 mg
Week 76 - EXT	01DEC2009	526	6	Placebo	0 mg
Week 76 - EXT	01DEC2009	526	6	Placebo	0 mg
Week 80 - EXT	13JAN2010	569	7	Golimumab	100 mg
Week 80 - EXT	13JAN2010	569	7	Placebo	0 mg
Week 80 - EXT	13JAN2010	569	7	Placebo	0 mg
Week 84 - EXT	09FEB2010	596	8	Golimumab	100 mg
Week 84 - EXT	09FEB2010	596	8	Placebo	0 mg
Week 84 - EXT	09FEB2010	596	8	Placebo	0 mg
Week 88 - EXT	02MAR2010	617	9	Placebo	0 mg
Week 88 - EXT	02MAR2010	617	9	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 92 - EXT	31MAR2010	646	10	Golimumab	100 mg
Week 92 - EXT	31MAR2010	646	10	Placebo	0 mg
Week 96 - EXT	27APR2010	673	11	Placebo	0 mg
Week 96 - EXT	27APR2010	673	11	Golimumab	100 mg
Week 100 - EXT	25MAY2010	701	12	Placebo	0 mg
Week 100 - EXT	25MAY2010	701	12	Golimumab	100 mg
Week 104 - EXT	24JUN2010	731	13	Placebo	0 mg
Week 104 - EXT	24JUN2010	731	13	Golimumab	100 mg
Week 108 - EXT	13JUL2010	750	14	Placebo	0 mg
Week 108 - EXT	13JUL2010	750	14	Golimumab	100 mg
Week 112 - EXT	10AUG2010	778	15	Placebo	0 mg
Week 112 - EXT	10AUG2010	778	15	Golimumab	100 mg
Week 116 - EXT	07SEP2010	806	16	Placebo	0 mg
Week 116 - EXT	07SEP2010	806	16	Golimumab	100 mg
Week 120 - EXT	05OCT2010	834	17	Golimumab	100 mg
Week 120 - EXT	05OCT2010	834	17	Placebo	0 mg
Week 124 - EXT	02NOV2010	862	18	Golimumab	100 mg
Week 124 - EXT	02NOV2010	862	18	Placebo	0 mg
Week 128 - EXT	24NOV2010	884	19	Placebo	0 mg
Week 128 - EXT	24NOV2010	884	19	Golimumab	100 mg
Week 132 - EXT	22DEC2010	912	20	Golimumab	100 mg
Week 132 - EXT	22DEC2010	912	20	Placebo	0 mg
Week 136 - EXT	18JAN2011	939	21	Golimumab	100 mg
Week 136 - EXT	18JAN2011	939	21	Placebo	0 mg
Week 140 - EXT	02MAR2011	982	22	Placebo	0 mg
Week 140 - EXT	02MAR2011	982	22	Golimumab	100 mg
Week 144 - EXT	05APR2011	1016	23	Golimumab	100 mg
Week 144 - EXT	05APR2011	1016	23	Placebo	0 mg
Week 148 - EXT	03MAY2011	1044	24	Golimumab	100 mg
Week 148 - EXT	03MAY2011	1044	24	Placebo	0 mg
Week 152 - EXT	31MAY2011	1072	25	Placebo	0 mg
Week 152 - EXT	31MAY2011	1072	25	Golimumab	100 mg
Week 156 - EXT	05JUL2011	1107	26	Placebo	0 mg
Week 156 - EXT	05JUL2011	1107	26	Golimumab	100 mg
Week 160 - EXT	26JUL2011	1128	27	Golimumab	100 mg
Week 160 - EXT	26JUL2011	1128	27	Placebo	0 mg
Week 164 - EXT	23AUG2011	1156	28	Golimumab	100 mg
Week 164 - EXT	23AUG2011	1156	28	Placebo	0 mg
Week 168 - EXT	20SEP2011	1184	29	Placebo	0 mg
Week 168 - EXT	20SEP2011	1184	29	Golimumab	100 mg
Week 172 - EXT	18OCT2011	1212	30	Golimumab	100 mg
Week 172 - EXT	18OCT2011	1212	30	Placebo	0 mg
Week 176 - EXT	21NOV2011	1246	31	Golimumab	100 mg
Week 176 - EXT	21NOV2011	1246	31	Placebo	0 mg
Week 180 - EXT	13DEC2011	1268	32	Golimumab	100 mg
Week 180 - EXT	13DEC2011	1268	32	Placebo	0 mg
Week 184 - EXT	10JAN2012	1296	33	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 188 - EXT	09FEB2012	1326	34	Golimumab	100 mg
Week 192 - EXT	08MAR2012	1354	35	Golimumab	100 mg
Week 196 - EXT	02APR2012	1379	36	Golimumab	100 mg
Week 200 - EXT	01MAY2012	1408	37	Golimumab	100 mg
Week 204 - EXT	29MAY2012	1436	38	Golimumab	100 mg
Week 208 - EXT	28JUN2012	1466	39	Golimumab	100 mg
Week 212 - EXT	24JUL2012	1492	40	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
PICO-SALAX,Oral	05OCT2009	06OCT2009
BISACODYL,Oral	05OCT2009	05OCT2009
FENTANYL,Intravenous	06OCT2009	06OCT2009
MIDAZOLAM,Intravenous	06OCT2009	06OCT2009
HYOSCINE,Intravenous	06OCT2009	06OCT2009
GOLYTELY,Oral	04OCT2010	04OCT2010
BISACODYL,Oral	04OCT2010	04OCT2010
NAPROXEN,Oral	10MAR2011	11MAR2011
COLCHICINE,Oral	10MAR2011	Ongoing
PANTOPRAZOLE,Oral	11MAR2011	Ongoing
CEFTRIAXONE,Intravenous	01NOV2011	05NOV2011
CLINDAMYCIN,Intravenous	06NOV2011	06NOV2011
CLINDAMYCIN,Oral	07NOV2011	19NOV2011
MAGNESIUM CITRATE,Oral	27DEC2011	27DEC2011
FENTANYL,Intravenous	28DEC2011	28DEC2011
MIDAZOLAM,Intravenous	28DEC2011	28DEC2011
HYOSCINE,Intravenous	28DEC2011	28DEC2011
NAPROXEN,Oral	07FEB2012	07FEB2012

被験者識別コード：7376-00002

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
14APR2011 (886)	肛門膿瘍 (PERIANAL ABCESS)	Yes	Severe/ Possible	Yes/ Yes	None/not applicable	Ongoing -

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
21JUL2010 (619)	発疹 (RASH BOTH FOREARMS)	Mild/ Unlikely	No/ NA	None/not applicable	28JUL2010 (626)
10SEP2011 (1035)	上気道感染 (URTI)	Mild/ Unlikely	Yes/ No	None/not applicable	Ongoing -

■ **Demographics and Baseline Characteristics**

□ Race: Other
□ Age (yrs): 4[redacted]
□ Sex: Male
□ Date of birth: 19JUN[redacted]
□ Height (cm): 170
□ Weight (kg): 90.5
□ Date of UC diagnosis: 28SEP1998
□ UC disease duration (years): 10.0
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 100mg -> 50mg SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	14DEC2009	400	1	Golimumab	100 mg
Week 56 - EXT	14DEC2009	400	1	Placebo	0 mg
Week 56 - EXT	14DEC2009	400	1	Placebo	0 mg
Week 60 - EXT	05JAN2010	422	2	Golimumab	100 mg
Week 60 - EXT	05JAN2010	422	2	Placebo	0 mg
Week 60 - EXT	05JAN2010	422	2	Placebo	0 mg
Week 64 - EXT	01FEB2010	449	3	Placebo	0 mg
Week 64 - EXT	01FEB2010	449	3	Golimumab	100 mg
Week 64 - EXT	01FEB2010	449	3	Placebo	0 mg
Week 68 - EXT	01MAR2010	477	4	Placebo	0 mg
Week 68 - EXT	01MAR2010	477	4	Golimumab	100 mg
Week 72 - EXT	29MAR2010	505	5	Golimumab	100 mg
Week 72 - EXT	29MAR2010	505	5	Placebo	0 mg
Week 76 - EXT	26APR2010	533	6	Placebo	0 mg
Week 76 - EXT	26APR2010	533	6	Golimumab	100 mg
Week 80 - EXT	24MAY2010	561	7	Golimumab	100 mg
Week 80 - EXT	24MAY2010	561	7	Placebo	0 mg
Week 84 - EXT	21JUN2010	589	8	Golimumab	100 mg
Week 84 - EXT	21JUN2010	589	8	Placebo	0 mg
Week 88 - EXT	19JUL2010	617	9	Golimumab	100 mg
Week 88 - EXT	19JUL2010	617	9	Placebo	0 mg
Week 92 - EXT	16AUG2010	645	10	Golimumab	100 mg
Week 92 - EXT	16AUG2010	645	10	Placebo	0 mg
Week 96 - EXT	13SEP2010	673	11	Placebo	0 mg
Week 96 - EXT	13SEP2010	673	11	Golimumab	100 mg
Week 100 - EXT	11OCT2010	701	12	Golimumab	100 mg
Week 100 - EXT	11OCT2010	701	12	Placebo	0 mg
Week 104 - EXT	08NOV2010	729	13	Placebo	0 mg
Week 104 - EXT	08NOV2010	729	13	Golimumab	100 mg
Week 108 - EXT	06DEC2010	757	14	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 108 - EXT	06DEC2010	757	14	Golimumab	100 mg
Week 112 - EXT	30DEC2010	781	15	Placebo	0 mg
Week 112 - EXT	30DEC2010	781	15	Golimumab	100 mg
Week 116 - EXT	07FEB2011	820	16	Golimumab	100 mg
Week 116 - EXT	07FEB2011	820	16	Placebo	0 mg
Week 120 - EXT	07MAR2011	848	17	Placebo	0 mg
Week 120 - EXT	07MAR2011	848	17	Golimumab	100 mg
Week 124 - EXT	04APR2011	876	18	Golimumab	100 mg
Week 124 - EXT	04APR2011	876	18	Placebo	0 mg
Week 128 - EXT	02MAY2011	904	19	Placebo	0 mg
Week 128 - EXT	02MAY2011	904	19	Golimumab	100 mg
Week 132 - EXT	02JUN2011	935	20	Golimumab	100 mg
Week 132 - EXT	02JUN2011	935	20	Placebo	0 mg
Week 136 - EXT	04JUL2011	967	21	Placebo	0 mg
Week 136 - EXT	04JUL2011	967	21	Golimumab	100 mg
Week 140 - EXT	03AUG2011	997	22	Golimumab	100 mg
Week 140 - EXT	03AUG2011	997	22	Placebo	0 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
FLUCLOXACILLIN,Oral	04APR2011	11APR2011
METRONIDAZOLE,Intravenous	15APR2011	17APR2011
CEFUROXIME,Intravenous	15APR2011	17APR2011
ENOXAPARIN,Subcutaneous	15APR2011	16APR2011
CODEINE,Oral	16APR2011	17APR2011
PARACETAMOL,Oral	16APR2011	19APR2011
FENTANYL,Intravenous	16APR2011	16APR2011
CEFACLOR,Oral	18APR2011	25APR2011
MIDAZOLAM,Intravenous	03AUG2011	03AUG2011
FENTANYL,Intravenous	03AUG2011	03AUG2011

被験者識別コード：7230-00018

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
02FEB2011 (546)	虫垂炎 (ACUT APPENDICITIS)	Yes	Severe/ Not related	Yes/ Yes	Temporary interruption/dose modification	21FEB2011 (565)

■ **Other Adverse Events**

No Other Adverse Events reported

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 4[redacted]
□ Sex: Female
□ Date of birth: 25JUN[redacted]
□ Height (cm): 164
□ Weight (kg): 84.5
□ Date of UC diagnosis: 28JAN2009
□ UC disease duration (years): 0.4
□ Relevant medical history at baseline: 喫煙（過去/現在）

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 200mg -> 100mg SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: Not applicable or N/A

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: Yes

□ Adjusted treatment group during LTE: Golimumab 100 mg

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	02SEP2010	393	1	Placebo	0 mg
Week 56 - EXT	02SEP2010	393	1	Golimumab	100 mg
Week 60 - EXT	30SEP2010	421	2	Placebo	0 mg
Week 60 - EXT	30SEP2010	421	2	Golimumab	100 mg
Week 64 - EXT	21OCT2010	442	3	Placebo	0 mg
Week 64 - EXT	21OCT2010	442	3	Golimumab	100 mg
Week 68 - EXT	11NOV2010	463	4	Placebo	0 mg
Week 68 - EXT	11NOV2010	463	4	Golimumab	100 mg
Week 72 - EXT	23DEC2010	505	5	Golimumab	100 mg
Week 72 - EXT	23DEC2010	505	5	Placebo	0 mg
Week 76 - EXT	20JAN2011	533	6	Placebo	0 mg
Week 76 - EXT	20JAN2011	533	6	Golimumab	100 mg
Week 80 - EXT	31MAR2011	603	7	Placebo	0 mg
Week 80 - EXT	31MAR2011	603	7	Golimumab	100 mg
Week 84 - EXT	14APR2011	617	8	Golimumab	100 mg
Week 84 - EXT	14APR2011	617	8	Placebo	0 mg
Week 88 - EXT	05MAY2011	638	9	Golimumab	100 mg
Week 88 - EXT	05MAY2011	638	9	Placebo	0 mg
Week 92 - EXT	26MAY2011	659	10	Golimumab	100 mg
Week 92 - EXT	26MAY2011	659	10	Placebo	0 mg
Week 96 - EXT	23JUN2011	687	11	Placebo	0 mg
Week 96 - EXT	23JUN2011	687	11	Golimumab	100 mg
Week 100 - EXT	21JUL2011	715	12	Golimumab	100 mg
Week 100 - EXT	21JUL2011	715	12	Placebo	0 mg
Week 104 - EXT	18AUG2011	743	1	Placebo	0 mg
Week 104 - EXT	18AUG2011	743	1	Golimumab	100 mg
Week 108 - EXT	15SEP2011	771	2	Placebo	0 mg
Week 108 - EXT	15SEP2011	771	2	Golimumab	100 mg
Week 112 - EXT	13OCT2011	799	3	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 112 - EXT	13OCT2011	799	3	Placebo	0 mg
Week 116 - EXT	10NOV2011	827	4	Placebo	0 mg
Week 116 - EXT	10NOV2011	827	4	Golimumab	100 mg
Week 120 - EXT	08DEC2011	855	5	Placebo	0 mg
Week 120 - EXT	08DEC2011	855	5	Golimumab	100 mg
Week 124 - EXT	05JAN2012	883	6	Golimumab	100 mg
Week 128 - EXT	02FEB2012	911	7	Golimumab	100 mg
Week 132 - EXT	01MAR2012	939	8	Golimumab	100 mg
Week 136 - EXT	29MAR2012	967	9	Golimumab	100 mg
Week 140 - EXT	26APR2012	995	10	Golimumab	100 mg
Week 144 - EXT	24MAY2012	1023	11	Golimumab	100 mg
Week 148 - EXT	21JUN2012	1051	12	Golimumab	100 mg
Week 152 - EXT	19JUL2012	1079	13	Golimumab	100 mg
Week 156 - EXT	16AUG2012	1107	14	Golimumab	100 mg
Week 160 - EXT	13SEP2012	1135	15	Golimumab	100 mg
Week 164 - EXT	11OCT2012	1163	16	Golimumab	100 mg
Week 168 - EXT	08NOV2012	1191	17	Golimumab	100 mg
Week 172 - EXT	06DEC2012	1219	18	Golimumab	100 mg
Week 176 - EXT	03JAN2013	1247	19	Golimumab	100 mg
Week 180 - EXT	31JAN2013	1275	20	Golimumab	100 mg
Week 184 - EXT	28FEB2013	1303	21	Golimumab	100 mg
Week 188 - EXT	28MAR2013	1331	22	Golimumab	100 mg
Week 192 - EXT	25APR2013	1359	23	Golimumab	100 mg
Week 196 - EXT	23MAY2013	1387	24	Golimumab	100 mg
Week 200 - EXT	20JUN2013	1415	25	Golimumab	100 mg
Week 204 - EXT	18JUL2013	1443	26	Golimumab	100 mg
Week 208 - EXT	15AUG2013	1471	27	Golimumab	100 mg
Week 212 - EXT	05SEP2013	1492	28	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
MOXIFLOXACIN,Oral	02FEB2011	21FEB2011
MOXIFLOXACIN,Oral	05FEB2011	16FEB2011

被験者識別コード：7263-00007

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
10MAR2013 (990)	咳嗽 (COUGH)	No	Mild/ Possible	Yes/ Yes	Permanent discontinuation of study agent	22MAR2013 (1002)

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
10MAR2013 (990)	発熱 (FEVER)	No	Mild/ Possible	Yes/ Yes	Permanent discontinuation of study agent	22MAR2013 (1002)
22MAR2013 (1002)	肺外結核 (EXTRA PULMONARY TUBERCULOSIS)	Yes	Moderate/ Possible	Yes/ Yes	Permanent discontinuation of study agent	08APR2013 (1019)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
08APR2013 (1019)	肺外結核 (EXTRA PULMONARY TUBERCULOSIS)	Mild/ Possible	Yes/ Yes	None/not applicable	Ongoing -

■ **Demographics and Baseline Characteristics**

□ Race: Asian
□ Age (yrs): 3[redacted]
□ Sex: Female
□ Date of birth: 01JAN[redacted]
□ Height (cm): 150
□ Weight (kg): 33.0
□ Date of UC diagnosis: 17AUG2009
□ UC disease duration (years): 0.7
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 200mg -> 100mg SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	29JUL2011	400	1	Placebo	0 mg
Week 56 - EXT	29JUL2011	400	1	Golimumab	100 mg
Week 60 - EXT	23AUG2011	425	2	Placebo	0 mg
Week 60 - EXT	23AUG2011	425	2	Golimumab	100 mg
Week 64 - EXT	28SEP2011	461	3	Golimumab	100 mg
Week 64 - EXT	28SEP2011	461	3	Placebo	0 mg
Week 68 - EXT	25OCT2011	488	4	Golimumab	100 mg
Week 68 - EXT	25OCT2011	488	4	Placebo	0 mg
Week 72 - EXT	25NOV2011	519	5	Placebo	0 mg
Week 72 - EXT	25NOV2011	519	5	Golimumab	100 mg
Week 76 - EXT	29DEC2011	553	6	Golimumab	100 mg
Week 80 - EXT	06FEB2012	592	7	Golimumab	100 mg
Week 84 - EXT	17FEB2012	603	8	Golimumab	100 mg
Week 88 - EXT	16MAR2012	631	9	Golimumab	100 mg
Week 92 - EXT	20APR2012	666	10	Golimumab	100 mg
Week 96 - EXT	19MAY2012	695	11	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 100 - EXT	02JUN2012	709	12	Golimumab	100 mg
Week 104 - EXT	03JUL2012	740	13	Golimumab	100 mg
Week 108 - EXT	03AUG2012	771	14	Golimumab	100 mg
Week 112 - EXT	31AUG2012	799	15	Golimumab	100 mg
Week 116 - EXT	28SEP2012	827	16	Golimumab	100 mg
Week 120 - EXT	26OCT2012	855	17	Golimumab	100 mg
Week 124 - EXT	23NOV2012	883	18	Golimumab	100 mg
Week 128 - EXT	26DEC2012	916	19	Golimumab	100 mg
Week 132 - EXT	17JAN2013	938	20	Golimumab	100 mg
Week 136 - EXT	13FEB2013	965	21	Golimumab	100 mg
Week 140 - EXT	12MAR2013	992	22	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
VITAMIN B-COMPLEX, OTHER COMBINATIONS,Oral	12MAR2013	16MAR2013
ANTIBACTERIALS FOR SYSTEMIC USE,Oral	12MAR2013	16MAR2013
CETIRIZINE,Oral	22MAR2013	24MAR2013
PANTOPRAZOLE,Oral	22MAR2013	24MAR2013
PIP/TAZO,Intravenous	22MAR2013	29MAR2013
STREPTOMYCIN,Intravenous	23MAR2013	08APR2013
MYRIN PLUS,Oral	23MAR2013	Ongoing
DIPHENHYDRAMINE,Oral	25MAR2013	04APR2013
OFLOXACIN,Oral	25MAR2013	Ongoing
CEFTRIAXONE,Intravenous	30MAR2013	08APR2013
VITAMIN B COMPLEX,Oral	05APR2013	Ongoing

被験者識別コード：7741-00005

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Interstitial lung disease

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
03AUG2011 (618)	間質性肺疾患 (INTERSTITIAL LUNG DISEASE)	Yes	Moderate/ Probable	No/ NA	Permanent discontinuation of study agent	14SEP2011 (660)
03AUG2011 (618)	肺臓炎 (PNEUMONITIS)	Yes	Moderate/ Probable	No/ NA	Permanent discontinuation of study agent	08DEC2011 (745)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
05JAN2011 (408)	無気肺 (ATLECTASIS)	Moderate/ Unlikely	No/ NA	None/not applicable	17JAN2011 (420)
07JAN2011 (410)	椎間板突出 (STENOSIS D/T DISC HERNIATION C5 & C6)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
23JAN2011 (426)	頭痛 (HEAD ACHE)	Mild/ Not related	No/ NA	None/not applicable	25JAN2011 (428)
23JAN2011 (426)	口腔咽頭痛 (SORE THROAT)	Mild/ Not related	No/ NA	None/not applicable	25JAN2011 (428)
23JAN2011 (426)	湿性咳嗽 (COUGH WITH MILD PHLEM)	Mild/ Not related	No/ NA	None/not applicable	01MAR2011 (463)
23JAN2011 (426)	鼻漏 (CLEAR IN COLOR NASAL DRAINAGE)	Mild/ Not related	No/ NA	None/not applicable	25JAN2011 (428)
02MAR2011 (464)	咳嗽 (COUGH, WITH DEEP BREATHS ONLY)	Mild/ Not related	No/ NA	None/not applicable	27JUN2011 (581)
27JUN2011 (581)	咳嗽 (INCREASED FREQUENCY OF DRY COUGH)	Moderate/ Possible	No/ NA	Temporary interruption/dose modification	06AUG2011 (621)
27JUN2011 (581)	呼吸困難 (SHORTNESS OF BREATH)	Mild/ Possible	No/ NA	Temporary interruption/dose modification	11AUG2011 (626)
29JUN2011 (583)	咳嗽 (CHEST TIGHTENING R/T INCREASED COUGH FREQUENCY)	Mild/ Possible	No/ NA	Temporary interruption/dose modification	08AUG2011 (623)
29JUN2011 (583)	呼吸困難 (TIRED FEELING R/T INCREASED SOB)	Moderate/ Possible	No/ NA	Temporary interruption/dose modification	08AUG2011 (623)
30JUN2011 (584)	咳嗽 (HEAD ACHES DUE TO INCREASED COUGHING)	Mild/ Possible	No/ NA	Temporary interruption/dose modification	05AUG2011 (620)
13JUL2011 (597)	高血圧 (MILD HYPERTENSION)	Mild/ Unlikely	No/ NA	None/not applicable	Ongoing -
15JUL2011 (599)	肺気腫 (EMPHYSEMA)	Mild/ Unlikely	No/ NA	None/not applicable	Ongoing -
02SEP2011 (648)	筋痙縮 (CRAMPING OF FINGERS)	Mild/ Not related	No/ NA	None/not applicable	07SEP2011 (653)
02SEP2011 (648)	筋痙縮 (CRAMPING OF TOES)	Mild/ Not related	No/ NA	None/not applicable	07SEP2011 (653)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 6[redacted]
□ Sex: Female
□ Date of birth: 14FEB[redacted]
□ Height (cm): 168
□ Weight (kg): 91.4
□ Date of UC diagnosis: 22JUL1999
□ UC disease duration (years): 10.2
□ Relevant medical history at baseline: 喫煙（過去/現在）

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 200mg -> 100mg SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	07JAN2011	410	1	Golimumab	100 mg
Week 56 - EXT	07JAN2011	410	1	Placebo	0 mg
Week 60 - EXT	25JAN2011	428	2	Placebo	0 mg
Week 60 - EXT	25JAN2011	428	2	Golimumab	100 mg
Week 64 - EXT	24FEB2011	458	3	Golimumab	100 mg
Week 64 - EXT	24FEB2011	458	3	Placebo	0 mg
Week 68 - EXT	22MAR2011	484	4	Golimumab	100 mg
Week 68 - EXT	22MAR2011	484	4	Placebo	0 mg
Week 72 - EXT	11APR2011	504	5	Golimumab	100 mg
Week 72 - EXT	11APR2011	504	5	Placebo	0 mg
Week 76 - EXT	16MAY2011	539	6	Golimumab	100 mg
Week 76 - EXT	16MAY2011	539	6	Placebo	0 mg
Week 80 - EXT	10JUN2011	564	7	Golimumab	100 mg
Week 80 - EXT	10JUN2011	564	7	Placebo	0 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
CARISOPRODOL,Oral	19JAN2011	22JAN2011
COUGH AND COLD PREPARATIONS,Oral	23JAN2011	25JAN2011
CYCLOBENZAPRINE,Oral	06FEB2011	06MAR2011
LIDOCAINE,Epidural	21FEB2011	21FEB2011
LIDOCAINE,Subcutaneous	21FEB2011	21FEB2011
IOHEXOL,Epidural	21FEB2011	21FEB2011
DEXAMETHASONE,Intraneural	21FEB2011	21FEB2011
FISH OIL,Oral	06JUN2011	03AUG2011
BEE POLLEN,Oral	06JUL2011	03AUG2011
HYDROCHLOROTHIAZIDE,Oral	13JUL2011	Ongoing
BUDESONIDE W/FORMOTEROL FUMARATE,Inhalation	16JUL2011	03AUG2011
HYDROCODONE,Oral	16JUL2011	03AUG2011
OMEPRAZOLE,Oral	21JUL2011	15AUG2011
PREDNISONE,Oral	03AUG2011	Ongoing

被験者識別コード：7746-00005

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
27NOV2012 (1344)	潰瘍性大腸炎 (CHRONIC ULCERATIVE COLITIS AT INCREASED RISK FOR DYSPLASIA)	No	Moderate/ Not related	No/ NA	Permanent discontinuation of study agent	29OCT2013 (1680)
12FEB2013 (1421)	骨盤内敗血症 (PELVIC SEPSIS)	Yes	Severe/ Not related	Yes/ Yes	None/not applicable	15FEB2013 (1424)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
13JUL2010 (476)	副鼻腔炎 (SINUS INFECTION)	Moderate/ Not related	Yes/ Yes	None/not applicable	19JUL2010 (482)
27DEC2010 (643)	上気道感染 (UPPER RESPIRATORY INFECTION)	Mild/ Not related	Yes/ No	None/not applicable	30DEC2010 (646)
29JAN2011 (676)	副鼻腔うっ血 (SINUS CONGESTION)	Mild/ Not related	Yes/ Yes	None/not applicable	05FEB2011 (683)
11AUG2011 (870)	血便排泄 (BLOOD IN STOOL)	Moderate/ Not related	No/ NA	None/not applicable	16AUG2011 (875)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 4[redacted]
□ Sex: Male
□ Date of birth: 24AUG[redacted]
□ Height (cm): 178
□ Weight (kg): 77.7
□ Date of UC diagnosis: -----1991
□ UC disease duration (years): 17.1
□ Relevant medical history at baseline: 喫煙（過去/現在）

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 200mg -> 100mg SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	15APR2010	387	1	Golimumab	100 mg
Week 56 - EXT	15APR2010	387	1	Placebo	0 mg
Week 60 - EXT	19MAY2010	421	2	Golimumab	100 mg
Week 60 - EXT	19MAY2010	421	2	Placebo	0 mg
Week 64 - EXT	14JUN2010	447	3	Golimumab	100 mg
Week 64 - EXT	14JUN2010	447	3	Placebo	0 mg
Week 68 - EXT	19JUL2010	482	4	Golimumab	100 mg
Week 68 - EXT	19JUL2010	482	4	Placebo	0 mg
Week 72 - EXT	11AUG2010	505	5	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 72 - EXT	11AUG2010	505	5	Placebo	0 mg
Week 76 - EXT	09SEP2010	534	6	Placebo	0 mg
Week 76 - EXT	09SEP2010	534	6	Golimumab	100 mg
Week 80 - EXT	06OCT2010	561	7	Placebo	0 mg
Week 80 - EXT	06OCT2010	561	7	Golimumab	100 mg
Week 84 - EXT	02NOV2010	588	8	Placebo	0 mg
Week 84 - EXT	02NOV2010	588	8	Golimumab	100 mg
Week 88 - EXT	06DEC2010	622	9	Placebo	0 mg
Week 88 - EXT	06DEC2010	622	9	Golimumab	100 mg
Week 92 - EXT	04JAN2011	651	10	Golimumab	100 mg
Week 92 - EXT	04JAN2011	651	10	Placebo	0 mg
Week 96 - EXT	01FEB2011	679	11	Golimumab	100 mg
Week 96 - EXT	01FEB2011	679	11	Placebo	0 mg
Week 100 - EXT	28FEB2011	706	12	Golimumab	100 mg
Week 100 - EXT	28FEB2011	706	12	Placebo	0 mg
Week 104 - EXT	22MAR2011	728	13	Golimumab	100 mg
Week 104 - EXT	22MAR2011	728	13	Placebo	0 mg
Week 108 - EXT	21APR2011	758	14	Golimumab	100 mg
Week 108 - EXT	21APR2011	758	14	Placebo	0 mg
Week 112 - EXT	17MAY2011	784	15	Golimumab	100 mg
Week 112 - EXT	17MAY2011	784	15	Placebo	0 mg
Week 116 - EXT	14JUN2011	812	16	Golimumab	100 mg
Week 116 - EXT	14JUN2011	812	16	Placebo	0 mg
Week 120 - EXT	14JUL2011	842	17	Golimumab	100 mg
Week 120 - EXT	14JUL2011	842	17	Placebo	0 mg
Week 124 - EXT	11AUG2011	870	18	Placebo	0 mg
Week 124 - EXT	11AUG2011	870	18	Golimumab	100 mg
Week 128 - EXT	12SEP2011	902	19	Golimumab	100 mg
Week 128 - EXT	12SEP2011	902	19	Placebo	0 mg
Week 132 - EXT	05OCT2011	925	20	Golimumab	100 mg
Week 132 - EXT	05OCT2011	925	20	Placebo	0 mg
Week 136 - EXT	31OCT2011	951	21	Golimumab	100 mg
Week 136 - EXT	31OCT2011	951	21	Placebo	0 mg
Week 140 - EXT	30NOV2011	981	22	Golimumab	100 mg
Week 140 - EXT	30NOV2011	981	22	Placebo	0 mg
Week 144 - EXT	22DEC2011	1003	23	Golimumab	100 mg
Week 148 - EXT	25JAN2012	1037	24	Golimumab	100 mg
Week 152 - EXT	23FEB2012	1066	25	Golimumab	100 mg
Week 156 - EXT	21MAR2012	1093	26	Golimumab	100 mg
Week 160 - EXT	19APR2012	1122	27	Golimumab	100 mg
Week 164 - EXT	16MAY2012	1149	28	Golimumab	100 mg
Week 168 - EXT	13JUN2012	1177	29	Golimumab	100 mg
Week 172 - EXT	11JUL2012	1205	30	Golimumab	100 mg
Week 176 - EXT	08AUG2012	1233	31	Golimumab	100 mg
Week 180 - EXT	10SEP2012	1266	32	Golimumab	100 mg
Week 184 - EXT	02OCT2012	1288	33	Golimumab	100 mg
Week 188 - EXT	30OCT2012	1316	34	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
FLUDROCORTISONE,Oral	--JAN2013	Ongoing
AMOXICILLIN,Oral	15JUL2010	25JUL2010
OMEPRAZOLE,Oral	16DEC2010	Ongoing
ASCORBIC ACID W/HERBAL NOS/LEVOGLUTAMIDE/LYSI,Oral	27DEC2010	27DEC2010
AZITHROMYCIN,Oral	01FEB2011	06FEB2011
MESALAZINE,Oral	29APR2011	Ongoing
VITAMIN B12 NOS,Intramuscular	14JUN2011	14JUL2011
MACROGOL,Oral	10AUG2011	10AUG2011
BISACODYL,Oral	10AUG2011	10AUG2011
MIDAZOLAM,Intravenous	11AUG2011	11AUG2011
PROPOFOL,Intravenous	11AUG2011	11AUG2011
LIDOCAINE,Intravenous	11AUG2011	11AUG2011
TAMSULOSIN,Oral	12FEB2013	15FEB2013
CIPROFLOXACIN,Intravenous	12FEB2013	15FEB2013
HYDROMORPHONE,Intravenous	12FEB2013	13FEB2013
METRONIDAZOLE,Intravenous	12FEB2013	15FEB2013
ENOXAPARIN,Subcutaneous	13FEB2013	15FEB2013
PANTOPRAZOLE,Intravenous	13FEB2013	15FEB2013
KETOROLAC,Intravenous	13FEB2013	15FEB2013
CEFOTETAN,Intravenous	13FEB2013	13FEB2013
PIP/TAZO,Intravenous	14FEB2013	15FEB2013
PARACETAMOL,Intravenous	14FEB2013	15FEB2013
IRON,Intravenous	14FEB2013	14FEB2013
AUGMENTIN /00756801/,Oral	15FEB2013	28FEB2013
OXYCOCET,Oral	15FEB2013	Ongoing
IBUPROFEN,Oral	15FEB2013	Ongoing
ASCORBIC ACID,Oral	15FEB2013	Ongoing

被験者識別コード：7753-00004

■ **REASON FOR NARRATIVE SELECTION**

Death

SAE

Discontinuation of study agent due to AE

Event of interest: Malignancy

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
10APR2013 (1028)	Ｔ細胞性リンパ腫 (T CELL LYMPHOMA)	Yes	Mild/ Possible	No/ NA	Permanent discontinuation of study agent	Ongoing -
05AUG2013 (1145)	誤嚥 (MASSIVE ASPIRATION)	Yes	Severe/ Not related	No/ NA	None/not applicable	05AUG2013 (1145)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
--FEB2012 -	浮動性めまい (LIGHTHEADED)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
06OCT2011 (476)	嚢胞 (REMOVAL OF CYST ON BACK OF NECK)	Mild/ Not related	No/ NA	None/not applicable	07OCT2011 (477)
05DEC2011 (536)	鼻咽頭炎 (HEAD COLD)	Mild/ Unlikely	Yes/ Yes	None/not applicable	10DEC2011 (541)
16MAR2012 (638)	インフルエンザ (INFLUENZA)	Mild/ Not related	No/ NA	None/not applicable	25MAR2012 (647)
15SEP2012 (821)	気管支炎 (BRONCHITIS)	Mild/ Not related	Yes/ Yes	None/not applicable	11JAN2013 (939)
14NOV2012 (881)	白血球数増加 (ELEVATED WHITE BLOOD CELL COUNT)	Mild/ Possible	No/ NA	None/not applicable	Ongoing -
01JAN2013 (929)	振戦 (TREMORS)	Mild/ Possible	No/ NA	None/not applicable	Ongoing -
16FEB2013 (975)	副鼻腔炎 (SINUS INFECTION)	Mild/ Possible	Yes/ Yes	None/not applicable	25FEB2013 (984)
24APR2013 (1042)	気管支炎 (BRONCHITIS)	Mild/ Not related	Yes/ Yes	None/not applicable	08MAY2013 (1056)
11MAY2013 (1059)	痔核 (HEMORRHOIDS)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -

■ **Demographics and Baseline Characteristics**

□ Race: Black
□ Age (yrs): 5[redacted]
□ Sex: Male
□ Date of birth: 30JUN[redacted]
□ Height (cm): 185
□ Weight (kg): 105.5
□ Date of UC diagnosis: 13JUL2009
□ UC disease duration (years): 0.8
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 200mg -> 100mg SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: Yes

□ Adjusted treatment group during LTE: Golimumab 100 mg

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	21JUL2011	399	1	Golimumab	100 mg
Week 56 - EXT	21JUL2011	399	1	Placebo	0 mg
Week 60 - EXT	12AUG2011	421	1	Placebo	0 mg
Week 60 - EXT	12AUG2011	421	1	Golimumab	100 mg
Week 64 - EXT	14SEP2011	454	2	Golimumab	100 mg
Week 64 - EXT	14SEP2011	454	2	Placebo	0 mg
Week 68 - EXT	07OCT2011	477	3	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 68 - EXT	07OCT2011	477	3	Golimumab	100 mg
Week 72 - EXT	04NOV2011	505	4	Placebo	0 mg
Week 72 - EXT	04NOV2011	505	4	Golimumab	100 mg
Week 76 - EXT	08DEC2011	539	5	Golimumab	100 mg
Week 76 - EXT	08DEC2011	539	5	Placebo	0 mg
Week 80 - EXT	11JAN2012	573	6	Golimumab	100 mg
Week 84 - EXT	06FEB2012	599	7	Golimumab	100 mg
Week 88 - EXT	05MAR2012	627	8	Golimumab	100 mg
Week 92 - EXT	03APR2012	656	9	Golimumab	100 mg
Week 96 - EXT	02MAY2012	685	10	Golimumab	100 mg
Week 100 - EXT	19JUN2012	733	11	Golimumab	100 mg
Week 104 - EXT	28JUN2012	742	12	Golimumab	100 mg
Week 108 - EXT	27JUL2012	771	13	Golimumab	100 mg
Week 112 - EXT	13AUG2012	788	14	Golimumab	100 mg
Week 116 - EXT	18SEP2012	824	15	Golimumab	100 mg
Week 120 - EXT	17OCT2012	853	16	Golimumab	100 mg
Week 124 - EXT	16NOV2012	883	17	Golimumab	100 mg
Week 128 - EXT	12DEC2012	909	18	Golimumab	100 mg
Week 132 - EXT	11JAN2013	939	19	Golimumab	100 mg
Week 136 - EXT	04FEB2013	963	20	Golimumab	100 mg
Week 140 - EXT	20FEB2013	979	21	Golimumab	100 mg
Week 144 - EXT	12MAR2013	999	22	Golimumab	100 mg

■ **Treatment and Study Status**

□ Date of study discontinuation: 27Jul2013

□ Reason for noncompletion: Lost to follow-up

□ Other reason for noncompletion/details: -

□ Date of disposition status: 27Jul2013

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
FLUTICASONE,Inhalation	--JAN2013	Ongoing
VICODIN,Oral	06OCT2011	10OCT2011
FISH OIL,Oral	04NOV2011	--MAY2012
MOMETASONE,Intranasal	06DEC2011	12DEC2011
LEVOFLOXACIN,Oral	06DEC2011	12DEC2011
SPEKTRAMOX,Oral	06DEC2011	12DEC2011
NOTUSS /01603401/,Oral	06DEC2011	11DEC2011
PARACETAMOL,Oral	16MAR2012	25MAR2012
OSELTAMIVIR,Oral	16MAR2012	25MAR2012
COUGH AND COLD PREPARATIONS,Intramuscular	16MAR2012	16MAR2012
CODEINE PHOSPHATE W/GUAIFENESIN/PHENIRAMINE M,Oral	01OCT2012	11JAN2013
AMOXICILLIN,Oral	06OCT2012	16OCT2012
AMOXICILLIN,Oral	02DEC2012	12DEC2012
VALSARTAN,Oral	13FEB2013	Ongoing
AUGMENTIN /00756801/,Oral	16FEB2013	25FEB2013
AMOXICILLIN,Oral	24APR2013	08MAY2013
GUAIFENESIN,Oral	24APR2013	08MAY2013

Prior/Concomitant Therapy, Route	Start Date	End Date
HYDROCODONE,Oral	24APR2013	08MAY2013
ANTIBIOTICS,Intramuscular	24APR2013	24APR2013
COUGH AND COLD PREPARATIONS,Intramuscular	24APR2013	24APR2013
HYDROCORTISONE,Topical	11MAY2013	Ongoing

被験者識別コード：7776-00005

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: Malignancy

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
17AUG2012 (1123)	遠隔転移を伴う腎癌 (METASTIC CARCINOMA OF THE RIGHT KIDNEY)	Yes	Severe/ Unlikely	No/ NA	Permanent discontinuation of study agent	16SEP2012 (1153)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
22SEP2010 (428)	上気道感染 (UPPER RESPIRATORY INFECTION)	Mild/ Not related	Yes/ Yes	None/not applicable	12OCT2010 (448)
15OCT2010 (451)	ウイルス性上気道感染 (POST VIRAL COUGH)	Moderate/ Not related	No/ NA	None/not applicable	08DEC2010 (505)
01FEB2011 (560)	潰瘍性大腸炎 (WORSENING ULCERATIVE COLITIS)	Mild/ Not related	No/ NA	None/not applicable	30MAR2011 (617)
01NOV2011 (833)	上気道感染 (UPPER RESPIRATORY TRACT INFECTION)	Mild/ Not related	Yes/ Yes	None/not applicable	07DEC2011 (869)
08MAR2012 (961)	カンジダ感染 (CANDIDIASIS OF INNER THIGHS)	Mild/ Not related	Yes/ No	None/not applicable	22MAR2012 (975)
14MAR2012 (967)	睡眠時無呼吸症候群 (OBSTRUCTIVE SLEEP APNEA)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
20JUN2012 (1065)	潰瘍性大腸炎 (WORSENING ULCERATIVE COLITIS)	Moderate/ Not related	No/ NA	None/not applicable	18JUL2012 (1093)
25JUL2012 (1100)	上腹部痛 (RIGHT UPPER QUADRANT PAIN)	Mild/ Unlikely	No/ NA	None/not applicable	12SEP2012 (1149)
15AUG2012 (1121)	消化不良 (HEARTBURN)	Mild/ Not related	No/ NA	None/not applicable	14NOV2012 (1212)
12SEP2012 (1149)	貧血 (ANEMIA)	Mild/ Not related	No/ NA	None/not applicable	12SEP2012 (1149)
12SEP2012 (1149)	疲労 (FATIGUE)	Moderate/ Not related	No/ NA	None/not applicable	14NOV2012 (1212)

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
12SEP2012 (1149)	体重減少 (WEIGHT LOSS)	Mild/ Not related	No/ NA	None/not applicable	14NOV2012 (1212)
25OCT2012 (1192)	低血圧 (HYPOTENSION)	Moderate/ Not related	No/ NA	None/not applicable	14NOV2012 (1212)
03NOV2012 (1201)	末梢性浮腫 (EDEMA, BILATERAL ANKLES)	Moderate/ Not related	No/ NA	None/not applicable	14NOV2012 (1212)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 4[redacted]
□ Sex: Female
□ Date of birth: 24DEC[redacted]
□ Height (cm): 168
□ Weight (kg): 118.6
□ Date of UC diagnosis: --AUG1975
□ UC disease duration (years): 33.8
□ Relevant medical history at baseline: 喫煙（過去/現在）, 結腸切除

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 200mg -> 100mg SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	23AUG2010	398	1	Placebo	0 mg
Week 56 - EXT	23AUG2010	398	1	Golimumab	100 mg
Week 60 - EXT	16SEP2010	422	2	Placebo	0 mg
Week 60 - EXT	16SEP2010	422	2	Golimumab	100 mg
Week 64 - EXT	13OCT2010	449	3	Golimumab	100 mg
Week 64 - EXT	13OCT2010	449	3	Placebo	0 mg
Week 68 - EXT	10NOV2010	477	4	Golimumab	100 mg
Week 68 - EXT	10NOV2010	477	4	Placebo	0 mg
Week 72 - EXT	08DEC2010	505	5	Placebo	0 mg
Week 72 - EXT	08DEC2010	505	5	Golimumab	100 mg
Week 76 - EXT	05JAN2011	533	6	Placebo	0 mg
Week 76 - EXT	05JAN2011	533	6	Golimumab	100 mg
Week 80 - EXT	02FEB2011	561	7	Placebo	0 mg
Week 80 - EXT	02FEB2011	561	7	Golimumab	100 mg
Week 84 - EXT	03MAR2011	590	8	Golimumab	100 mg
Week 84 - EXT	03MAR2011	590	8	Placebo	0 mg
Week 88 - EXT	30MAR2011	617	9	Placebo	0 mg
Week 88 - EXT	30MAR2011	617	9	Golimumab	100 mg
Week 92 - EXT	28APR2011	646	10	Placebo	0 mg
Week 92 - EXT	28APR2011	646	10	Golimumab	100 mg
Week 96 - EXT	25MAY2011	673	11	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 96 - EXT	25MAY2011	673	11	Golimumab	100 mg
Week 100 - EXT	22JUN2011	701	12	Placebo	0 mg
Week 100 - EXT	22JUN2011	701	12	Golimumab	100 mg
Week 104 - EXT	20JUL2011	729	13	Golimumab	100 mg
Week 104 - EXT	20JUL2011	729	13	Placebo	0 mg
Week 108 - EXT	17AUG2011	757	14	Golimumab	100 mg
Week 108 - EXT	17AUG2011	757	14	Placebo	0 mg
Week 112 - EXT	14SEP2011	785	15	Placebo	0 mg
Week 112 - EXT	14SEP2011	785	15	Golimumab	100 mg
Week 116 - EXT	12OCT2011	813	16	Golimumab	100 mg
Week 116 - EXT	12OCT2011	813	16	Placebo	0 mg
Week 120 - EXT	09NOV2011	841	17	Placebo	0 mg
Week 120 - EXT	09NOV2011	841	17	Golimumab	100 mg
Week 124 - EXT	07DEC2011	869	18	Placebo	0 mg
Week 124 - EXT	07DEC2011	869	18	Golimumab	100 mg
Week 128 - EXT	04JAN2012	897	19	Golimumab	100 mg
Week 132 - EXT	01FEB2012	925	20	Golimumab	100 mg
Week 136 - EXT	29FEB2012	953	21	Golimumab	100 mg
Week 140 - EXT	28MAR2012	981	22	Golimumab	100 mg
Week 144 - EXT	23APR2012	1007	23	Golimumab	100 mg
Week 148 - EXT	23MAY2012	1037	24	Golimumab	100 mg
Week 152 - EXT	18JUN2012	1063	25	Golimumab	100 mg
Week 156 - EXT	18JUL2012	1093	26	Golimumab	100 mg
Week 160 - EXT	15AUG2012	1121	27	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
TUSSIN DM,Oral	22SEP2010	12OCT2010
SALBUTAMOL,Oral	30SEP2010	12OCT2010
AMOXICILLIN,Oral	30SEP2010	07OCT2010
AZATHIOPRINE,Oral	07FEB2011	09MAY2011
METHYLPREDNISOLONE,Oral	07FEB2011	13FEB2011
MESALAZINE,Oral	24FEB2011	Ongoing
AZATHIOPRINE,Oral	10MAY2011	05SEP2012
AZITHROMYCIN,Oral	05NOV2011	08NOV2011
AMOXICILLIN,Oral	17NOV2011	28NOV2011
CLOTRIMAZOLE,Topical	08MAR2012	22MAR2012
OXYGEN,Intranasal	02APR2012	01OCT2012
BUDESONIDE,Oral	02JUL2012	30OCT2012
VICODIN,Oral	15AUG2012	Ongoing
ONDANSETRON,Intravenous	12SEP2012	12SEP2012
RED BLOOD CELLS,Intravenous	12SEP2012	12SEP2012
FLEBOBAG RING LACT,Intravenous	12SEP2012	13SEP2012
PROCET /01554201/,Oral	12SEP2012	17SEP2012
OSMOTAN,Intravenous	12SEP2012	12SEP2012
DOCUSATE W/SENNA,Oral	12SEP2012	17SEP2012
HEPARIN,Intravenous	12SEP2012	17SEP2012
PETHIDINE,Intravenous	12SEP2012	12SEP2012

Prior/Concomitant Therapy, Route	Start Date	End Date
MIDAZOLAM,Intravenous	12SEP2012	12SEP2012
LABETALOL,Intravenous	12SEP2012	12SEP2012
CEFAZOLIN,Intravenous	12SEP2012	12SEP2012
MORPHINE,Intravenous	12SEP2012	12SEP2012
HYDROMORPHONE,Intravenous	12SEP2012	12SEP2012
SODIUM CHLORIDE,Intravenous	12SEP2012	12SEP2012
INFUKOLL HES,Intravenous	13SEP2012	13SEP2012
DEXAMETHASONE,Intravenous	13SEP2012	13SEP2012
DEXTROSE AND SODIUM CHLORIDE INJECTION,Intravenous	13SEP2012	16SEP2012
MORPHINE,Intravenous	13SEP2012	13SEP2012
FUROSEMIDE,Intravenous	13SEP2012	14SEP2012
SODIUM CHLORIDE,Intravenous	13SEP2012	13SEP2012
DIPHENHYDRAMINE,Intravenous	14SEP2012	14SEP2012
PARACETAMOL,Oral	14SEP2012	14SEP2012
HYDROCHLOROTHIAZIDE,Oral	03NOV2012	Ongoing

被験者識別コード：7822-00001

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
29JAN2013 (1188)	肛門膿瘍 (PERIANAL ABSCESS)	No	Moderate/ Probable	Yes/ Yes	Permanent discontinuation of study agent	18JAN2014 (1542)
07FEB2013 (1197)	肛門膿瘍 (PERIANAL ABSSESS)	Yes	Moderate/ Probable	Yes/ Yes	Temporary interruption/dose modification	14FEB2013 (1204)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
16DEC2010 (413)	鼻咽頭炎 (COMMON COLD)	Mild/ Not related	No/ NA	None/not applicable	15JAN2011 (443)
03SEP2011 (674)	口内炎 (STOMATITIS)	Mild/ Not related	No/ NA	None/not applicable	05NOV2011 (737)

■ **Demographics and Baseline Characteristics**

□ Race: Asian
□ Age (yrs): 2[redacted]
□ Sex: Male
□ Date of birth: 14JUN[redacted]
□ Height (cm): 164
□ Weight (kg): 65.0
□ Date of UC diagnosis: 02DEC2005
□ UC disease duration (years): 3.8
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 200mg -> 100mg SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	20NOV2010	387	1	Golimumab	100 mg
Week 56 - EXT	20NOV2010	387	1	Placebo	0 mg
Week 60 - EXT	18DEC2010	415	2	Placebo	0 mg
Week 60 - EXT	18DEC2010	415	2	Golimumab	100 mg
Week 64 - EXT	15JAN2011	443	3	Placebo	0 mg
Week 64 - EXT	15JAN2011	443	3	Golimumab	100 mg
Week 68 - EXT	22FEB2011	481	4	Placebo	0 mg
Week 68 - EXT	22FEB2011	481	4	Golimumab	100 mg
Week 72 - EXT	19MAR2011	506	5	Placebo	0 mg
Week 72 - EXT	19MAR2011	506	5	Golimumab	100 mg
Week 76 - EXT	23APR2011	541	6	Placebo	0 mg
Week 76 - EXT	23APR2011	541	6	Golimumab	100 mg
Week 80 - EXT	20MAY2011	568	7	Golimumab	100 mg
Week 80 - EXT	20MAY2011	568	7	Placebo	0 mg
Week 84 - EXT	18JUN2011	597	8	Placebo	0 mg
Week 84 - EXT	18JUN2011	597	8	Golimumab	100 mg
Week 88 - EXT	16JUL2011	625	9	Golimumab	100 mg
Week 88 - EXT	16JUL2011	625	9	Placebo	0 mg
Week 92 - EXT	05AUG2011	645	10	Golimumab	100 mg
Week 92 - EXT	05AUG2011	645	10	Placebo	0 mg
Week 96 - EXT	03SEP2011	674	11	Placebo	0 mg
Week 96 - EXT	03SEP2011	674	11	Golimumab	100 mg
Week 100 - EXT	01OCT2011	702	12	Golimumab	100 mg
Week 100 - EXT	01OCT2011	702	12	Placebo	0 mg
Week 104 - EXT	05NOV2011	737	13	Golimumab	100 mg
Week 104 - EXT	05NOV2011	737	13	Placebo	0 mg
Week 108 - EXT	26NOV2011	758	14	Placebo	0 mg
Week 108 - EXT	26NOV2011	758	14	Golimumab	100 mg
Week 112 - EXT	17DEC2011	779	15	Golimumab	100 mg
Week 112 - EXT	17DEC2011	779	15	Placebo	0 mg
Week 116 - EXT	21JAN2012	814	16	Golimumab	100 mg
Week 120 - EXT	24FEB2012	848	17	Golimumab	100 mg
Week 124 - EXT	30MAR2012	883	18	Golimumab	100 mg
Week 128 - EXT	17APR2012	901	19	Golimumab	100 mg
Week 132 - EXT	16MAY2012	930	20	Golimumab	100 mg
Week 136 - EXT	16JUN2012	961	21	Golimumab	100 mg
Week 140 - EXT	13JUL2012	988	22	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 144 - EXT	08AUG2012	1014	23	Golimumab	100 mg
Week 148 - EXT	31AUG2012	1037	24	Golimumab	100 mg
Week 152 - EXT	05OCT2012	1072	25	Golimumab	100 mg
Week 156 - EXT	27OCT2012	1094	26	Golimumab	100 mg
Week 160 - EXT	24NOV2012	1122	27	Golimumab	100 mg
Week 164 - EXT	22DEC2012	1150	28	Golimumab	100 mg
Week 168 - EXT	19JAN2013	1178	29	Golimumab	100 mg

■ **Treatment and Study Status**

□ Date of study discontinuation: 10Sep2013

□ Reason for noncompletion: Other

□ Other reason for noncompletion/details: Assessment of jpkk and mm of quintiles due to long discontinuation.

□ Date of disposition status: 10Sep2013

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
TRIAMCINOLONE,Topical	01OCT2011	05NOV2011
MIDAZOLAM,Intravenous	08AUG2012	08AUG2012
DIMETICONE,Oral	08AUG2012	08AUG2012
COLYTE /00751601/,Oral	08AUG2012	08AUG2012
FLUMAZENIL,Intravenous	08AUG2012	08AUG2012
CHLOMY-P,Topical	29JAN2013	07FEB2013
LEVOFLOXACIN,Oral	29JAN2013	04FEB2013
OSELTAMIVIR,Oral	30JAN2013	03FEB2013
CEFMETAZOLE,Intravenous	06FEB2013	13FEB2013
CEFCAPENE,Oral	06FEB2013	07FEB2013
REBAMIPIDE,Oral	06FEB2013	07FEB2013
LOXOPROFEN,Oral	06FEB2013	07FEB2013
CEFCAPENE,Oral	14FEB2013	15MAR2013
ENTEROCOCCUS FAECALIS,Oral	02MAR2013	20APR2013
MOXIFLOXACIN,Oral	16MAR2013	20APR2013
VITANEURIN /02072701/,Oral	30MAR2013	20APR2013
LACTOMIN,Oral	20APR2013	Ongoing
MOXIFLOXACIN,Oral	29JUN2013	06JUL2013
MIDAZOLAM,Intravitreous	31JUL2013	31JUL2013
DIMETICONE,Oral	31JUL2013	31JUL2013
LIDOCAINE,Topical	31JUL2013	31JUL2013
COLYTE /00751601/,Oral	31JUL2013	31JUL2013
FLUMAZENIL,Intravenous	31JUL2013	31JUL2013
CEFCAPENE,Oral	07DEC2013	20DEC2013

被験者識別コード：7003-00010

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
14JAN2011 (492)	下痢 (DIARRHOEA)	Yes	Mild/ Not related	No/ NA	None/not applicable	18JAN2011 (496)
22JAN2011 (500)	腎盂腎炎 (PYELONEPHRITIS)	Yes	Moderate/ Possible	Yes/ Yes	None/not applicable	24JAN2011 (502)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
14DEC2010 (461)	咳嗽 (COUGH)	Moderate/ Unlikely	Yes/ Yes	None/not applicable	27JAN2011 (505)
03FEB2011 (512)	咳嗽 (COUGH)	Moderate/ Possible	No/ NA	None/not applicable	05MAY2011 (603)
20MAR2011 (557)	口腔咽頭痛 (SORE THROAT)	Mild/ Not related	Yes/ No	None/not applicable	04APR2011 (572)
20APR2011 (588)	上気道感染 (UPPER RESPIRATORY INFECTION)	Moderate/ Not related	Yes/ Yes	None/not applicable	11MAY2011 (609)
10MAY2011 (608)	悪心 (NAUSEA)	Mild/ Not related	No/ NA	None/not applicable	25MAY2011 (623)
03JUN2011 (632)	耳不快感 (BLOCKED RIGHT EAR CANAL)	Moderate/ Not related	No/ NA	None/not applicable	10JUN2011 (639)
25NOV2011 (807)	筋骨格痛 (RIGHT SHOULDER PAIN)	Moderate/ Not related	No/ NA	None/not applicable	Ongoing -
02JAN2012 (845)	関節炎 (OLIGOARTHRITIS OF LEFT KNEE)	Moderate/ Not related	No/ NA	None/not applicable	Ongoing -
25JAN2012 (868)	関節痛 (RIGHT ELBOW PAIN)	Mild/ Not related	No/ NA	None/not applicable	05APR2012 (939)
04JAN2013 (1213)	胃腸炎 (INFECTIOUS GASTROENTERITIS)	Moderate/ Not related	Yes/ Yes	None/not applicable	21JAN2013 (1230)
01MAY2013 (1330)	潰瘍性大腸炎 (EXACERBATION OF ULCERATIVE COLITIS)	Mild/ Unlikely	No/ NA	None/not applicable	01JUN2013 (1361)
14MAY2013 (1343)	インフルエンザ (FLU)	Moderate/ Unlikely	Yes/ Yes	None/not applicable	20MAY2013 (1349)
09JAN2014 (1583)	上気道感染 (URTI)	Mild/ Unlikely	Yes/ Yes	None/not applicable	14JAN2014 (1588)

■ **Demographics and Baseline Characteristics**

□ Race: Asian
□ Age (yrs): 5[redacted]
□ Sex: Male
□ Date of birth: 12JUN[redacted]
□ Height (cm): 166
□ Weight (kg): 68.0
□ Date of UC diagnosis: --APR2006
□ UC disease duration (years): 3.3
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 400mg -> 200mg SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	07OCT2010	393	1	Placebo	0 mg
Week 56 - EXT	07OCT2010	393	1	Golimumab	100 mg
Week 60 - EXT	04NOV2010	421	2	Placebo	0 mg
Week 60 - EXT	04NOV2010	421	2	Golimumab	100 mg
Week 64 - EXT	03DEC2010	450	3	Golimumab	100 mg
Week 64 - EXT	03DEC2010	450	3	Placebo	0 mg
Week 68 - EXT	04JAN2011	482	4	Placebo	0 mg
Week 68 - EXT	04JAN2011	482	4	Golimumab	100 mg
Week 72 - EXT	27JAN2011	505	5	Placebo	0 mg
Week 72 - EXT	27JAN2011	505	5	Golimumab	100 mg
Week 76 - EXT	24FEB2011	533	6	Golimumab	100 mg
Week 76 - EXT	24FEB2011	533	6	Placebo	0 mg
Week 80 - EXT	24MAR2011	561	7	Placebo	0 mg
Week 80 - EXT	24MAR2011	561	7	Golimumab	100 mg
Week 84 - EXT	21APR2011	589	8	Placebo	0 mg
Week 84 - EXT	21APR2011	589	8	Golimumab	100 mg
Week 88 - EXT	19MAY2011	617	9	Golimumab	100 mg
Week 88 - EXT	19MAY2011	617	9	Placebo	0 mg
Week 92 - EXT	17JUN2011	646	10	Placebo	0 mg
Week 92 - EXT	17JUN2011	646	10	Golimumab	100 mg
Week 96 - EXT	15JUL2011	674	11	Golimumab	100 mg
Week 96 - EXT	15JUL2011	674	11	Placebo	0 mg
Week 100 - EXT	12AUG2011	702	12	Golimumab	100 mg
Week 100 - EXT	12AUG2011	702	12	Placebo	0 mg
Week 104 - EXT	09SEP2011	730	13	Golimumab	100 mg
Week 104 - EXT	09SEP2011	730	13	Placebo	0 mg
Week 108 - EXT	11OCT2011	762	14	Golimumab	100 mg
Week 108 - EXT	11OCT2011	762	14	Placebo	0 mg
Week 112 - EXT	03NOV2011	785	15	Golimumab	100 mg
Week 112 - EXT	03NOV2011	785	15	Placebo	0 mg
Week 116 - EXT	29NOV2011	811	16	Placebo	0 mg
Week 116 - EXT	29NOV2011	811	16	Golimumab	100 mg
Week 120 - EXT	03JAN2012	846	17	Golimumab	100 mg
Week 124 - EXT	25JAN2012	868	18	Golimumab	100 mg
Week 128 - EXT	23FEB2012	897	19	Golimumab	100 mg
Week 132 - EXT	20MAR2012	923	20	Golimumab	100 mg
Week 136 - EXT	19APR2012	953	21	Golimumab	100 mg
Week 140 - EXT	16MAY2012	980	22	Golimumab	100 mg
Week 144 - EXT	12JUN2012	1007	23	Golimumab	100 mg
Week 148 - EXT	10JUL2012	1035	24	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 152 - EXT	09AUG2012	1065	25	Golimumab	100 mg
Week 156 - EXT	06SEP2012	1093	26	Golimumab	100 mg
Week 160 - EXT	04OCT2012	1121	27	Golimumab	100 mg
Week 164 - EXT	01NOV2012	1149	28	Golimumab	100 mg
Week 168 - EXT	28NOV2012	1176	29	Golimumab	100 mg
Week 172 - EXT	08JAN2013	1217	30	Golimumab	100 mg
Week 176 - EXT	24JAN2013	1233	31	Golimumab	100 mg
Week 180 - EXT	21FEB2013	1261	32	Golimumab	100 mg
Week 184 - EXT	21MAR2013	1289	33	Golimumab	100 mg
Week 188 - EXT	24APR2013	1323	34	Golimumab	100 mg
Week 192 - EXT	22MAY2013	1351	35	Golimumab	100 mg
Week 196 - EXT	13JUN2013	1373	36	Golimumab	100 mg
Week 200 - EXT	11JUL2013	1401	37	Golimumab	100 mg
Week 204 - EXT	08AUG2013	1429	38	Golimumab	100 mg
Week 208 - EXT	03SEP2013	1455	39	Golimumab	100 mg
Week 212 - EXT	30SEP2013	1482	40	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
SERETIDE,Intranasal	25NOV2010	10MAR2011
TERBUTALINE,Inhalation	24DEC2010	Ongoing
AMOXICILLIN,Oral	24DEC2010	30DEC2010
ERYTHROMYCIN,Oral	04JAN2011	10JAN2011
HYDROCORTISONE,Intravenous	14JAN2011	17JAN2011
METRONIDAZOLE,Intravenous	14JAN2011	15JAN2011
METOCLOPRAMIDE,Intravenous	15JAN2011	15JAN2011
PARACETAMOL,Oral	15JAN2011	18JAN2011
DALTEPARIN,Subcutaneous	15JAN2011	17JAN2011
METRONIDAZOLE,Oral	16JAN2011	16JAN2011
METOCLOPRAMIDE,Intravenous	22JAN2011	22JAN2011
PANADEINE CO,Oral	22JAN2011	22JAN2011
PARACETAMOL,Oral	22JAN2011	24JAN2011
CEFTRIAXONE,Intravenous	22JAN2011	24JAN2011
DALTEPARIN,Subcutaneous	23JAN2011	23JAN2011
GENTAMICIN,Intravenous	24JAN2011	24JAN2011
AMOXICILLIN W/CLAVULANATE POTASSIUM,Oral	24JAN2011	28JAN2011
BROMHEXINE HYDROCHLORIDE W/GUAIFENESIN,Oral	18APR2011	12MAY2011
AMOXICILLIN,Oral	20APR2011	12MAY2011
METHOTREXATE,Oral	23MAY2011	16APR2012
DICLOFENAC,Topical	26NOV2011	Ongoing
BETAMETHASONE,Intraarticular	16DEC2011	16DEC2011
PARACETAMOL,Oral	02JAN2012	Ongoing
METHOTREXATE,Oral	23APR2012	29OCT2013
GLUCOSAMINE,Oral	01MAY2012	Ongoing
MORPHINE,Intravenous	30JUL2012	30JUL2012
FENTANYL,Intravenous	30JUL2012	30JUL2012
CEFAZOLIN,Intravenous	30JUL2012	30JUL2012
TRAMADOL,Intravenous	30JUL2012	30JUL2012

Prior/Concomitant Therapy, Route	Start Date	End Date
ATROPINE,Intravenous	30JUL2012	30JUL2012
ENOXAPARIN,Intravenous	30JUL2012	30JUL2012
PROPOFOL,Intravenous	30JUL2012	30JUL2012
LINAGLIPTIN,Oral	13SEP2012	Ongoing
ROSUVASTATIN,Oral	13SEP2012	Ongoing
HYDROCORTISONE,Intraarticular	20NOV2012	20NOV2012
MESALAZINE,Oral	06DEC2012	Ongoing
CIPROFLOXACIN,Oral	08JAN2013	14JAN2013
AMOXICILLIN,Oral	14MAY2013	20MAY2013
TERBUTALINE,Inhalation	16MAY2013	Ongoing
SERETIDE,Inhalation	16MAY2013	Ongoing
METHOTREXATE,Oral	30OCT2013	Ongoing
AMOXICILLIN,Oral	10JAN2014	20JAN2014

被験者識別コード：7077-00006

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
05APR2011 (516)	毛巣嚢胞 (PILONIDAL ABSCESS)	Yes	Severe/ Not related	Yes/ Yes	None/not applicable	13APR2011 (524)
06APR2011 (517)	肛門膿瘍 (PUNCTION OF PERIANAL ABSCESS)	Yes	Moderate/ Not related	Yes/ Yes	None/not applicable	13APR2011 (524)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
16DEC2010 (406)	好酸球増加症 (EOSINOPHILIA)	Mild/ Not related	No/ NA	None/not applicable	01MAR2011 (481)
03JAN2011 (424)	咳嗽 (COUGHT)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
04JAN2011 (425)	発熱 (HIGH TEMPERATURE)	Moderate/ Not related	No/ NA	None/not applicable	08JAN2011 (429)
06APR2011 (517)	発熱 (FEVER -37,6 C)	Mild/ Not related	Yes/ Yes	None/not applicable	07APR2011 (518)
14APR2011 (525)	肛門周囲痛 (PAIN IN THE ANAL AREA)	Mild/ Not related	Yes/ Yes	None/not applicable	15JUN2011 (587)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 4[redacted]
□ Sex: Male
□ Date of birth: 11NOV[redacted]
□ Height (cm): 175
□ Weight (kg): 68.0
□ Date of UC diagnosis: 28MAY2007
□ UC disease duration (years): 2.3
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 400mg -> 200mg SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	16DEC2010	406	1	Golimumab	100 mg
Week 56 - EXT	16DEC2010	406	1	Placebo	0 mg
Week 60 - EXT	13JAN2011	434	2	Golimumab	100 mg
Week 60 - EXT	13JAN2011	434	2	Placebo	0 mg
Week 64 - EXT	01FEB2011	453	3	Golimumab	100 mg
Week 64 - EXT	01FEB2011	453	3	Placebo	0 mg
Week 68 - EXT	01MAR2011	481	4	Golimumab	100 mg
Week 68 - EXT	01MAR2011	481	4	Placebo	0 mg
Week 72 - EXT	08APR2011	519	5	Placebo	0 mg
Week 72 - EXT	08APR2011	519	5	Golimumab	100 mg
Week 76 - EXT	09MAY2011	550	6	Placebo	0 mg
Week 76 - EXT	09MAY2011	550	6	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
METRONIDAZOLE,Intravenous	06APR2011	13APR2011
CEFAZOLIN,Intravenous	06APR2011	13APR2011
GLUCOSE,Intravenous	06APR2011	13APR2011
ELECTROLYTES NOS,Intravenous	06APR2011	13APR2011
METAMIZOLE,Oral	06APR2011	13APR2011

被験者識別コード：7207-00012

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
06JUL2010 (477)	ウイルス性髄膜炎 (VIRAL MENINGITIS)	Yes	Moderate/ Possible	Yes/ Yes	Permanent discontinuation of study agent	21JUL2010 (492)

■ **Other Adverse Events**

No Other Adverse Events reported

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 2[redacted]
□ Sex: Male
□ Date of birth: 01FEB[redacted]
□ Height (cm): 175
□ Weight (kg): 74.5
□ Date of UC diagnosis: -----2005
□ UC disease duration (years): 3.1
□ Relevant medical history at baseline: 喫煙（過去/現在），関節痛

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 400mg -> 200mg SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	14APR2010	394	1	Golimumab	100 mg
Week 56 - EXT	14APR2010	394	1	Placebo	0 mg
Week 60 - EXT	17MAY2010	427	2	Golimumab	100 mg
Week 60 - EXT	17MAY2010	427	2	Placebo	0 mg
Week 64 - EXT	15JUN2010	456	3	Golimumab	100 mg
Week 64 - EXT	15JUN2010	456	3	Placebo	0 mg

■ **Treatment and Study Status**

□ Date of study discontinuation: 27JUL2010

□ Reason for noncompletion: Other

□ Other reason for noncompletion/details: AE

□ Date of disposition status: 27JUL2010

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
IBUPROFEN,Oral	--JUL2010	Ongoing
PARACETAMOL,Oral	--JUL2010	Ongoing
ACICLOVIR,Intravenous	06JUL2010	20JUL2010

被験者識別コード：7213-00008

■ **REASON FOR NARRATIVE SELECTION**

Death

SAE

Discontinuation of study agent due to AE

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
19NOV2011 (585)	潰瘍性大腸炎 (WORSENING OF UC)	Yes	Severe/ Not related	No/ NA	Permanent discontinuation of study agent	24NOV2011 (590)
19NOV2011 (585)	遠隔転移を伴う結腸癌 (METASTATIC ADENOCARCINOMA OF THE COLON)	Yes	Severe/ Not related	No/ NA	None/not applicable	23JUL2014 (1562)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
--AUG2011 -	細菌の過剰増殖 (BACTERIAL OVERGROWTH SYNDROM)	Mild/ Not related	Yes/ Yes	None/not applicable	-- SEP2011 -
24NOV2011 (590)	腎嚢胞 (PARAPELVIC RENAL CYSTE UPPER LEFT POLE)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 2[redacted]
□ Sex: Male
□ Date of birth: 01DEC[redacted]
□ Height (cm): 189
□ Weight (kg): 75.2
□ Date of UC diagnosis: --MAR1988
□ UC disease duration (years): 21.9
□ Relevant medical history at baseline: 喫煙（過去/現在），関節痛

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 400mg -> 200mg SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	06MAY2011	388	1	Golimumab	100 mg
Week 56 - EXT	06MAY2011	388	1	Placebo	0 mg
Week 60 - EXT	07JUN2011	420	2	Placebo	0 mg
Week 60 - EXT	07JUN2011	420	2	Golimumab	100 mg
Week 64 - EXT	27JUN2011	440	3	Placebo	0 mg
Week 64 - EXT	27JUN2011	440	3	Golimumab	100 mg
Week 68 - EXT	01AUG2011	475	4	Golimumab	100 mg
Week 68 - EXT	01AUG2011	475	4	Placebo	0 mg
Week 72 - EXT	29AUG2011	503	5	Golimumab	100 mg
Week 72 - EXT	29AUG2011	503	5	Placebo	0 mg
Week 76 - EXT	23SEP2011	528	6	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 76 - EXT	23SEP2011	528	6	Golimumab	100 mg
Week 80 - EXT	27OCT2011	562	7	Golimumab	100 mg
Week 80 - EXT	27OCT2011	562	7	Placebo	0 mg

■ **Treatment and Study Status**

□ Date of study discontinuation: 23NOV2011

□ Reason for noncompletion: Other

□ Other reason for noncompletion/details: Patient underwent colektomie and was diagnosed a colon carcinoma. He is now under chemotherapy and will not be able to come to another visit.

□ Date of disposition status: 23NOV2011

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
MESALAZINE,Oral	--JUL2011	Ongoing
OTHER ANTIEMETICS,Intravenous	--NOV2011	--NOV2011
ANALGESICS,Intravenous	--NOV2011	--NOV2011
BUDESONIDE,Oral	--JUL2011	Ongoing
PREDNISOLONE,Intravenous	--NOV2011	--NOV2011
CIPROFLOXACIN,Oral	16AUG2011	30AUG2011
NYSTATIN,Oral	16AUG2011	30AUG2011
METRONIDAZOLE,Oral	16AUG2011	30AUG2011
MESALAZINE,Oral	01OCT2011	Ongoing
OMEPRAZOLE,Oral	01OCT2011	Ongoing
INFLIXIMAB,Intravenous	25OCT2011	Ongoing

被験者識別コード：7413-00003

■ **REASON FOR NARRATIVE SELECTION**

SAE

Event of interest: Serious infection

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
12JUL2011 (883)	帯状疱疹 (ZOSTER ON THE LEFT SIDE OF THE TRUNK)	Yes	Moderate/ Possible	Yes/ No	None/not applicable	18JUL2011 (889)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
11MAR2010 (395)	血小板減少症 (THROMBOCYTOPENIA)	Mild/ Unlikely	No/ NA	None/not applicable	02JUN2010 (478)
20JUL2010 (526)	潰瘍性大腸炎 (ULCERATIVE COLITIS WORSENING)	Mild/ Unlikely	No/ NA	None/not applicable	23SEP2010 (591)
21OCT2010 (619)	頻脈 (TACHYCARDIA)	Mild/ Unlikely	No/ NA	None/not applicable	27JUL2011 (898)

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
16MAY2011 (826)	耳感染 (OTITIS RIGHT)	Moderate/ Not related	Yes/ No	None/not applicable	22MAY2011 (832)

■ **Demographics and Baseline Characteristics**

□ Race: Caucasian
□ Age (yrs): 3[redacted]
□ Sex: Male
□ Date of birth: 18OCT[redacted]
□ Height (cm): 177
□ Weight (kg): 87.0
□ Date of UC diagnosis: 21AUG2001
□ UC disease duration (years): 7.3
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 400mg -> 200mg SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	11MAR2010	395	1	Golimumab	100 mg
Week 56 - EXT	11MAR2010	395	1	Placebo	0 mg
Week 60 - EXT	08APR2010	423	2	Golimumab	100 mg
Week 60 - EXT	08APR2010	423	2	Placebo	0 mg
Week 64 - EXT	06MAY2010	451	3	Golimumab	100 mg
Week 64 - EXT	06MAY2010	451	3	Placebo	0 mg
Week 68 - EXT	02JUN2010	478	4	Golimumab	100 mg
Week 68 - EXT	02JUN2010	478	4	Placebo	0 mg
Week 72 - EXT	01JUL2010	507	5	Golimumab	100 mg
Week 72 - EXT	01JUL2010	507	5	Placebo	0 mg
Week 76 - EXT	29JUL2010	535	6	Placebo	0 mg
Week 76 - EXT	29JUL2010	535	6	Golimumab	100 mg
Week 80 - EXT	26AUG2010	563	7	Golimumab	100 mg
Week 80 - EXT	26AUG2010	563	7	Placebo	0 mg
Week 84 - EXT	23SEP2010	591	8	Golimumab	100 mg
Week 84 - EXT	23SEP2010	591	8	Placebo	0 mg
Week 88 - EXT	21OCT2010	619	9	Golimumab	100 mg
Week 88 - EXT	21OCT2010	619	9	Placebo	0 mg
Week 92 - EXT	18NOV2010	647	10	Placebo	0 mg
Week 92 - EXT	18NOV2010	647	10	Golimumab	100 mg
Week 96 - EXT	16DEC2010	675	11	Placebo	0 mg
Week 96 - EXT	16DEC2010	675	11	Golimumab	100 mg
Week 100 - EXT	13JAN2011	703	12	Golimumab	100 mg
Week 100 - EXT	13JAN2011	703	12	Placebo	0 mg
Week 104 - EXT	10FEB2011	731	13	Golimumab	100 mg
Week 104 - EXT	10FEB2011	731	13	Placebo	0 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 108 - EXT	10MAR2011	759	14	Golimumab	100 mg
Week 108 - EXT	10MAR2011	759	14	Placebo	0 mg
Week 112 - EXT	07APR2011	787	15	Golimumab	100 mg
Week 112 - EXT	07APR2011	787	15	Placebo	0 mg
Week 116 - EXT	04MAY2011	814	16	Placebo	0 mg
Week 116 - EXT	04MAY2011	814	16	Golimumab	100 mg
Week 120 - EXT	02JUN2011	843	17	Placebo	0 mg
Week 120 - EXT	02JUN2011	843	17	Golimumab	100 mg
Week 124 - EXT	30JUN2011	871	18	Placebo	0 mg
Week 124 - EXT	30JUN2011	871	18	Golimumab	100 mg
Week 128 - EXT	27JUL2011	898	19	Placebo	0 mg
Week 128 - EXT	27JUL2011	898	19	Golimumab	100 mg
Week 132 - EXT	25AUG2011	927	20	Placebo	0 mg
Week 132 - EXT	25AUG2011	927	20	Golimumab	100 mg
Week 136 - EXT	22SEP2011	955	21	Golimumab	100 mg
Week 136 - EXT	22SEP2011	955	21	Placebo	0 mg
Week 140 - EXT	20OCT2011	983	22	Golimumab	100 mg
Week 140 - EXT	20OCT2011	983	22	Placebo	0 mg
Week 144 - EXT	17NOV2011	1011	23	Golimumab	100 mg
Week 144 - EXT	17NOV2011	1011	23	Placebo	0 mg
Week 148 - EXT	15DEC2011	1039	24	Placebo	0 mg
Week 148 - EXT	15DEC2011	1039	24	Golimumab	100 mg
Week 152 - EXT	12JAN2012	1067	25	Golimumab	100 mg
Week 156 - EXT	09FEB2012	1095	26	Golimumab	100 mg
Week 160 - EXT	08MAR2012	1123	27	Golimumab	100 mg
Week 164 - EXT	05APR2012	1151	28	Golimumab	100 mg
Week 168 - EXT	08MAY2012	1184	29	Golimumab	100 mg
Week 172 - EXT	31MAY2012	1207	30	Golimumab	100 mg
Week 176 - EXT	28JUN2012	1235	31	Golimumab	100 mg
Week 180 - EXT	26JUL2012	1263	32	Golimumab	100 mg
Week 184 - EXT	23AUG2012	1291	33	Golimumab	100 mg
Week 188 - EXT	20SEP2012	1319	34	Golimumab	100 mg
Week 192 - EXT	17OCT2012	1346	35	Golimumab	100 mg
Week 196 - EXT	15NOV2012	1375	36	Golimumab	100 mg
Week 200 - EXT	13DEC2012	1403	37	Golimumab	100 mg
Week 204 - EXT	10JAN2013	1431	38	Golimumab	100 mg
Week 208 - EXT	05FEB2013	1457	39	Golimumab	100 mg
Week 212 - EXT	07MAR2013	1487	40	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
IRON,Oral	09APR2010	Ongoing
VITAMIN B12 NOS,Intramuscular	09APR2010	Ongoing
METHYLPREDNISOLONE,Oral	16AUG2010	06DEC2010
METOPROLOL,Oral	11FEB2011	25AUG2011
AMOXICILLIN,Oral	16MAY2011	22MAY2011
CLAVULANIC ACID,Oral	16MAY2011	22MAY2011
CARBAMAZEPINE,Oral	12JUL2011	Ongoing

Prior/Concomitant Therapy, Route	Start Date	End Date
ACICLOVIR,Intravenous	12JUL2011	17JUL2011
ANTIVIRALS,Topical	12JUL2011	18JUL2011
VITAMIN B-COMPLEX, PLAIN,Oral	12JUL2011	21SEP2011
DERMATOLOGICALS,Topical	12JUL2011	17AUG2011
ACICLOVIR,Oral	18JUL2011	22JUL2011

被験者識別コード：7791-00001

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
27OCT2011 (563)	慢性胆嚢炎 (CHRONIC CHOLECYSTITIS WITH CHOLELITHIASIS)	Yes	Severe/ Unlikely	No/ NA	None/not applicable	02NOV2011 (569)
03FEB2012 (662)	潰瘍性大腸炎 (WORSENING OF ULCERATIVE COLITITS)	Yes	Mild/ Not related	No/ NA	None/not applicable	05FEB2012 (664)
31OCT2012 (933)	潰瘍性大腸炎 (WORSENING OF ULCERATIVE COLITIS)	Yes	Mild/ Not related	No/ NA	Permanent discontinuation of study agent	Ongoing -

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
03JUN2011 (417)	歯痛 (TOOTH PAIN)	Mild/ Not related	No/ NA	None/not applicable	03JUN2011 (417)
06JUN2011 (420)	上腹部痛 (STOMACH CRAMPING)	Moderate/ Not related	No/ NA	None/not applicable	09JUN2011 (423)
28SEP2011 (534)	嘔吐 (VOMITING)	Moderate/ Not related	No/ NA	None/not applicable	30SEP2011 (536)
20OCT2011 (556)	腹痛 (ABDOMINAL PAIN)	Moderate/ Not related	No/ NA	None/not applicable	02NOV2011 (569)
20OCT2011 (556)	下痢 (DIARRHEA)	Moderate/ Not related	No/ NA	None/not applicable	02NOV2011 (569)
20OCT2011 (556)	直腸出血 (RECTAL BLEEDING)	Mild/ Not related	No/ NA	None/not applicable	02NOV2011 (569)
27OCT2011 (563)	悪心 (NAUSEA)	Moderate/ Not related	No/ NA	None/not applicable	02NOV2011 (569)
02NOV2011 (569)	貧血 (ANEMIA)	Mild/ Not related	No/ NA	None/not applicable	Ongoing -
02AUG2012 (843)	腹痛 (ABDOMINAL PAIN)	Moderate/ Not related	No/ NA	None/not applicable	05AUG2012 (846)
02AUG2012 (843)	尿路感染 (URINARY TRACT INFECTION)	Mild/ Not related	Yes/ Yes	None/not applicable	05AUG2012 (846)

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
31OCT2012 (933)	膣感染 (VAGINITIS)	Mild/ Not related	Yes/ Yes	None/not applicable	02NOV2012 (935)

■ **Demographics and Baseline Characteristics**

□ Race: Black
□ Age (yrs): 2[redacted]
□ Sex: Female
□ Date of birth: 29OCT[redacted]
□ Height (cm): 165
□ Weight (kg): 51.3
□ Date of UC diagnosis: 12JUL2009
□ UC disease duration (years): 0.6
□ Relevant medical history at baseline: -

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 400mg -> 200mg SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	23MAY2011	406	1	Golimumab	100 mg
Week 56 - EXT	23MAY2011	406	1	Placebo	0 mg
Week 60 - EXT	06JUN2011	420	2	Golimumab	100 mg
Week 60 - EXT	06JUN2011	420	2	Placebo	0 mg
Week 64 - EXT	05JUL2011	449	3	Golimumab	100 mg
Week 64 - EXT	05JUL2011	449	3	Placebo	0 mg
Week 68 - EXT	01AUG2011	476	4	Golimumab	100 mg
Week 68 - EXT	01AUG2011	476	4	Placebo	0 mg
Week 72 - EXT	29AUG2011	504	5	Golimumab	100 mg
Week 72 - EXT	29AUG2011	504	5	Placebo	0 mg
Week 76 - EXT	30SEP2011	536	6	Golimumab	100 mg
Week 76 - EXT	30SEP2011	536	6	Placebo	0 mg
Week 80 - EXT	08NOV2011	575	7	Golimumab	100 mg
Week 80 - EXT	08NOV2011	575	7	Placebo	0 mg
Week 84 - EXT	29NOV2011	596	8	Golimumab	100 mg
Week 84 - EXT	29NOV2011	596	8	Placebo	0 mg
Week 88 - EXT	21DEC2011	618	9	Golimumab	100 mg
Week 92 - EXT	13JAN2012	641	10	Golimumab	100 mg
Week 96 - EXT	09FEB2012	668	11	Golimumab	100 mg
Week 100 - EXT	07MAR2012	695	12	Golimumab	100 mg
Week 104 - EXT	04APR2012	723	13	Golimumab	100 mg
Week 108 - EXT	08MAY2012	757	14	Golimumab	100 mg
Week 112 - EXT	06JUN2012	786	15	Golimumab	100 mg
Week 116 - EXT	11JUL2012	821	16	Golimumab	100 mg
Week 120 - EXT	01AUG2012	842	17	Golimumab	100 mg
Week 124 - EXT	30AUG2012	871	18	Golimumab	100 mg

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 128 - EXT	25SEP2012	897	19	Golimumab	100 mg

■ **Treatment and Study Status**

□ Date of study discontinuation: 08Nov2012

□ Reason for noncompletion: Other

□ Other reason for noncompletion/details: Adverse event

□ Date of disposition status: 08Nov2012

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
CEFALEXIN,Oral	03JUN2011	09JUN2011
SOLPADEINE /00154101/,Oral	12JUL2011	Ongoing
LEVOFLOXACIN,Intravenous	27OCT2011	02NOV2011
PANTOPRAZOLE,Intravenous	27OCT2011	02NOV2011
I.V. SOLUTIONS,Intravenous	27OCT2011	02NOV2011
ONDANSETRON,Intravenous	28OCT2011	02NOV2011
SUCRALFATE,Oral	28OCT2011	02NOV2011
FENTANYL,Intravenous	28OCT2011	28OCT2011
PROMETHAZINE,Intravenous	28OCT2011	02NOV2011
DIAZEPAM,Intravenous	28OCT2011	28OCT2011
ANESTHETICS,Intravenous	01NOV2011	01NOV2011
CYANOCOBALAMIN,Subcutaneous	02NOV2011	Ongoing
IRON,Oral	02NOV2011	Ongoing
PROMETHAZINE,Oral	08NOV2011	Ongoing
HYDROCODONE,Oral	22NOV2011	Ongoing
I.V. SOLUTIONS,Intravenous	03FEB2012	05FEB2012
PETHIDINE,Intravenous	03FEB2012	04FEB2012
NITROFURANTOIN,Oral	02AUG2012	12AUG2012
ONDANSETRON,Intravenous	31OCT2012	02NOV2012
ERTAPENEM,Intravenous	31OCT2012	02NOV2012
TEMAZEPAM,Oral	31OCT2012	02NOV2012
PROMETHAZINE,Intravenous	31OCT2012	02NOV2012
SODIUM CHLORIDE,Intravenous	31OCT2012	02NOV2012
PETHIDINE,Intravenous	31OCT2012	02NOV2012
BUSPIRONE,Oral	01NOV2012	02NOV2012
LEVOFLOXACIN,Intravenous	01NOV2012	02NOV2012
TRAZODONE,Oral	01NOV2012	Ongoing
HYOSCYAMINE,Oral	01NOV2012	02NOV2012
METRONIDAZOLE,Intravenous	01NOV2012	02NOV2012

被験者識別コード：7819-00001

■ **REASON FOR NARRATIVE SELECTION**

SAE

Discontinuation of study agent due to AE

■ **Deaths, SAEs, Discontinuations due to AEs, and Other Events of Interest**

Start date (Study day)	Preferred Term (Verbatim Term)	SAE	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
07FEB2011 (575)	子宮頚部上皮異形成 (HIGH GRADE CERVICAL DYSPLASIA)	Yes	Moderate/ Possible	No/ NA	Permanent discontinuation of study agent	15APR2011 (642)

■ **Other Adverse Events**

Start date (Study day)	Preferred Term (Verbatim Term)	Intensity/ Relatedness	Inf/ Trt?	Action Taken	End date (Study day)
20JAN2011 (557)	鼻咽頭炎 (COMMON COLD)	Mild/ Unlikely	Yes/ No	None/not applicable	04FEB2011 (572)

■ **Demographics and Baseline Characteristics**

□ Race: Asian
□ Age (yrs):3[redacted]
□ Sex:Female
□ Date of birth: 09OCT[redacted]
□ Height (cm): 156
□ Weight (kg): 53.8
□ Date of UC diagnosis: -----1994
□ UC disease duration (years): 14.4
□ Relevant medical history at baseline: 関節炎，喫煙（過去/現在），関節痛

■ **Treatment Groups**

□ Induction study: C0524T17

□ Treatment group in induction: 400mg -> 200mg SC

□ Treatment group in maintenance: Non-randomized subject/non-responder to golimumab induction dosing and received golimumab 100 mg in maintenance

□ Dose adjusted?: No

□ Adjusted treatment group: -

□ Treatment group during start of LTE: Golimumab 100 mg

□ Dose adjusted during LTE: No

□ Adjusted treatment group during LTE: -

■ **Treatment Received**

Visit	Start Date	Study Day	Dose Number	Actual Treatment	Dose
Week 56 - EXT	06AUG2010	390	1	Golimumab	100 mg
Week 56 - EXT	06AUG2010	390	1	Placebo	0 mg
Week 60 - EXT	10SEP2010	425	2	Golimumab	100 mg
Week 60 - EXT	10SEP2010	425	2	Placebo	0 mg
Week 64 - EXT	08OCT2010	453	3	Golimumab	100 mg
Week 64 - EXT	08OCT2010	453	3	Placebo	0 mg
Week 68 - EXT	05NOV2010	481	4	Golimumab	100 mg
Week 68 - EXT	05NOV2010	481	4	Placebo	0 mg
Week 72 - EXT	03DEC2010	509	5	Placebo	0 mg
Week 72 - EXT	03DEC2010	509	5	Golimumab	100 mg
Week 76 - EXT	07JAN2011	544	6	Placebo	0 mg
Week 76 - EXT	07JAN2011	544	6	Golimumab	100 mg

■ **Concomitant Medications**

Prior/Concomitant Therapy, Route	Start Date	End Date
OSELTAMIVIR,Oral	20JAN2011	24JAN2011
POLYGALA SENEGA,Oral	20JAN2011	24JAN2011
PARACETAMOL,Oral	20JAN2011	24JAN2011

Prior/Concomitant Therapy, Route	Start Date	End Date
CYPROHEPTADINE,Oral	20JAN2011	24JAN2011
TRANEXAMIC ACID,Oral	20JAN2011	24JAN2011
CLOPERASTINE,Oral	20JAN2011	24JAN2011
AMBROXOL,Oral	20JAN2011	24JAN2011
CEFCAPENE,Oral	14MAR2011	16MAR2011
CARBOHYDRATES NOS W/POTASSIUM CHLORIDE/SODIUM,Intravenous	15MAR2011	15MAR2011
JONOSTERIL /01263001/,Intravenous	15MAR2011	15MAR2011
REMIFENTANIL,Intravenous	15MAR2011	15MAR2011
FENTANYL,Intravenous	15MAR2011	15MAR2011
CEFAZOLIN,Intravenous	15MAR2011	15MAR2011

2.7.6.5　臨床第 III 相試験（CNTO148UCO3001）（評価資料：5.3.5.1.5）

標題：

中等症から重症の活動期日本人潰瘍性大腸炎（以下 UC）患者を対象に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評価を目的とした第 III 相，多施設共同，プラセボ対照，二重盲検，Randomized withdrawal 試験

実施期間：2013 年 2 月 ■日～2016 年 1 月 ■日

実施施設：49 施設

開発の相：第 III 相

試験の目的：

注）各治療期の時点は，寛解導入期は I-Week x，寛解維持期は M-Week x と表記する。

主目的：寛解導入期にゴリムマブにより clinical response（Mayo スコアが I-Week 0 から 30%以上かつ 3 ポイント以上減少するとともに，直腸出血サブスコアが 1 点以上減少するか，若しくは 0 又は 1 になった状態）が認められた中等症から重症の活動期日本人 UC 被験者を対象に，M-Week 54 までの clinical response 維持を指標として，4 週ごとにゴリムマブ 100 mg を皮下投与したときの有効性を評価すること。中等症から重症の活動期日本人 UC 被験者を対象に，ゴリムマブの安全性を評価すること。本試験及び C0524T18 試験の有効性及び安全性の類似性を確認すること。

副次目的：寛解導入期にゴリムマブにより clinical response が認められた日本人被験者を対象に，M-Week 30 及び 54 の両時点での clinical remission（Mayo スコアが 2 点以下であり，1 を超えるサブスコアがない状態）を指標として，ゴリムマブの有効性を評価すること。寛解導入期にゴリムマブにより clinical response が認められた日本人被験者を対象に，M-Week 30 及び 54 の両時点での mucosal healing（Mayo スコアの内視鏡検査サブスコアが 0 又は 1 の状態）を指標として，ゴリムマブの有効性を評価すること。

その他の目的：寛解導入期にゴリムマブにより clinical remission が認められた日本人被験者を対象に，M-Week 30 及び 54 の両時点での clinical remission 維持を指標として，ゴリムマブの有効性を評価すること。M-Week 0 でコルチコステロイドを併用していた日本人被験者のうち，M-Week 54 でコルチコステロイドの併用を中止していた被験者での clinical remission を指標として，ゴリムマブの有効性を評価すること。日本人被験者における C-反応性たん白（以下 CRP），糞便中カルプロテクチン，糞便中ラクトフェリン及び生検検体で得られるバイオマーカーの変化を指標とし，ゴリムマブの薬物動態と併せて薬力学を評価すること。日本人被験者におけるゴリムマブの免疫原性（抗ゴリムマブ抗体）を評価すること。

試験方法：

本試験は，中等症から重症の活動期日本人 UC 被験者を対象に，ゴリムマブ投与による寛解維持療法の有効性及び安全性を評価する，第 III 相，二重盲検，プラセボ対照，2 群，並行群間，多施設共同，randomized withdrawal 試験である。試験の構成及び重要な事項を以下に要約する。

- 本試験は，スクリーニング期，非盲検寛解導入期 6 週間，二重盲検寛解維持期 54 週間（投与は 52 週まで）及び治験薬投与終了後の後観察期 16 週間から構成された。
- スクリーニング後，適格な被験者に，寛解導入療法としてゴリムマブを I-Week 0（200 mg）及び I-Week 2（100 mg）に皮下投与した。
- I-Week 6（すなわち，M-Week 0）に，ゴリムマブの寛解導入療法により clinical response が認められた被験者（以下ゴリムマブ寛解導入 responder）を，プラセボ群又はゴリムマブ 100 mg 群（以下 100 mg 群）のいずれかに 1：1 の比でランダムに割り付け，M-Week 52 まで 4 週ごとに治験薬を皮下投与した。
- ゴリムマブの寛解導入療法により clinical response を認めなかった被験者（以下ゴリムマブ寛解導入 non-responder）も寛解維持期に組入れ可能とした。しかしながら，これらの被験者についてはランダムに割り付けず，M-Week 0 及び 4 にゴリムマブ 100 mg を皮下投与した。I-Week 0 の Mayo スコアと比較して，M-Week 8 までにゴリムマブによる clinical response を認めなかった被験者は，治験薬投与を中止した。M-Week 8 までに clinical response が認められた被験者は，M-Week 8 以降も投与を継続し，M-Week 52 まで 4 週ごとにゴリムマブ 100 mg を皮下投与した。
- ランダム割付けされた被験者が，寛解維持期に clinical response の基準に合致しなくなった場合，以下の方法で治験薬の用量を調節した。

  1. プラセボを投与していた被験者には，4 週ごとにゴリムマブ 100 mg を皮下投与した。
  2. 4 週ごとにゴリムマブ 100 mg を皮下投与していた被験者には，4 週ごとにゴリムマブ 100 mg を皮下投与した（すなわち，同じ用量を継続した）。
     上記の用量調節は，試験中に 1 回だけ行うことができることとした。用量調節後の初回投与後 12 週までに疾患活動性の改善（I-Week 0 の Mayo スコアと比較した clinical response）が認められない場合は，当該被験者への治験薬投与を中止した。疾患活動性の改善が認められた被験者には，M-Week 52 まで同じ用量で投与を継続した。

主要な有効性解析の target population は，ゴリムマブ寛解導入 responder であり寛解維持期にランダム割付けされた被験者とした。ゴリムマブ寛解導入 non-responder であり寛解維持期にランダム割付けされなかった被験者（すなわち，target population に含まれなかった被験者）についても有効性を評価したが，主要な有効性解析に含めなかった。すべての被験者を対象にして，安全性を評価した。寛解維持期の有効性は M-Week 54 まで，安全性は M-Week 68 までのデータを用いて評価した。

被験者数：

計画時：計画時の被験者数は約 200 例であった。しかしながら，本試験に必要な被験者数は，ゴリムマブの寛解導入療法により clinical response が認められランダム割付けされる被験者数に左右された。寛解維持療法の評価に必要な被験者数（全体で 60 例）を確保するために，二重盲検寛解維持期にランダム割付けされる被験者数をモニタリングすることとした。I-Week 6 に clinical response が認められた被験者数に応じて，登録被験者数が 200 例を超えても良い，又は 200 例に到達する前に登録を終了しても良いこととした。

解析時：寛解導入期では，144 例が治験薬を投与された。このうち 123 例が寛解導入期を完了し，I-Week 6/M-Week 0 に clinical response を評価された。123 例のうち 63 例がゴリムマブ寛解導入 responder であり，寛解維持期に 100 mg 群又はプラセボ群のいずれかに 1：1 の比でランダム割付けされた。ほかの 60 例はゴリムマブ寛解導入 non-responder であり，寛解維持期に非盲検でゴリムマブ 100 mg を投与された。

診断及び主な組入れ基準：

日本人の男性又は女性で，18 歳以上，ベースライン（I-Week 0）に中等症から重症の活動期 UC（Mayo スコアが 6～12 点）かつ内視鏡検査サブスコアが 2 点以上の被験者を対象とした。UC の診断と一致する生検結果がある外来被験者（すなわち，結腸切除のリスクが切迫していない被験者）で，経口 5-アミノサリチル酸（以下 ASA）化合物，経口コルチコステロイド，免疫調節薬（アザチオプリン若しくは 6-メルカプトプリンなど）のうち 1 つ以上の UC 化合物に対し，効果が不十分であった被験者若しくは忍容性が不良であった被験者，又はコルチコステロイド依存が認められる被験者を対象とした。TNFα 薬の投与歴を有する被験者は，本試験の対象としなかった。

被験薬：

ゴリムマブは，単回使用プレフィルドシリンジ（以下 PFS）の皮下注射用滅菌液として供給された［ロット番号：[redacted]（使用期限：[redacted]年[redacted]月[redacted]日），[redacted]（使用期限：[redacted]年[redacted]月[redacted]日），[redacted]（使用期限：[redacted]年[redacted]月[redacted]日）］。各 PFS（薬液 1 mL 充填）には，ヒスチジン，ソルビトール及びポリソルベート 80 が含まれた pH が 5.5 の水溶性媒体に，ゴリムマブ 100 mg が充填された。寛解導入期では，ゴリムマブを I-Week 0 に 200 mg，I-Week 2 に 100 mg 皮下投与した。寛解維持期では，4 週ごとにゴリムマブ 100 mg を皮下投与した。

対照薬：

プラセボは，単回使用 PFS の皮下注射用滅菌液として供給された［ロット番号：[redacted]（使用期限：[redacted]年[redacted]月[redacted]日），[redacted]（使用期限：[redacted]年[redacted]月[redacted]日）］。各 PFS（薬液 1 mL 充填）には，ヒスチジン，ソルビトール及びポリソルベート 80 が含まれた pH が 5.5 の水溶性媒体が充填された。注射用プラセボを，寛解維持期にプラセボ群にランダム割付けされた被験者に投与した。

投与期間：

寛解導入療法として，ゴリムマブを I-Week 0（200 mg）及び I-Week 2（100 mg）に皮下投与した。ゴリムマブ寛解導入 responder を 100 mg 群又はプラセボ群のいずれかに 1：1 の比でランダムに割り付け，M-Week 52 まで 4 週ごとに治験薬を皮下投与した。ゴリムマブ寛解導入 non-responder には，M-Week 4 までゴリムマブ 100 mg を投与した。M-Week 8 までに clinical response が認められた被験者には，M-Week 52 まで同じ用量で投与を継続した。

本試験で予定していたゴリムマブの投与期間は，58 週間（寛解導入期 6 週間を含む）であった。

評価：

薬物動態及び免疫原性：血清中ゴリムマブ濃度（I-Week 0，2 及び 4，I-Week 6/M-Week 0，並びに M-Week 4，8，12，20，28，30，36，44，52，54 及び 68）及び抗ゴリムマブ抗体（I-Week 0，I-Week 6/M-Week 0，並びに M-Week 28，30，52，54 及び 68）

薬物動態／薬力学評価：ゴリムマブ曝露量と有効性（clinical response）の関係性の探索

バイオマーカー：CRP，糞便中ラクトフェリン及び糞便中カルプロテクチン並びに mRNA 発現解析用粘膜生検。mRNA 発現解析用粘膜生検検体は，同意を別途取得した被験者からのみ採取した。

有効性：Mayo スコア，partial Mayo スコア，患者報告アウトカム［Inflammatory Bowel Disease Questionnaire（以下 IBDQ），Euro QOL（以下 EQ）-5D］。有効性評価基準は以下のとおりとした：Mayo スコアに基づく clinical response（Mayo スコアが I-Week 0 から，30%以上かつ 3 ポイント以上減少するとともに，直腸出血サブスコアが 1 点以上減少するか，若しくは 0 又は 1 になった状態），Mayo スコアに基づく clinical remission（Mayo スコアが 2 点以下であり，1 を超えるサブスコアがない状態）及び mucosal healing（Mayo スコアの内視鏡検査サブスコアが 0 又は 1 の状態）

安全性：有害事象，治験担当医師により感染症と判断された有害事象，注射部位反応，臨床検査，バイタルサイン（血圧，脈拍数，呼吸数，体温），身体所見，結核検査，抗核抗体（以下 ANA）及び抗 dsDNA 抗体。有害事象名は MedDRA ver. 18.1 を用いてコーディングした。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」又は「ほぼ確実」の有害事象を治験薬と関連性がある有害事象とした。

医療資源利用度：本試験中の各来院時に情報が得られた UC による入院，UC による結腸切除及び UC による手術

統計手法：

症例数の設定：C0524T18 試験で，100 mg 群とプラセボ群とで M-Week 54 までに clinical response が認められた被験者の割合の差は 19.2%（95%信頼区間：8.5%～29.9%）であり，本試験ではその 95%信頼区間の下限値の 8.5%以上を有効性の主要評価項目の基準とした。また，100 mg 群とプラセボ群の M-Week 54 までに clinical response が認められる被験者の割合は，C0524T18 試験の全集団と日本人集団とで同様であると想定し，シミュレーションした。その結果，80%を超える統計的確率で有効性の主要評価項目の基準を達成するためには，1 群あたり少

なくとも 30 例が必要と考えられた。登録被験者数は，寛解維持期にランダム割付けされた target population に左右された。C0524T17 試験の日本人部分集団の結果に基づき，寛解導入期に clinical renponse が認められる被験者の割合を約 30%と推定した。その推定に基づき，二重盲検寛解維持期に 60 例がランダム割付けされるためには，200 例の登録が必要であった。しかしながら，ランダム割付けされる被験者の必要数である 60 例を確保するために，寛解維持期にランダム割付けされる被験者数をモニタリングし，登録被験者数を増減できることとした。

解析対象集団：

・ 有効性は，以下の有効性の解析対象集団に基づき評価した：

1. 寛解維持期の有効性の最大解析対象集団（以下 FAS-I）：寛解導入期に治験薬を投与されたすべての被験者
2. 二重盲検寛解維持期の有効性の主要解析対象集団（以下 FAS-DB）：M-Week 0 にランダム割付けされたすべての被験者（すなわち，target population）
3. 非盲検寛解維持期の有効性の最大解析対象集団（以下 FAS-OL）：ランダム割付けされなかった被験者で寛解維持期に治験薬を投与された被験者

・ 安全性は，以下の安全性の解析対象集団に基づき評価した：

1. 寛解導入期の安全性の解析対象集団（以下 SF-I）：寛解導入期に，部分的な投与も含め，治験薬を 1 回以上投与された被験者
2. 二重盲検寛解維持期の安全性の解析対象集団（以下 SF-DB）：ランダム割付けされ寛解維持期に治験薬を投与された被験者
3. 非盲検寛解維持期の安全性の解析対象集団（以下 SF-OL）：ランダム割付けされなかった被験者で寛解維持期に治験薬を投与された被験者
4. 寛解維持期の安全性の解析対象集団（以下 SF-M）：寛解維持期に治験薬を 1 回以上投与された被験者

・ 薬物動態は，以下の薬物動態の解析対象集団に基づき評価した：

1. 寛解導入期の薬物動態の解析対象集団（以下 PK-I）：ゴリムマブを 1 回以上投与され，寛解導入期のゴリムマブ投与後の薬物動態の測定値［定量限界未満（以下 BQL）の値を含む］を 1 つ以上有する被験者
2. 二重盲検寛解維持期の薬物動態の解析対象集団（以下 PK-DB）：ランダム割付けされた被験者で，寛解維持期に治験薬を投与され，寛解維持期のゴリムマブ投与後の薬物動態の測定値（BQL の値を含む）を 1 つ以上有する被験者
3. 非盲検寛解維持期の薬物動態の解析対象集団（以下 PK-OL）：ランダム割付けされなかった被験者で，寛解維持期に治験薬を投与され，寛解維持期のゴリムマブ投与後の薬物動態の測定値（BQL の値を含む）を 1 つ以上有する被験者
   なお，PK-DB 及び PK-OL に含まれた被験者は，寛解導入期に正しい用量のゴリムマブが投与された被験者である。

4. 寛解維持期の薬物動態の解析対象集団（以下 PK-M）：寛解維持期に治験薬を投与され，寛解維持期のゴリムマブ投与後の薬物動態の測定値（BQL の値を含む）を 1 つ以上有する被験者，すなわち PK-DB と PK-OL を合わせた集団

・ 免疫原性は，以下の免疫原性の解析対象集団に基づき評価した：
免疫原性の解析対象集団：ゴリムマブを 1 回以上投与され，ゴリムマブ投与後の免疫原性の測定値を 1 つ以上有する被験者

解析は，被験者がランダム割付けされた投与群ではなく，被験者が実際に投与された治験薬に基づいて行った。

薬物動態：各検体採取時点の血清中ゴリムマブ濃度の記述統計量［平均値，標準偏差，変動係数，中央値，最小値，最大値，四分位（第 1 四分位及び第 3 四分位）］を要約した。ゴリムマブの初回投与後の血清中ゴリムマブ濃度の中央値－時間推移をプロットした。

免疫原性：免疫原性の解析対象集団について，試験中の抗ゴリムマブ抗体の発現割合及び各被験者の発現状況（いずれかの時点で陽性，又は陰性）を要約した。

ANA の存在は，I-Week 0 及び 6 並びに M-Week 30 及び 54 に採取した血液検体で決定した。ANA 陽性の被験者については，抗 dsDNA 抗体も検査した。I-Week た。で ANA 陰性及び抗 dsDNA 抗体陰性であった被験者を対象に，I-Week 0 から M-Week 54 までのいずれかの時点及び M-Week ずれか以前の最終評価時又は M-Week 又は時で ANA 陽性及び抗 dsDNA 抗体陽性となった被験者の割合を，1：160 で陽性を示す ANA 力価のカットオフ値を用いて投与群ごとに要約した。本項では，ANA 及び抗 dsDNA 抗体の結果は，安全性解析の結果に含めて記載する。

バイオマーカー：バイオマーカー（CRP，糞便中ラクトフェリン及び糞便中カルプロテクチン）は FAS-I，FAS-DB 及び FAS-OL について評価した。CRP 濃度の記述統計量及びベースライン（I-Week 0 及び M-Week 0 の両時点）からの経時的な変化量を要約し，I-Week 6，M-Week 16，30 及び 54 の値を 100 mg 群とプラセボ群で比較した。糞便中ラクトフェリン及び糞便中カルプロテクチンの対数変換値及びベースラインからの変化量を要約し，100 mg 群とプラセボ群を比較した。mRNA 発現解析用粘膜生検検体は，同意を別途取得した被験者からのみ採取した。粘膜生検の結果は個別の報告書が作成されるため，本項には記載していない。

有効性：有効性の主要評価項目である M-Week 54 までの clinical response は，target population（FAS-DB）を対象に解析した。主要な解析は，100 mg 群及びプラセボ群で M-Week 54 まで clinical response が維持された被験者の割合とした。投与群間の差（CR_{100}-CR_P，CR_{100} 及び CR_P はそれぞれ 100 mg 群及びプラセボ群の M-Week 54 まで clinical response が維持された被験者の割合の点推定値）を算出し，CR_{100}-CR_P が 8.5%以上の場合，寛解維持期のゴリムマブに意味のある効果ありと判断した。特に明記しない限り，有意水準両側 5%にて群間比較した。信頼区間は必要に応じ，推定した。

副次評価項目は，FAS-DB における，M-Week 30 及び 54 ともに clinical remission が認められた被験者の割合，並びに M-Week 30 及び 54 ともに mucosal healing が認められた被験者の割合を投与群ごとに要約した。

その他の評価項目は，以下のとおり解析した：

1. FAS-DB における，M-Week 30 及び 54 ともに clinical remission を維持された被験者の割合を投与群ごとに算出した。
2. FAS-DB における，M-Week 30 及び 54 でコルチコステロイドの併用を中止しており clinical remission が認められた被験者の割合を投与群ごとに算出した。
3. FAS-I，FAS-DB 及び FAS-OL における，Mayo スコア及び partial Mayo スコアの実測値及びベースラインからの変化量を投与群ごとに経時的に要約した。
4. FAS-I，FAS-DB 及び FAS-OL における，mucosal healing が認められた被験者の割合を投与群ごとに経時的に算出した。
5. FAS-DB 及び FAS-OL における，コルチコステロイドの 1 日投与量（prednisone 換算）の平均値の，M-Week 30 及び 54 の M-Week 0 からの変化量を投与群ごとに要約した。

患者報告アウトカム：IBDQ 及び EQ-5D のデータを以下のように解析した：

1. M-Week 0 の IBDQ スコアが I-Week 0 から 21 以上改善した被験者のうち，M-Week 30 及び 54 でその改善が維持された被験者の割合を投与群ごとに要約した。
2. FAS-I における，IBDQ の総スコア及び 4 つのカテゴリーのスコアの，I-Week 6 の I-Week 0 からの変化量を要約した。
3. FAS-DB 及び FAS-OL における，IBDQ の総スコア及び 4 つのカテゴリーのスコアの，M-Week 30 及び 54 の I-Week 0 からの変化量を要約した。
4. FAS-I，FAS-DB 及び FAS-OL における，ベースラインの EQ-5D の各項目の 3 段階評価の分布を要約した。
5. FAS-I，FAS-DB 及び FAS-OL における，EQ-5D index スコア及び EQ-5D Visual Analogue Scale（以下 VAS）の，I-Week 6，M-Week 30 及び 54 のベースラインからの変化量を投与群ごとに要約した。

安全性：安全性は，既述した解析対象集団にて解析した。すべての有害事象（治験薬投与下で新たに発現した有害事象，重篤な有害事象，治験薬の投与中止に至った有害事象），治験担当医師により感染症と判断された有害事象，注射部位反応，臨床検査の解析値及びベースライン後の顕著な異常変動が認められた被験者の割合，並びに身体所見を投与群ごとに要約した。有害事象は，治験薬投与下で新たに発現した有害事象を集計対象とした。バイタルサインを測定したが，測定値は電子症例報告書で収集しなかった。抗ゴリムマブ抗体の発現と安全性との関連性は，M-Week 54 までの注射部位反応及び抗ゴリムマブ抗体の発現を要約することにより評価した。

医療資源利用度：医療資源利用度は，以下のとおり解析した：

1. UC による入院と治験担当医師が判断した被験者の割合を，寛解導入期（I-Week 0 から I-Week 6 まで）及び寛解維持期（M-Week 0 から M-Week 54 まで）のそれぞれについて，投与群ごとに要約した。

2. UC による結腸切除を受けた被験者の割合を，寛解導入期（I-Week 0 から I-Week 6 まで）及び寛解維持期（M-Week 0 から M-Week 54 まで）のそれぞれについて，投与群ごとに要約した。
3. UC による手術（結腸切除を含む）を受けた被験者の割合を，寛解導入期（I-Week 0 から I-Week 6 まで）及び寛解維持期（M-Week 0 から M-Week 54 まで）のそれぞれについて，投与群ごとに要約した。

試験結果：

対象患者集団

スクリーニングされた 186 例のうち，144/186 例（77.4%）が寛解導入期にゴリムマブによる寛解導入療法を受けた。このうち 123/144 例（85.4%）が I-Week 6 に寛解導入期を完了し，寛解維持期に移行した。寛解導入期にゴリムマブを投与された被験者のうち 21/144 例（14.6%）は寛解維持期に移行しなかった。寛解維持期に移行した被験者の内訳を表 2.7.6.5-1 に示す。

表 2.7.6.5-1 被験者の内訳（寛解導入期に移行した被験者，M-Week 54）

	Randomized Subjects					Nonrandomized Subjects	
				Dose Adjustment			
	Placebo	Golimumab 100 mg	Total	Placebo → Golimumab 100 mg	Golimumab 100 mg → Golimumab 100 mg	Golimumab 100 mg	All Golimumab[a]
Analysis set: SF-M	31	32	63	19	8	60	111
Subjects who were randomized	31 (100.0%)	32 (100.0%)	63 (100.0%)	19 (100.0%)	8 (100.0%)	0	51 (45.9%)
Subjects who started administration	31 (100.0%)	32 (100.0%)	63 (100.0%)	19 (100.0%)	8 (100.0%)	60 (100.0%)	111 (100.0%)
Subjects who terminated study participation	12 (38.7%)	5 (15.6%)	17 (27.0%)	8 (42.1%)	2 (25.0%)	43 (71.7%)	56 (50.5%)
Reason for discontinuation							
Adverse event	1 (3.2%)	0	1 (1.6%)	0	0	1 (1.7%)	1 (0.9%)
Lost to follow-up	0	0	0	0	0	0	0
Withdrawal of consent	2 (6.5%)	1 (3.1%)	3 (4.8%)	1 (5.3%)	0	3 (5.0%)	5 (4.5%)
Death	0	0	0	0	0	0	0
Lack of efficacy	7 (22.6%)	3 (9.4%)	10 (15.9%)	5 (26.3%)	2 (25.0%)	38 (63.3%)	46 (41.4%)
Protocol violation	0	0	0	0	0	0	0
Physician decision	2 (6.5%)	0	2 (3.2%)	2 (10.5%)	0	1 (1.7%)	3 (2.7%)
Pregnancy	0	1 (3.1%)	1 (1.6%)	0	0	0	1 (0.9%)
Subjects who completed this maintenance phase	19 (61.3%)	27 (84.4%)	46 (73.0%)	11 (57.9%)	6 (75.0%)	17 (28.3%)	55 (49.5%)

SF-M=safety analysis set for maintenance phase

[a] Includes 1) subjects who were randomized to golimumab 100 mg; 2) subjects who were dose adjusted to golimumab 100 mg from placebo; 3) subjects who were not randomized and received golimumab 100 mg.

参照元：CNTO148UCO3001 Clinical Study Report Synopsis

人口統計学的特性，ベースラインの疾患特性及びほかの UC 治療薬（コルチコステロイド，免疫調整薬及び ASA）を併用していた被験者の割合は，ランダム割付けされた被験者のいずれの

投与群でもおおむね同様であり，ランダム割付けされなかった被験者の結果とおおむね一致していた。ランダム割付けされた被験者の人口統計学的特性を表 2.7.6.5-2 に示す。

表 2.7.6.5-2 人口統計学的特性（ランダム割付けされた被験者）

				Dose Adjustment	
	Placebo	Golimumab 100 mg	Total	Placebo → Golimumab 100 mg	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

参照元：CNTO148UCO3001 Clinical Study Report Table 2

薬物動態及び免疫原性

薬物動態

- 寛解導入期では，I-Week 0 にゴリムマブ 100 mg を 2 回（すなわち，200 mg）皮下投与したため，血清中ゴリムマブ濃度の中央値が最も高かったのは，I-Week 2 の投与前であった（7.72 µg/mL）。寛解導入期の終了時（I-Week 6）では，投与前の血清中ゴリムマブ濃度の中央値は 2.33 µg/mL であった。
- 寛解維持期に 100 mg 群にランダム割付けされた被験者では，プラセボ群にランダム割付けされた被験者とは対照的に，血清中ゴリムマブ濃度が維持された。100 mg 群では，血清中ゴリムマブ濃度の中央値は，M-Week 54 まで定量限界を上回っていた。血清中ゴリムマブ濃度は M-Week 4 までに定常状態に到達した。プラセボ群にランダム割付けされた被験者

では，M-Week 12 の血清中ゴリムマブ濃度の中央値は BQL であった。主要な有効性解析時点である M-Week 30 及び 54 で，血清中ゴリムマブ濃度の中央値はそれぞれ 5.68 µg/mL 及び 5.09 µg/mL であった。M-Week 68 の血清中ゴリムマブ濃度の中央値は 0.06 µg/mL で，定量限界をわずかに上回っていた。

・ ランダム割付けされなかった被験者では，ゴリムマブのトラフ濃度の中央値は，M-Week 0 から M-Week 4 に減少した後，M-Week 52 までおおむね維持された。M-Week 30 及び 54 の血清中ゴリムマブ濃度の中央値は，それぞれ 4.48 µg/mL 及び 3.86 µg/mL であった。M-Week 68 の血清中ゴリムマブ濃度の中央値は BQL であった。

・ I-Week 0 のゴリムマブ初回投与前では，141/144 例（97.9%）で血清中ゴリムマブ濃度が BQL であった。寛解維持期にゴリムマブを投与された被験者で，M-Week 0 から M-Week 54 までに血清中ゴリムマブ濃度が BQL であった被験者はいなかった。M-Week 68 では，寛解維持期にゴリムマブを投与された被験者の 50/82 例（61.0%）で血清中ゴリムマブ濃度が BQL であった。

免疫原性

・ 寛解導入期では，抗ゴリムマブ抗体が陽性であった被験者はいなかった。寛解維持期では，M-Week 54 までに，プラセボ群にランダム割付けされた被験者 4/31 例及びランダム割付けされなかった被験者 1/60 例で抗ゴリムマブ抗体が陽性であった。このうち，プラセボ群にランダム割付けされた被験者 2/31 例では 1：24 と最も高い力価を示した。I-Week 0 から M-Week 68 までは，寛解維持期にプラセボ群にランダム割付けされた被験者 6/31 例（19.4%）及び寛解維持期にゴリムマブ 100 mg を投与された被験者 7/92 例（7.6%）で抗ゴリムマブ抗体が陽性であった。このうち最も高い力価は，ゴリムマブ 100 mg を投与された被験者 1 例の 1：48 であった。

バイオマーカー

・ ランダム割付けされた被験者では，CRP 濃度の平均値は I-Week 0 から M-Week 0 にかけて減少し，M-Week 54 まで 100 mg 群でプラセボ群と比較し減少が維持された。

・ ランダム割付けされた被験者では，糞便中ラクトフェリン濃度及び糞便中カルプロテクチン濃度（対数変換値）の中央値は I-Week 0 から M-Week 0 にかけて減少し，M-Week 30 及び 54 において 100 mg 群でプラセボ群と比較し減少が維持された。

・ 同様に，ランダム割付けされなかった被験者では，CRP 濃度の平均値，及び糞便中ラクトフェリン濃度並びに糞便中カルプロテクチン濃度の中央値は I-Week 0 から M-Week 0 にかけて減少し，M-Week 54 まで減少が維持された。

CRP，糞便中ラクトフェリン及び糞便中カルプロテクチンは，UC のような炎症性疾患の臨床活動性に関連するマーカーである。ゴリムマブの寛解導入療法によりこれらのバイオマーカーの濃度が減少し，寛解維持療法によりその減少が維持された。この結果により，ゴリムマブが中等症から重症の活動期 UC の炎症を長期にわたってコントロールするという治療効果が示された。

有効性

ランダム割付けされた被験者（Target Population）の臨床的有効性

主要評価項目

・ M-Week 54 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）］でプラセボ群［19.4%（6/31 例）］と比較し高かった。

副次評価項目

・ M-Week 30 及び 54 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）］でプラセボ群［6.5%（2/31 例）］と比較し高かった。

・ M-Week 30 及び 54 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）］でプラセボ群［16.1%（5/31 例）］と比較し高かった。

その他の評価項目

・ M-Week 0 に clinical remission が認められた 27 例で，M-Week 30 及び 54 ともに clinical remission が維持された被験者の割合は，100 mg 群［64.3%（9/14 例）］でプラセボ群［15.4%（2/13 例）］と比較し高かった。

・ M-Week 30 及び 54 の M-Week 0 からのコルチコステロイドの 1 日投与量（平均値）の減少量は，いずれも 100 mg 群がプラセボ群と比較して大きかった。さらに，M-Week 0 にコルチコステロイドを併用していた被験者のうち，M-Week 54 に clinical remission が認められ，かつコルチコステロイドの併用を中止していた被験者の割合は，100 mg 群［55.6%（5/9 例）］でプラセボ群［11.1%（1/9 例）］と比較し高かった。

・ I-Week 0 から M-Week 0 にかけて減少した Mayo スコアは，100 mg 群では M-Week 30 及び 54 でその減少が維持されていたが，プラセボ群では M-Week 54 で I-Week 0 の値まで増加した。I-Week 0 から M-Week 54 までの partial Mayo スコアの変化でも同様の結果が認められた。

・ M-Week 30 又は 54 のいずれかの時点で mucosal healing が認められた被験者の割合は，100 mg 群でプラセボ群と比較し高かった。M-Week 30 に mucosal healing が認められた被験者の割合は，100 mg 群では 59.4%（19/32 例）であったが，プラセボ群では 25.8%（8/31 例）であった。

ランダム割付けされなかった被験者の臨床的有効性

・ ランダム割付けされゴリムマブを投与された被験者と同様に，ランダム割付けされなかった被験者においての，M-Week 54 の Mayo スコア及び partial Mayo スコアの平均値は，ベースライン（M-Week 0）の平均値から変化がなかった。これらの被験者はゴリムマブ寛解導入 non-responder であり，Mayo スコアの平均値は M-Week 54 まで I-Week 0 と同程度で推移した。

・ ランダム割付けされなかった被験者で，M-Week 8，30 及び 54 に clinical response が認められた被験者は，それぞれ 18/47 例（38.3%），15/60 例（25.0%）及び 11/60 例（18.3%）であった。M-Week 8，30 及び 54 に mucosal healing が認められた被験者は，それぞれ 13/60 例

（21.7%），9/60 例（15.0%）及び 9/60 例（15.0%）であった。M-Week 8，30 及び 54 に clinical remission が認められた被験者は，それぞれ 2/47 例（4.3%），4/60 例（6.7%），6/60 例（10.0%）であった。

・ コルチコステロイドの 1 日投与量の平均値は，M-Week 0 からわずかに減少した。コルチコステロイドの 1 日投与量の平均値（標準偏差）は，M-Week 0［prednisone 換算 9.08 mg/day（6.201 mg/day）］と比べて，M-Week 30 及び 54 で減少した［平均減少量（標準偏差）は，それぞれ prednisone 換算 1.72 mg/day（3.417 mg/day）及び 1.50 mg/day（3.524 mg/day）］。

寛解導入期の全投与被験者の臨床的有効性

・ 寛解導入期に治験薬が投与された 144 例のうち，53 例（36.8%）で I-Week 6 に mucosal healing が認められた。

・ Mayo スコアの平均値（標準偏差）は，I-Week 6 で I-Week 0［8.1（1.39）］から 2.3（2.89）減少し，同様に， partial Mayo スコアも I-Week 6 で I-Week 0 から減少した。

患者報告アウトカム

・ M-Week 0 の IBDQ スコアが I-Week 0 から 21 以上改善した被験者のうち M-Week 54 までその改善が維持された被験者の割合は，ランダム割付けされた被験者では 100 mg 群［55.0%（11/20 例）］でプラセボ群［22.2%（6/27 例）］と比較し高く，ランダム割付けされなかった被験者では 20%（2/10 例）であった。

・ IBDQ スコアの中央値は，FAS-I で上昇した（I-Week 6 の I-Week 0 からの変化量の中央値は 11.0）ことから，中等症から重症の活動期 UC 患者の QOL の改善に対する，ゴリムマブによる寛解導入効果が示された。ゴリムマブによる寛解維持療法では，M-Week 0 の IBDQ スコアの中央値が I-Week 0 から上昇後 M-Week 54 まで維持され（M-Week 54 の M-Week 0 からの変化量の中央値は 1.0），プラセボと比較し良好な結果が示された。プラセボ群では，IBDQ スコアの中央値が M-Week 54 まで低下した（M-Week 54 の M-Week 0 からの変化量の中央値は−33.0）ことから，UC が悪化し，その後 QOL の改善が認められなくなったことが示された。ランダム割付けされなかった被験者では，M-Week 30 及び 54 ともに，IBDQ スコアの中央値の M-Week 0 からの変化量はわずかであった（いずれの時点でも中央値は 2.0）。

・ ランダム割付けされた被験者では，IBDQ のすべてのカテゴリーのスコアにおける，M-Week 30 及び 54 での M-Week 0 からの変化量の平均値は，100 mg 群でプラセボ群と比較し低かった。ランダム割付けされなかった被験者では，M-Week 30 及び 54 の bowel，systemic 及び social カテゴリーのスコアの中央値に，M-Week 0 からわずかな上昇が認められた。

・ ランダム割付けされた被験者では，EQ-5D index スコアはいずれの投与群でも維持された。一方で，EQ VAS スコアは 100 mg 群でプラセボ群と比較し変化が少なかった。健康状態の尺度である EQ VAS スコアの変化量は，100 mg 群でプラセボ群と比較し良好であった。EQ VAS スコアの M-Week 54 の M-Week 0 からの変化量の平均値（標準偏差）は，プラセボ群で−15.40（17.705），100 mg 群で−0.98（23.597）であった。ランダム割付けされなかった

被験者では，EQ-5D index スコアの M-Week 30 及び 54 の M-Week 0 からの変化量の平均値（標準偏差）は，それぞれ−0.009（0.1112）及び−0.005（0.1174）であり，わずかであった。同様に，EQ VAS スコアの M-Week 30 及び 54 の M-Week 0 からの変化量の平均値（標準偏差）は，それぞれ 5.62（18.221）及び 3.48（18.969）であった。

・ ランダム割付けされた被験者では，M-Week 30 及び 54 に，不安／ふさぎ込み及び痛み／不快感のわずかな改善が認められ，投与群間で同程度であった。同様に，ランダム割付けされなかった被験者の大部分では，EQ-5D の 5 項目で M-Week 0 のスコアが維持された。

有効性及び薬物動態

100 mg 群にランダム割付けされた被験者では，血清中ゴリムマブ濃度の上昇と，M-Week 54 まで clinical response が維持された被験者の割合並びに M-Week 30 及び 54 の両時点で clinical remission が認められた被験者の割合が高かったこととの関連性が認められた。

安全性

日本人被験者にゴリムマブ 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。安全性の結果を以下に要約する：

有害事象

寛解導入期

・ 有害事象は，45.1%（65/144 例）に認められた。最も高頻度に認められた有害事象は，鼻咽頭炎及び潰瘍性大腸炎（すなわち，悪化）であった。

・ 寛解導入期では，治験薬と関連性がある有害事象は，10.4%（15/144 例）に認められた。最も高頻度に認められた治験薬と関連性がある有害事象は，注射部位紅斑（5 例）及び血中ビリルビン増加（2 例）であった。

・ 寛解導入期では，重篤な有害事象は 5 例に認められた。重篤な有害事象は潰瘍性大腸炎（すなわち，UC の悪化）及びサイトメガロウイルス性大腸炎で，それぞれ 4 例及び 1 例に認められた。すべての重篤な有害事象は寛解導入期の 2 回目のゴリムマブ投与後に発現し，いずれも治験薬の投与中止に至った事象であった。

・ スクリーニング期間中の重篤な有害事象は 4 例に認められ，潰瘍性大腸炎（2 例）並びに大腸腺腫及び大腸ポリープ（各 1 例）であった。大腸腺腫を発現した被験者は試験を継続し，大腸腺腫が回復した後に寛解導入期の投与を受けた。

・ 寛解導入期に治験薬の投与中止に至った有害事象は，6.9%（10/144 例）に認められた。最も高頻度に認められた治験薬の投与中止に至った有害事象は，潰瘍性大腸炎［8/144 例（5.6%）］であった。

・ 寛解導入期に治験担当医師により感染症と判断された有害事象は 16.0%（23/144 例）に認められ，そのうち 1 例に認められたサイトメガロウイルス性大腸炎は重篤な有害事象であった。注射部位反応の発現は少なく［4.9%（7/144 例）］，最も高頻度に認められた注射部位反応は注射部位紅斑（5 例）であった。

・ 寛解導入期に，活動性結核又は悪性腫瘍は認められなかった。

寛解維持期

・ 寛解維持期に有害事象が認められた被験者の割合は，プラセボを投与された被験者で 71.0%（22/31 例），ゴリムマブを投与された被験者で 85.6%（95/111 例）であった。ランダム割付けされた被験者及びランダム割付けされなかった被験者で最も高頻度に認められた有害事象は，鼻咽頭炎，注射部位紅斑及び潰瘍性大腸炎であった。

・ 治験薬と関連性がある有害事象が認められた被験者の割合は，プラセボを投与された被験者で 6.5%（2/31 例），ゴリムマブを投与された被験者（ランダム割付けされた被験者及びランダム割付けされなかった被験者のデータを含む）で 21.6%（24/111 例）であった。最も高頻度に認められた治験薬と関連性がある有害事象は注射部位紅斑（8.1%，9/111 例）であり，すべてゴリムマブを投与された被験者に認められた。

・ 寛解維持期の全投与被験者（ランダム割付けされた被験者及びランダム割付けされなかった被験者）で，重篤な有害事象が認められた被験者の割合は，プラセボを投与された被験者で 12.9%（4/31 例），ゴリムマブを投与された被験者で 9.0%（10/111 例）であった。プラセボを投与された被験者に認められ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（各 1 件），ゴリムマブを投与された被験者に認められた重篤な有害事象は，高安動脈炎及び咽頭炎（各 1 例），潰瘍性大腸炎（5 例）並びに帯状疱疹（2 例）であった。

・ 寛解維持期に治験薬の投与中止に至った有害事象は 3 例に認められ，プラセボを投与された被験者 1 例（重篤な有害事象である脳梗塞）及びゴリムマブを投与された被験者 2 例（潰瘍性大腸炎）に認められた。

・ プラセボを投与された被験者の 35.5%（11/31 例）及びゴリムマブを投与された被験者の 49.5%（55/111 例）に，試験中に治験担当医師により感染症と判断された有害事象（重篤な有害事象を含む）が認められた。鼻咽頭炎は，プラセボを投与された被験者及びゴリムマブを投与された被験者で，最も高頻度に認められた。M-Week 54 までに治験担当医師により感染症と判断された重篤な有害事象は，ゴリムマブを投与された被験者 4 例で認められ，帯状疱疹（2 例）並びにサイトメガロウイルス性大腸炎，喉頭炎及び咽頭炎（各 1 例）であった。

・ 寛解維持期では，注射部位反応はゴリムマブを投与された被験者にのみ認められた。注射部位紅斑が最も高頻度に認められた注射部位反応であった。同一被験者で認められた注射部位紅斑及び注射部位そう痒感は，治験担当医師により中等度と判断された。これらの 2 件を除いたすべての注射部位反応は，治験担当医師により軽度で非重篤と判断された。

・ 寛解維持期の M-Week 54 までに，活動性結核又は悪性腫瘍は認められなかった。

後観察期

後観察期に認められた有害事象について，以下に要約する：

・ 重篤な有害事象が 9 例に認められた。認められた事象は，潰瘍性大腸炎（4 例），中毒性皮疹，直腸腺癌，細菌性肺炎，双極 1 型障害及びサイトメガロウイルス感染（各 1 例）であった。

- 直腸腺癌の重症度は中等度であり，治験薬との関連性は「多分なし」と判断された。
- 細菌性肺炎の重症度は中等度，サイトメガロウイルス感染は高度であり，いずれも治験薬との関連性は「可能性小」と判断された。

- M-Week 68 までに活動性結核の報告はなかった。

臨床検査

- 寛解導入期及び寛解維持期の両期間で，血液学的検査値の顕著な異常変動が数例の被験者でみられ，最も高頻度に認められた異常変動はプラセボ群でのリンパ球絶対数減少であった。
- 血液学的検査の異常値の大部分が Grade 0 又は Grade 1 であった。本試験中に重篤な有害事象として報告された血液学的異常はなかった。
- ベースライン後に血液生化学検査値の顕著な異常変動が認められた被験者の割合は全体的に低く，ベースライン後に顕著な異常変動が 2 回以上認められた被験者はほとんどいなかった。
- ベースライン後の総ビリルビン，ALT 及び AST の最大値におけるすべての変化は一過性であり，治験薬の処置に至った臨床検査値の変化はなかった。本試験中に重篤な有害事象として報告された血液生化学異常はなかった。

体重及び身体所見

- 寛解維持期では，ランダム割付けされた被験者又はランダム割付けされなかった被験者のいずれにも体重変化と関連性のある有害事象は認められなかった。寛解導入期では，Day 1 の治験薬投与後に体重増加の有害事象が 1 例に認められた。当該事象の重症度は軽度であり，治験薬と関連性がないと判断された。
- いずれの評価時点でも，ゴリムマブによる寛解導入療法（寛解導入期）又は寛解維持療法（寛解維持期のゴリムマブ 100 mg 又はプラセボ）による悪化を示唆する身体所見に，傾向は認められなかった。

抗ゴリムマブ抗体

- 寛解維持期に，プラセボ群にランダム割付けされた被験者 4 例及びランダム割付けされなかった被験者 1 例の計 5 例で抗ゴリムマブ抗体陽性であったが，この 5 例に M-Week 54 までに注射部位反応は認められなかった。M-Week 54 までの本試験期間中に，抗ゴリムマブ抗体の発現と注射部位反応に関連性は認められなかった。
- 寛解維持期のいずれかの時点で初めて ANA 陽性（≥1:160）となった被験者は，用量調節（プラセボ→ゴリムマブ 100 mg）後に陽性となった 1 例であった。治験薬を投与され，評価されたすべての被験者で，M-Week 0 に抗 dsDNA 抗体陰性であった。寛解導入期及び寛解維持期に治験薬を投与され，その後 M-Week 54 までに抗 dsDNA 抗体陽性となった被験者はいなかった。

医療資源利用度

ランダム割付けされた被験者を対象に，医療資源利用度について解析した。ゴリムマブによる治療の潜在的な薬剤経済学的利益を，直接的な医療資源利用度の差を投与群間で比較することにより検討した。

- UC により入院した被験者は，全体で，寛解維持期に入院した 2 例（いずれもプラセボ群）のみであった。
- 寛解維持期に UC による手術／処置を受けた被験者の割合は，プラセボ群（51.6%，16/31 例）と 100 mg 群（56.3%，18/32 例）で同程度であった。
- ランダム割付けされた被験者で，M-Week 54 までの本試験期間中に UC による結腸切除を受けた被験者はいなかった。

試験の限界（Study limitations）

治験依頼者が特定した特筆すべき試験の限界はなかった。

結論

- ゴリムマブ 100 mg を 4 週ごとに皮下投与する寛解維持療法では，寛解導入療法で clinical response が認められた後も UC の疾患活動性の改善が維持された。ゴリムマブ 100 mg の臨床的有効性は，有効性の示標全体（特に，clinical response 及び clinical remission を維持したこと，並びに mucosal healing を得られたこと）で認められた。
- 日本人被験者にゴリムマブ 100 mg を皮下投与したときの忍容性はおおむね良好であり，安全性プロファイルは本剤の既知の安全性プロファイルと一致していた。
- 日本人被験者にゴリムマブ 100 mg を投与したときに，臨床的に重要な安全性シグナルは認められなかった。
- 本試験の安全性及び有効性の結果は，ゴリムマブの皮下投与による寛解導入療法及び寛解維持療法の良好なベネフィット・リスクプロファイルを支持するものであった。

表 2.7.6.5-3 すべての有害事象（寛解導入期の安全性の解析対象集団）

	Golimumab 200 mg -> 100 mg
Analysis set: SF-I	144
Average duration of follow-up (weeks)	5.9
Average exposure (number of administrations)	3.0
Subjects with 1 or more adverse events	65 (45.1%)
System-organ class/preferred term	
感染症および寄生虫症	23 (16.0%)
鼻咽頭炎	17 (11.8%)
上気道感染	3 (2.1%)
サイトメガロウイルス性大腸炎	1 (0.7%)
帯状疱疹	1 (0.7%)
咽頭炎	1 (0.7%)
胃腸障害	17 (11.8%)
潰瘍性大腸炎	9 (6.3%)
齲歯	2 (1.4%)
痔核	2 (1.4%)
下痢	1 (0.7%)
びらん性胃炎	1 (0.7%)
血栓性痔核	1 (0.7%)
大腸ポリープ	1 (0.7%)
急性膵炎	1 (0.7%)
一般・全身障害および投与部位の状態	12 (8.3%)
注射部位紅斑	5 (3.5%)
悪寒	2 (1.4%)
発熱	2 (1.4%)
異常感	1 (0.7%)
全身性浮腫	1 (0.7%)
注射部位内出血	1 (0.7%)
注射部位そう痒感	1 (0.7%)
注射部位小水疱	1 (0.7%)
皮膚および皮下組織障害	7 (4.9%)
ざ瘡	2 (1.4%)
皮脂欠乏性湿疹	1 (0.7%)

表 2.7.6.5-3 すべての有害事象（寛解導入期の安全性の解析対象集団）（続き）

	Golimumab 200 mg -> 100 mg
紅斑	1 (0.7%)
発疹	1 (0.7%)
全身性皮疹	1 (0.7%)
脂漏性皮膚炎	1 (0.7%)
臨床検査	6 (4.2%)
血中ビリルビン増加	2 (1.4%)
血中クレアチンホスホキナーゼ増加	1 (0.7%)
肝機能検査異常	1 (0.7%)
体重増加	1 (0.7%)
白血球数減少	1 (0.7%)
筋骨格系および結合組織障害	5 (3.5%)
筋骨格痛	2 (1.4%)
関節痛	1 (0.7%)
背部痛	1 (0.7%)
筋骨格不快感	1 (0.7%)
神経系障害	4 (2.8%)
頭痛	3 (2.1%)
傾眠	1 (0.7%)
呼吸器、胸郭および縦隔障害	3 (2.1%)
咳嗽	1 (0.7%)
口腔咽頭痛	1 (0.7%)
咽頭の炎症	1 (0.7%)
湿性咳嗽	1 (0.7%)
血液およびリンパ系障害	1 (0.7%)
貧血	1 (0.7%)
内分泌障害	1 (0.7%)
クッシング様症状	1 (0.7%)
傷害、中毒および処置合併症	1 (0.7%)
挫傷	1 (0.7%)

表 2.7.6.5-3 すべての有害事象（寛解導入期の安全性の解析対象集団）（続き）

	Golimumab 200 mg -> 100 mg
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 (0.7%)
脂漏性角化症	1 (0.7%)
生殖系および乳房障害	1 (0.7%)
乳房出血	1 (0.7%)

Note: Adverse events were coded using MedDRA Version 18.1.

[TSFAE01IN.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW68\RE_CSRW68\TSFAE01IN.sas] 07MAR2016, 14:13

参照元：CNTO148UCO3001 Clinical Study Report TSFAE01IN

表 2.7.6.5-4 すべての有害事象（二重盲検寛解維持期の安全性の解析対象集団）

	Placebo[a]	Golimumab 100mg	Dose Adj. Placebo -> 100 mg[b]	All Golimumab[c]
Analysis set: SF-DB	31	32	19	51
Average duration of follow-up (weeks)	24.2	49.0	28.5	41.4
Average exposure (number of administrations)	6.4	12.6	7.7	10.8
Subjects with 1 or more adverse events	22 (71.0%)	31 (96.9%)	17 (89.5%)	48 (94.1%)
System-organ class/preferred term				
感染症および寄生虫症	13 (41.9%)	20 (62.5%)	8 (42.1%)	28 (54.9%)
鼻咽頭炎	7 (22.6%)	17 (53.1%)	5 (26.3%)	22 (43.1%)
インフルエンザ	1 (3.2%)	4 (12.5%)	1 (5.3%)	5 (9.8%)
結膜炎	1 (3.2%)	1 (3.1%)	1 (5.3%)	2 (3.9%)
口角口唇炎	1 (3.2%)	0	1 (5.3%)	1 (2.0%)
せつ	0	0	1 (5.3%)	1 (2.0%)
単純ヘルペス	0	1 (3.1%)	0	1 (2.0%)
喉頭炎	0	0	1 (5.3%)	1 (2.0%)
口腔カンジダ症	0	1 (3.1%)	0	1 (2.0%)
口腔ヘルペス	3 (9.7%)	1 (3.1%)	0	1 (2.0%)
爪囲炎	0	1 (3.1%)	0	1 (2.0%)
上気道感染	1 (3.2%)	1 (3.1%)	0	1 (2.0%)
気管支炎	1 (3.2%)	0	0	0
麦粒腫	1 (3.2%)	0	0	0
感染	1 (3.2%)	0	0	0
咽頭炎	1 (3.2%)	0	0	0
手白癬	1 (3.2%)	0	0	0
扁桃炎	1 (3.2%)	0	0	0
一般・全身障害および投与部位の状態	2 (6.5%)	8 (25.0%)	5 (26.3%)	13 (25.5%)
注射部位紅斑	0	5 (15.6%)	3 (15.8%)	8 (15.7%)
発熱	0	2 (6.3%)	1 (5.3%)	3 (5.9%)
注射部位疼痛	0	2 (6.3%)	0	2 (3.9%)
注射部位腫脹	0	1 (3.1%)	1 (5.3%)	2 (3.9%)
倦怠感	0	1 (3.1%)	1 (5.3%)	2 (3.9%)
注入部位血管外漏出	0	1 (3.1%)	0	1 (2.0%)
注射部位そう痒感	0	1 (3.1%)	0	1 (2.0%)
末梢腫脹	0	0	1 (5.3%)	1 (2.0%)

表 2.7.6.5-4 すべての有害事象（二重盲検寛解維持期の安全性の解析対象集団）（続き）

	Placebo[a]	Golimumab 100mg	Dose Adj. Placebo -> 100 mg[b]	All Golimumab[c]
医薬品副作用	1 (3.2%)	0	0	0
末梢性浮腫	1 (3.2%)	0	0	0
胃腸障害	5 (16.1%)	5 (15.6%)	4 (21.1%)	9 (17.6%)
上腹部痛	1 (3.2%)	2 (6.3%)	0	2 (3.9%)
潰瘍性大腸炎	2 (6.5%)	0	2 (10.5%)	2 (3.9%)
齲歯	1 (3.2%)	1 (3.1%)	1 (5.3%)	2 (3.9%)
腹部不快感	0	1 (3.1%)	0	1 (2.0%)
裂肛	0	1 (3.1%)	0	1 (2.0%)
慢性胃炎	0	1 (3.1%)	0	1 (2.0%)
裂孔ヘルニア	0	0	1 (5.3%)	1 (2.0%)
悪心	0	1 (3.1%)	0	1 (2.0%)
肛門周囲痛	0	1 (3.1%)	0	1 (2.0%)
口唇炎	1 (3.2%)	0	0	0
痔核	1 (3.2%)	0	0	0
皮膚および皮下組織障害	7 (22.6%)	7 (21.9%)	2 (10.5%)	9 (17.6%)
湿疹	2 (6.5%)	2 (6.3%)	1 (5.3%)	3 (5.9%)
ざ瘡	1 (3.2%)	1 (3.1%)	0	1 (2.0%)
脱毛症	0	1 (3.1%)	0	1 (2.0%)
ざ瘡様皮膚炎	0	0	1 (5.3%)	1 (2.0%)
アトピー性皮膚炎	0	1 (3.1%)	0	1 (2.0%)
汗疹	0	1 (3.1%)	0	1 (2.0%)
膿疱性乾癬	0	1 (3.1%)	0	1 (2.0%)
発疹	1 (3.2%)	1 (3.1%)	0	1 (2.0%)
蕁麻疹	0	1 (3.1%)	0	1 (2.0%)
皮脂欠乏性湿疹	1 (3.2%)	0	0	0
寝汗	1 (3.2%)	0	0	0
そう痒症	1 (3.2%)	0	0	0
乾癬	1 (3.2%)	0	0	0
筋骨格系および結合組織障害	2 (6.5%)	7 (21.9%)	0	7 (13.7%)
背部痛	1 (3.2%)	2 (6.3%)	0	2 (3.9%)
関節痛	0	1 (3.1%)	0	1 (2.0%)

表 2.7.6.5-4 すべての有害事象（二重盲検寛解維持期の安全性の解析対象集団）（続き）

	Placebo[a]	Golimumab 100mg	Dose Adj. Placebo -> 100 mg[b]	All Golimumab[c]
関節炎	0	1 (3.1%)	0	1 (2.0%)
筋骨格系胸痛	0	1 (3.1%)	0	1 (2.0%)
筋肉痛	0	1 (3.1%)	0	1 (2.0%)
四肢痛	0	1 (3.1%)	0	1 (2.0%)
腱鞘炎	1 (3.2%)	0	0	0
傷害、中毒および処置合併症	4 (12.9%)	4 (12.5%)	1 (5.3%)	5 (9.8%)
足骨折	0	1 (3.1%)	1 (5.3%)	2 (3.9%)
節足動物咬傷	1 (3.2%)	1 (3.1%)	0	1 (2.0%)
第３度熱傷	0	1 (3.1%)	0	1 (2.0%)
挫傷	0	1 (3.1%)	0	1 (2.0%)
靭帯捻挫	0	1 (3.1%)	0	1 (2.0%)
手骨折	1 (3.2%)	0	0	0
関節脱臼	1 (3.2%)	0	0	0
裂傷	1 (3.2%)	0	0	0
処置による疼痛	1 (3.2%)	0	0	0
臨床検査	1 (3.2%)	3 (9.4%)	2 (10.5%)	5 (9.8%)
白血球数減少	0	2 (6.3%)	1 (5.3%)	3 (5.9%)
アラニンアミノトランスフェラーゼ増加	0	1 (3.1%)	0	1 (2.0%)
血中ビリルビン増加	0	0	1 (5.3%)	1 (2.0%)
好中球数減少	0	1 (3.1%)	0	1 (2.0%)
白血球数増加	1 (3.2%)	0	0	0
神経系障害	4 (12.9%)	3 (9.4%)	2 (10.5%)	5 (9.8%)
頭痛	2 (6.5%)	1 (3.1%)	1 (5.3%)	2 (3.9%)
感覚鈍麻	0	1 (3.1%)	1 (5.3%)	2 (3.9%)
片頭痛	0	1 (3.1%)	0	1 (2.0%)
脳梗塞	1 (3.2%)	0	0	0
意識消失	1 (3.2%)	0	0	0
呼吸器、胸郭および縦隔障害	3 (9.7%)	4 (12.5%)	1 (5.3%)	5 (9.8%)
咳嗽	1 (3.2%)	2 (6.3%)	0	2 (3.9%)
口腔咽頭痛	1 (3.2%)	1 (3.1%)	1 (5.3%)	2 (3.9%)
上気道の炎症	0	1 (3.1%)	0	1 (2.0%)

表 2.7.6.5-4 すべての有害事象（二重盲検寛解維持期の安全性の解析対象集団）（続き）

	Placebo[a]	Golimumab 100mg	Dose Adj. Placebo -> 100 mg[b]	All Golimumab[c]
喘息	1 (3.2%)	0	0	0
鼻漏	1 (3.2%)	0	0	0
血液およびリンパ系障害	0	1 (3.1%)	2 (10.5%)	3 (5.9%)
貧血	0	0	2 (10.5%)	2 (3.9%)
リンパ節症	0	1 (3.1%)	0	1 (2.0%)
血管障害	2 (6.5%)	1 (3.1%)	2 (10.5%)	3 (5.9%)
高血圧	1 (3.2%)	0	2 (10.5%)	2 (3.9%)
高安動脈炎	0	1 (3.1%)	0	1 (2.0%)
表在性静脈炎	1 (3.2%)	0	0	0
耳および迷路障害	1 (3.2%)	1 (3.1%)	0	1 (2.0%)
回転性めまい	1 (3.2%)	1 (3.1%)	0	1 (2.0%)
内分泌障害	0	1 (3.1%)	0	1 (2.0%)
クッシング様症状	0	1 (3.1%)	0	1 (2.0%)
眼障害	0	1 (3.1%)	0	1 (2.0%)
眼瞼炎	0	1 (3.1%)	0	1 (2.0%)
肝胆道系障害	1 (3.2%)	1 (3.1%)	0	1 (2.0%)
肝機能異常	0	1 (3.1%)	0	1 (2.0%)
脂肪肝	1 (3.2%)	0	0	0
免疫系障害	0	1 (3.1%)	0	1 (2.0%)
季節性アレルギー	0	1 (3.1%)	0	1 (2.0%)
代謝および栄養障害	0	0	1 (5.3%)	1 (2.0%)
糖尿病	0	0	1 (5.3%)	1 (2.0%)
精神障害	1 (3.2%)	1 (3.1%)	0	1 (2.0%)
抑うつ症状	0	1 (3.1%)	0	1 (2.0%)
不眠症	1 (3.2%)	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] Includes data from the time of the first golimumab dose onward.
Note: Adverse events were coded using MedDRA Version 18.1.

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参照元：CNTO148UCO3001 Clinical Study Report TSFAE01DB

表 2.7.6.5-5 すべての有害事象（寛解維持期の安全性の解析対象集団）

	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 adverse events	22 (71.0%)	95 (85.6%)
System-organ class/preferred term		
感染症および寄生虫症	13 (41.9%)	54 (48.6%)
鼻咽頭炎	7 (22.6%)	36 (32.4%)
インフルエンザ	1 (3.2%)	8 (7.2%)
結膜炎	1 (3.2%)	3 (2.7%)
胃腸炎	0	3 (2.7%)
帯状疱疹	0	3 (2.7%)
口腔ヘルペス	3 (9.7%)	3 (2.7%)
口角口唇炎	1 (3.2%)	2 (1.8%)
口腔カンジダ症	0	2 (1.8%)
急性副鼻腔炎	0	1 (0.9%)
蜂巣炎	0	1 (0.9%)
毛包炎	0	1 (0.9%)
せつ	0	1 (0.9%)
単純ヘルペス	0	1 (0.9%)
膿痂疹	0	1 (0.9%)
喉頭炎	0	1 (0.9%)
眼部単純ヘルペス	0	1 (0.9%)
中耳炎	0	1 (0.9%)
爪囲炎	0	1 (0.9%)
咽頭炎	1 (3.2%)	1 (0.9%)
副鼻腔炎	0	1 (0.9%)
レンサ球菌感染	0	1 (0.9%)
皮下組織膿瘍	0	1 (0.9%)
扁桃炎	1 (3.2%)	1 (0.9%)
上気道感染	1 (3.2%)	1 (0.9%)
気管支炎	1 (3.2%)	0
麦粒腫	1 (3.2%)	0

表 2.7.6.5-5 すべての有害事象（寛解維持期の安全性の解析対象集団）（続き）

	Placebo[a]	Golimumab 100mg[b]
感染	1 (3.2%)	0
手白癬	1 (3.2%)	0
胃腸障害	5 (16.1%)	27 (24.3%)
潰瘍性大腸炎	2 (6.5%)	8 (7.2%)
齲歯	1 (3.2%)	4 (3.6%)
上腹部痛	1 (3.2%)	3 (2.7%)
裂肛	0	2 (1.8%)
便秘	0	2 (1.8%)
悪心	0	2 (1.8%)
肛門周囲痛	0	2 (1.8%)
腹部不快感	0	1 (0.9%)
慢性胃炎	0	1 (0.9%)
排便障害	0	1 (0.9%)
小腸炎	0	1 (0.9%)
胃炎	0	1 (0.9%)
痔核	1 (3.2%)	1 (0.9%)
裂孔ヘルニア	0	1 (0.9%)
大腸ポリープ	0	1 (0.9%)
急性膵炎	0	1 (0.9%)
口内炎	0	1 (0.9%)
口唇炎	1 (3.2%)	0
一般・全身障害および投与部位の状態	2 (6.5%)	19 (17.1%)
注射部位紅斑	0	9 (8.1%)
発熱	0	5 (4.5%)
倦怠感	0	3 (2.7%)
注射部位疼痛	0	2 (1.8%)
注射部位腫脹	0	2 (1.8%)
胸部不快感	0	1 (0.9%)
治癒不良	0	1 (0.9%)
注入部位血管外漏出	0	1 (0.9%)
注射部位そう痒感	0	1 (0.9%)

表 2.7.6.5-5 すべての有害事象（寛解維持期の安全性の解析対象集団）（続き）

	Placebo[a]	Golimumab 100mg[b]
注射部位小水疱	0	1 (0.9%)
末梢腫脹	0	1 (0.9%)
医薬品副作用	1 (3.2%)	0
末梢性浮腫	1 (3.2%)	0
皮膚および皮下組織障害	7 (22.6%)	16 (14.4%)
湿疹	2 (6.5%)	3 (2.7%)
発疹	1 (3.2%)	3 (2.7%)
脱毛症	0	2 (1.8%)
ざ瘡	1 (3.2%)	1 (0.9%)
皮膚炎	0	1 (0.9%)
ざ瘡様皮膚炎	0	1 (0.9%)
アトピー性皮膚炎	0	1 (0.9%)
水疱性皮膚炎	0	1 (0.9%)
紅斑	0	1 (0.9%)
多形紅斑	0	1 (0.9%)
汗疹	0	1 (0.9%)
そう痒症	1 (3.2%)	1 (0.9%)
膿疱性乾癬	0	1 (0.9%)
そう痒性皮疹	0	1 (0.9%)
蕁麻疹	0	1 (0.9%)
皮脂欠乏性湿疹	1 (3.2%)	0
寝汗	1 (3.2%)	0
乾癬	1 (3.2%)	0
筋骨格系および結合組織障害	2 (6.5%)	12 (10.8%)
背部痛	1 (3.2%)	4 (3.6%)
四肢痛	0	2 (1.8%)
関節痛	0	1 (0.9%)
関節炎	0	1 (0.9%)
筋痙縮	0	1 (0.9%)
筋骨格系胸痛	0	1 (0.9%)
筋骨格痛	0	1 (0.9%)

表 2.7.6.5-5 すべての有害事象（寛解維持期の安全性の解析対象集団）（続き）

	Placebo[a]	Golimumab 100mg[b]
筋肉痛	0	1 (0.9%)
変形性脊椎症	0	1 (0.9%)
腱鞘炎	1 (3.2%)	0
呼吸器、胸郭および縦隔障害	3 (9.7%)	12 (10.8%)
上気道の炎症	0	5 (4.5%)
咳嗽	1 (3.2%)	4 (3.6%)
口腔咽頭痛	1 (3.2%)	4 (3.6%)
喘息	1 (3.2%)	0
鼻漏	1 (3.2%)	0
神経系障害	4 (12.9%)	10 (9.0%)
頭痛	2 (6.5%)	3 (2.7%)
感覚鈍麻	0	3 (2.7%)
浮動性めまい	0	1 (0.9%)
片頭痛	0	1 (0.9%)
ヘルペス後神経痛	0	1 (0.9%)
失神寸前の状態	0	1 (0.9%)
脳梗塞	1 (3.2%)	0
意識消失	1 (3.2%)	0
血液およびリンパ系障害	0	9 (8.1%)
貧血	0	5 (4.5%)
鉄欠乏性貧血	0	2 (1.8%)
骨髄機能不全	0	1 (0.9%)
リンパ節症	0	1 (0.9%)
傷害、中毒および処置合併症	4 (12.9%)	9 (8.1%)
挫傷	0	2 (1.8%)
足骨折	0	2 (1.8%)
節足動物咬傷	1 (3.2%)	1 (0.9%)
第３度熱傷	0	1 (0.9%)
靭帯捻挫	0	1 (0.9%)
外傷後頚部症候群	0	1 (0.9%)
肋骨骨折	0	1 (0.9%)

表 2.7.6.5-5 すべての有害事象（寛解維持期の安全性の解析対象集団）（続き）

	Placebo[a]	Golimumab 100mg[b]
創傷	0	1 (0.9%)
手骨折	1 (3.2%)	0
関節脱臼	1 (3.2%)	0
裂傷	1 (3.2%)	0
処置による疼痛	1 (3.2%)	0
臨床検査	1 (3.2%)	9 (8.1%)
白血球数減少	0	3 (2.7%)
好中球数減少	0	2 (1.8%)
アラニンアミノトランスフェラーゼ増加	0	1 (0.9%)
血中ビリルビン増加	0	1 (0.9%)
血中乳酸脱水素酵素増加	0	1 (0.9%)
血中マグネシウム減少	0	1 (0.9%)
肝機能検査異常	0	1 (0.9%)
白血球数増加	1 (3.2%)	1 (0.9%)
血管障害	2 (6.5%)	5 (4.5%)
高血圧	1 (3.2%)	2 (1.8%)
動脈硬化症	0	1 (0.9%)
静脈炎	0	1 (0.9%)
高安動脈炎	0	1 (0.9%)
表在性静脈炎	1 (3.2%)	0
精神障害	1 (3.2%)	4 (3.6%)
不眠症	1 (3.2%)	3 (2.7%)
抑うつ症状	0	1 (0.9%)
眼障害	0	3 (2.7%)
眼瞼炎	0	3 (2.7%)
免疫系障害	0	3 (2.7%)
季節性アレルギー	0	3 (2.7%)
心臓障害	0	2 (1.8%)
動悸	0	2 (1.8%)
耳および迷路障害	1 (3.2%)	2 (1.8%)
耳漏	0	1 (0.9%)
回転性めまい	1 (3.2%)	1 (0.9%)

表 2.7.6.5-5 すべての有害事象（寛解維持期の安全性の解析対象集団）（続き）

	Placebo[a]	Golimumab 100mg[b]
肝胆道系障害	1 (3.2%)	2 (1.8%)
肝機能異常	0	2 (1.8%)
脂肪肝	1 (3.2%)	0
代謝および栄養障害	0	2 (1.8%)
糖尿病	0	1 (0.9%)
高血糖	0	1 (0.9%)
内分泌障害	0	1 (0.9%)
クッシング様症状	0	1 (0.9%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	1 (0.9%)
皮膚良性新生物	0	1 (0.9%)
腎および尿路障害	0	1 (0.9%)
尿路結石	0	1 (0.9%)
生殖系および乳房障害	0	1 (0.9%)
月経過多	0	1 (0.9%)

[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.

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参照元：CNTO148UCO3001 Clinical Study Report TSFAE01MA

表 2.7.6.5-6 治験薬と関連性がある有害事象（寛解導入期の安全性の解析対象集団）

	Golimumab 200 mg -> 100 mg
Analysis set: SF-I	144
Average duration of follow-up (weeks)	5.9
Average exposure (number of administrations)	3.0
Subjects with 1 or more reasonably related adverse events	15 (10.4%)
System-organ class/preferred term	
一般・全身障害および投与部位の状態	7 (4.9%)
注射部位紅斑	5 (3.5%)
異常感	1 (0.7%)
注射部位そう痒感	1 (0.7%)
注射部位小水疱	1 (0.7%)
臨床検査	4 (2.8%)
血中ビリルビン増加	2 (1.4%)
肝機能検査異常	1 (0.7%)
白血球数減少	1 (0.7%)
感染症および寄生虫症	2 (1.4%)
サイトメガロウイルス性大腸炎	1 (0.7%)
帯状疱疹	1 (0.7%)
皮膚および皮下組織障害	2 (1.4%)
発疹	1 (0.7%)
全身性皮疹	1 (0.7%)
胃腸障害	1 (0.7%)
潰瘍性大腸炎	1 (0.7%)

Note: Adverse events were coded using MedDRA Version 18.1.

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参照元：CNTO148UCO3001 Clinical Study Report TSFAEREL01IN

表 2.7.6.5-7 治験薬と関連性がある有害事象（二重盲検寛解維持期の安全性の解析対象集団）

	Placebo[a]	Golimumab 100mg	Dose Adj. Placebo -> 100 mg[b]	All Golimumab[c]
Analysis set: SF-DB	31	32	19	51
Average duration of follow-up (weeks)	24.2	49.0	28.5	41.4
Average exposure (number of administrations)	6.4	12.6	7.7	10.8
Subjects with 1 or more reasonably related adverse events	2 (6.5%)	11 (34.4%)	5 (26.3%)	16 (31.4%)
System-organ class/preferred term				
一般・全身障害および投与部位の状態	0	6 (18.8%)	3 (15.8%)	9 (17.6%)
注射部位紅斑	0	5 (15.6%)	3 (15.8%)	8 (15.7%)
注射部位腫脹	0	1 (3.1%)	1 (5.3%)	2 (3.9%)
注射部位疼痛	0	1 (3.1%)	0	1 (2.0%)
注射部位そう痒感	0	1 (3.1%)	0	1 (2.0%)
倦怠感	0	1 (3.1%)	0	1 (2.0%)
臨床検査	0	2 (6.3%)	1 (5.3%)	3 (5.9%)
アラニンアミノトランスフェラーゼ増加	0	1 (3.1%)	0	1 (2.0%)
血中ビリルビン増加	0	0	1 (5.3%)	1 (2.0%)
好中球数減少	0	1 (3.1%)	0	1 (2.0%)
白血球数減少	0	1 (3.1%)	0	1 (2.0%)
感染症および寄生虫症	1 (3.2%)	0	2 (10.5%)	2 (3.9%)
せつ	0	0	1 (5.3%)	1 (2.0%)
喉頭炎	0	0	1 (5.3%)	1 (2.0%)
口腔ヘルペス	1 (3.2%)	0	0	0
皮膚および皮下組織障害	0	2 (6.3%)	0	2 (3.9%)
ざ瘡	0	1 (3.1%)	0	1 (2.0%)
脱毛症	0	1 (3.1%)	0	1 (2.0%)
湿疹	0	1 (3.1%)	0	1 (2.0%)
膿疱性乾癬	0	1 (3.1%)	0	1 (2.0%)
呼吸器、胸郭および縦隔障害	0	1 (3.1%)	0	1 (2.0%)
口腔咽頭痛	0	1 (3.1%)	0	1 (2.0%)
血管障害	0	1 (3.1%)	0	1 (2.0%)
高安動脈炎	0	1 (3.1%)	0	1 (2.0%)

表 2.7.6.5-7 治験薬と関連性がある有害事象（二重盲検寛解維持期の安全性の解析対象集団）（続き）

	Placebo[a]	Golimumab 100mg	Dose Adj. Placebo -> 100 mg[b]	All Golimumab[c]
神経系障害	1 (3.2%)	0	0	0
脳梗塞	1 (3.2%)	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] Includes data from the time of the first golimumab dose onward.
Note: Adverse events were coded using MedDRA Version 18.1.

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参照元：CNTO148UCO3001 Clinical Study Report TSFAEREL01DB

表 2.7.6.5-8 治験薬と関連性がある有害事象（寛解維持期の安全性の解析対象集団）

	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 adverse events	2 (6.5%)	24 (21.6%)
System-organ class/preferred term		
一般・全身障害および投与部位の状態	0	11 (9.9%)
注射部位紅斑	0	9 (8.1%)
注射部位腫脹	0	2 (1.8%)
注射部位疼痛	0	1 (0.9%)
注射部位そう痒感	0	1 (0.9%)
注射部位小水疱	0	1 (0.9%)
倦怠感	0	1 (0.9%)
感染症および寄生虫症	1 (3.2%)	6 (5.4%)
帯状疱疹	0	2 (1.8%)
せつ	0	1 (0.9%)
喉頭炎	0	1 (0.9%)
鼻咽頭炎	0	1 (0.9%)
咽頭炎	0	1 (0.9%)
口腔ヘルペス	1 (3.2%)	0
臨床検査	0	4 (3.6%)
好中球数減少	0	2 (1.8%)
アラニンアミノトランスフェラーゼ増加	0	1 (0.9%)
血中ビリルビン増加	0	1 (0.9%)
白血球数減少	0	1 (0.9%)
皮膚および皮下組織障害	0	3 (2.7%)
ざ瘡	0	1 (0.9%)
脱毛症	0	1 (0.9%)
皮膚炎	0	1 (0.9%)
湿疹	0	1 (0.9%)
膿疱性乾癬	0	1 (0.9%)
呼吸器、胸郭および縦隔障害	0	2 (1.8%)
口腔咽頭痛	0	1 (0.9%)
上気道の炎症	0	1 (0.9%)

表 2.7.6.5-8 治験薬と関連性がある有害事象（寛解維持期の安全性の解析対象集団）（続き）

	Placebo[a]	Golimumab 100mg[b]
心臓障害	0	1 (0.9%)
動悸	0	1 (0.9%)
血管障害	0	1 (0.9%)
高安動脈炎	0	1 (0.9%)
神経系障害	1 (3.2%)	0
脳梗塞	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.

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参照元：CNTO148UCO3001 Clinical Study Report TSFAEREL01MA

表 2.7.6.5-9 重篤な有害事象を発現した症例の一覧

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	1	IND	100		齲歯	DENTAL CARIES	16	154	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	Yes/No
				2	MAIN	0		脳梗塞	CEREBRAL INFARCTION	54	12	RECOVERED/RESOLVED	Yes	MODERATE	POSSIBLE	DRUG WITHDRAWN	No	Yes	No/No
				3	MAIN	0		潰瘍性大腸炎	ULCERATIVE COLITIS AGGRAVATED	63	33	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				4	MAIN	0		脳梗塞	CEREBRAL INFARCTION	65	-	RECOVERING/RESOLVING	No	MILD	POSSIBLE	NOT APPLICABLE	No	Yes	No/No
				5	MAIN	0		脳梗塞	CEREBRAL INFARCTION	48	7	RECOVERED/RESOLVED	No	MODERATE	POSSIBLE	DOSE NOT CHANGED	No	No	No/No
				6	IND	100		鼻咽頭炎	COMMON COLD	41	13	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	No	Yes/No
		811701	3[redacted]/F	1	MAIN	0	Yes	喉頭炎	ACUTE SUBGLOTTIC LARYNGITIS	262	5	RECOVERED/RESOLVED	Yes	MODERATE	POSSIBLE	NOT APPLICABLE	No	Yes	Yes/No
				2	MAIN	0	Yes	喉頭炎	ACUTE SUBGLOTTIC LARYNGITIS	266	46	RECOVERED/RESOLVED	No	MODERATE	POSSIBLE	NOT APPLICABLE	No	Yes	Yes/No
				3	MAIN	0	Yes	鼻咽頭炎	COMMON COLD	245	15	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No
				4	IND	100		全身性浮腫	GENERALIZED EDEMA	17	103	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No
				5	IND	200		体重増加	WEIGHT GAIN	1	262	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	No	No/No

表 2.7.6.5-9 重篤な有害事象を発現した症例の一覧（続き）

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
		811703	5[redacted]/ M	1	MAIN	0		寝汗	NOCTURNAL PERSPIRATION	74	102	RECOVERED/RESOLVED	No	MILD	DOUBTFUL	DOSE NOT CHANGED	No	No	No/No
				3	MAIN	0		口唇炎	CHEILITIS	55	78	RECOVERED/RESOLVED	No	MILD	DOUBTFUL	DOSE NOT CHANGED	No	Yes	No/No
				4	MAIN	0		回転性めまい	VERTIGO	185	14	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	No	No/No
				5	MAIN	0		発疹	RASH(ANTERIOR CHEST NECK)	201	195	RECOVERED/RESOLVED	No	MILD	DOUBTFUL	DOSE NOT CHANGED	No	No	No/No
				6	MAIN	0	Yes	潰瘍性大腸炎	ULCERATIVE COLITIS	400	15	RECOVERED/RESOLVED	Yes	MODERATE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				7	MAIN	0		鼻咽頭炎	COMMON COLD	316	7	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	Yes/No
				8	FUP	0	Yes	インフルエンザ	INFLUENZA	449	5	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No
		812003	5[redacted]/ M	1	MAIN	0		関節脱臼	DISLOCATED RIGHT ACROMIOCLAVICULAR JOINT	121	5	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No
				2	MAIN	0		関節脱臼	DISLOCATED RIGHT ACROMIOCLAVICULAR JOINT	125	4	RECOVERED/RESOLVED	Yes	SEVERE	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No
				3	MAIN	0		関節脱臼	DISLOCATED RIGHT ACROMIOCLAVICULAR JOINT	128	253	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No

表 2.7.6.5-9 重篤な有害事象を発現した症例の一覧（続き）

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
				4	MAIN	0		インフルエンザ	INFLUENZA	140	8	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	DOSE NOT CHANGED	No	Yes	Yes/No
				5	MAIN	100	Yes	発熱	FEVER	265	2	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No
				6	MAIN	0	Yes	裂孔ヘルニア	ESOPHAGEAL HIATAL HERNIA	378	-	NOT RECOVERED/NOT RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
		812201	3[redacted]/ M	1	IND	100		鼻咽頭炎	COMMON COLD	40	7	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	Yes/No
				2	MAIN	0		脂肪肝	DETERIORATING HEPATIC STEATOSIS	46	195	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	No	No/No
				3	MAIN	0		潰瘍性大腸炎	COLITIS ULCERATIVE AGGRAVATED	166	5	RECOVERED/RESOLVED	Yes	MODERATE	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No
				4	MAIN	0		潰瘍性大腸炎	COLITIS ULCERATIVE AGGRAVATED	162	5	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No
				5	SCR	-		白血球数増加	WBC INCREASED	-39	54	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
				6	MAIN	0		白血球数増加	WBC INCREASED	173	15	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	No	No/No
				7	MAIN	0		潰瘍性大腸炎	COLITIS ULCERATIVE AGGRAVATED	170	18	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No

表 2.7.6.5-9 重篤な有害事象を発現した症例の一覧（続き）

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
				8	MAIN	100	Yes	感覚鈍麻	DORSAL NUMBNESS	240	2	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
		813303	5[redacted]/M	1	MAIN	0		鼻咽頭炎	COMMON COLD	185	9	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	Yes/No
				2	MAIN	0		手骨折	FRACTURE OF THE LEFT SECOND METACARPAL BONE	225	6	RECOVERED/RESOLVED	Yes	MODERATE	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No
				3	MAIN	0		手骨折	FRACTURE OF THE LEFT SECOND METACARPAL BONE	206	20	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No
				4	MAIN	0		手白癬	TINEA OF HAND	225	35	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	Yes/No
				5	MAIN	0		処置による疼痛	POSTOPERATIVE PAIN	227	6	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No
				6	MAIN	0		高血圧	AGGRAVATION OF HYPERTENSION	269	-	RECOVERING/RESOLVING	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No
				7	MAIN	0		不眠症	AGGRAVATION OF INSOMNIA	322	-	RECOVERING/RESOLVING	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No
		813903	4[redacted]/F	1	MAIN	0		皮脂欠乏性湿疹	ECZEMA ASTEATOTIC(GENERALIZED)	222	169	RECOVERED/RESOLVED	No	MILD	DOUBTFUL	DOSE NOT CHANGED	No	Yes	No/No
				2	FUP	0		鼻咽頭炎	COMMON COLD	443	9	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No

表 2.7.6.5-9 重篤な有害事象を発現した症例の一覧（続き）

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				3	FUP	0		中毒性皮疹	TOXICODERMA(GENERALIZED)	446	4	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				4	FUP	0		中毒性皮疹	TOXICODERMA(GENERALIZED)	449	8	RECOVERED/RESOLVED	Yes	MODERATE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				6	FUP	0		中毒性皮疹	TOXICODERMA(GENERALIZED)	456	22	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				7	FUP	0		皮脂欠乏性湿疹	ECZEMA ASTEATOTIC(GENERALIZED)	477	-	RECOVERING/RESOLVING	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
		814701	5[redacted]/F	1	MAIN	0		口腔ヘルペス	HERPES LABIALIS	72	27	RECOVERED/RESOLVED	No	MILD	PROBABLE	DOSE NOT CHANGED	No	Yes	Yes/No
				2	MAIN	0		乾癬	WORSENING OF PSORIASIS	51	83	RECOVERED/RESOLVED	No	MILD	DOUBTFUL	DOSE NOT CHANGED	No	Yes	No/No
				3	MAIN	100	Yes	高血圧	HYPERTENSION	210	-	NOT RECOVERED/NOT RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No
				6	MAIN	100	Yes	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	231	22	RECOVERED/RESOLVED	Yes	MODERATE	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No
				7	MAIN	100	Yes	せつ	FURUNCLE	130	25	RECOVERED/RESOLVED	No	MILD	POSSIBLE	DOSE NOT CHANGED	No	Yes	Yes/No
				8	MAIN	100	Yes	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	210	22	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No
	100mg	813202	4[redacted]/F	1	MAIN	100	Yes	悪心	QUEASY	99	7	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No

表 2.7.6.5-9 重篤な有害事象を発現した症例の一覧（続き）

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
				2	MAIN	100	Yes	発疹	ERUPTION OF LIMBS	119	64	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No
				3	MAIN	0	Yes	高安動脈炎	TAKAYASU'S ARTERITIS	202	17	RECOVERED/RESOLVED	No	MODERATE	POSSIBLE	NOT APPLICABLE	No	Yes	No/No
				4	MAIN	0	Yes	高安動脈炎	TAKAYASU'S ARTERITIS	218	-	NOT RECOVERED/NOT RESOLVED	Yes	MODERATE	POSSIBLE	NOT APPLICABLE	No	Yes	No/No
				6	MAIN	0	Yes	慢性胃炎	CHRONIC GASTRITIS	221	-	NOT RECOVERED/NOT RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				7	MAIN	0	Yes	鼻咽頭炎	COLD SYMPTOMS	236	14	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No
				8	MAIN	0	Yes	クッシング様症状	MOON FACE	246	-	NOT RECOVERED/NOT RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
				9	MAIN	0	Yes	注入部位血管外漏出	INFUSION SITE EXTRAVASATION	220	2	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
				10	MAIN	0	Yes	注入部位血管外漏出	INFUSION SITE EXTRAVASATION	223	2	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
No	100mg	810109	3[redacted]/M	1	IND	200		上気道感染	ACUTE UPPER RESPIRATORY INFECTION	8	2	RECOVERED/RESOLVED	No	MILD	DOUBTFUL	DOSE NOT CHANGED	No	Yes	Yes/No
				2	MAIN	100		肛門周囲痛	ANAL PAIN	38	223	RECOVERED/RESOLVED	No	MILD	DOUBTFUL	DOSE NOT CHANGED	No	Yes	No/No

表 2.7.6.5-9 重篤な有害事象を発現した症例の一覧（続き）

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
				3	MAIN	100		結膜炎	CONJUNCTIVITIS	136	32	RECOVERED/RESOLVED	No	MILD	DOUBTFUL	DOSE NOT CHANGED	No	Yes	Yes/No
				4	MAIN	100		帯状疱疹	HERPES ZOSTER(RIGHT FOREHEAD, RIGHT PERIOCULAR)	139	4	RECOVERED/RESOLVED	No	MODERATE	POSSIBLE	DOSE NOT CHANGED	No	Yes	Yes/No
				5	MAIN	100		帯状疱疹	HERPES ZOSTER(RIGHT FOREHEAD, RIGHT PERIOCULAR)	142	8	RECOVERED/RESOLVED	Yes	SEVERE	POSSIBLE	DOSE NOT CHANGED	No	Yes	Yes/No
				6	MAIN	100		帯状疱疹	HERPES ZOSTER(RIGHT FOREHEAD, RIGHT PERIOCULAR)	149	35	RECOVERED/RESOLVED	No	MODERATE	POSSIBLE	DOSE NOT CHANGED	No	Yes	Yes/No
		810604	5[redacted]/ M	1	MAIN	100		そう痒性皮疹	ITCHY RASH(WHOLE BODY)	64	70	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	Yes/No
				2	MAIN	100		上気道の炎症	UPPER RESPIRATORY INFLAMMATION	80	87	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	Yes/No
				3	MAIN	100		そう痒性皮疹	ITCHY RASH(WHOLE BODY)	202	-	NOT RECOVERED/NOT RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No
				4	MAIN	100		耳漏	OTORRHOEA	403	15	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No

表 2.7.6.5-9 重篤な有害事象を発現した症例の一覧（続き）

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
				5	FUP	0		直腸腺癌	TUBULAR ADENOCARCINOMA,WELL DIFFERENTIATED TYPE(RECTUM)	425	41	RECOVERED/RESOLVED	Yes	MODERATE	DOUBTFUL	NOT APPLICABLE	No	Yes	No/No
				6	MAIN	100		胃腸炎	ACUTE GASTROENTERITIS	367	34	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	No	Yes/No
				7	FUP	0		不眠症	INSOMNIA	462	-	NOT RECOVERED/NOT RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				8	FUP	0		処置による疼痛	POSTOPERATION PAIN	465	9	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
		811302	4[redacted]/M	1	IND	100		脂漏性角化症	SEBORRHEIC KERATOSIS	15	-	NOT RECOVERED/NOT RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	No	No/No
				2	MAIN	100		潰瘍性大腸炎	EXACEBATION OF UC	44	15	RECOVERED/RESOLVED	No	SEVERE	NOT RELATED	DRUG WITHDRAWN	No	No	No/No
				3	MAIN	0		潰瘍性大腸炎	EXACEBATION OF UC	58	-	RECOVERING/RESOLVING	Yes	SEVERE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				4	MAIN	0		発熱	FEVER	90	66	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No
		812302	2[redacted]/M	1	MAIN	100		潰瘍性大腸炎	EXACERBATION OF UC	57	24	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	DRUG WITHDRAWN	No	Yes	No/No
				2	MAIN	0		潰瘍性大腸炎	EXACERBATION OF UC	80	30	RECOVERED/RESOLVED	Yes	MODERATE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No

表 2.7.6.5-9 重篤な有害事象を発現した症例の一覧（続き）

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
				3	MAIN	100		鼻咽頭炎	COMMON COLD	57	25	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	No	Yes/No
				4	MAIN	0		感覚鈍麻	NUMBNESS IN HAND	90	8	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
		813502	5[redacted]/ M	1	MAIN	0		潰瘍性大腸炎	EXACERBATION OF UC	56	37	RECOVERED/RESOLVED	Yes	SEVERE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				2	MAIN	0		潰瘍性大腸炎	EXACERBATION OF UC	148	36	RECOVERED/RESOLVED	Yes	SEVERE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				3	MAIN	0		不眠症	INSOMNIA	57	3	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				4	MAIN	0		発疹	ERUPTION(FOREHEAD,RETROAURICULAR,FRONT OF RIGHT SHIN BONE)	148	53	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
				5	MAIN	0		静脈炎	RIGHT SUBCLAVIAN PHLEBITIS	171	30	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
				6	MAIN	0		貧血	ANEMIA	151	50	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
		813705	7[redacted]/ M	1	MAIN	0		咽頭炎	PHARYNGITIS	101	16	RECOVERED/RESOLVED	Yes	MODERATE	POSSIBLE	NOT APPLICABLE	No	Yes	Yes/No
				2	MAIN	100		上気道の炎症	UPPER RESPIRATORY INFLAMMATION	38	36	RECOVERED/RESOLVED	No	MILD	POSSIBLE	DOSE NOT CHANGED	No	Yes	Yes/No
				3	MAIN	100		咽頭炎	PHARYNGITIS	87	15	RECOVERED/RESOLVED	No	MILD	POSSIBLE	DOSE NOT CHANGED	No	Yes	Yes/No

表 2.7.6.5-9 重篤な有害事象を発現した症例の一覧（続き）

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				4	MAIN	0		潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	101	8	RECOVERED/RESOLVED	Yes	MODERATE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				5	MAIN	0		膿痂疹	IMPETIGO(BACK OF THIGH)	102	46	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No
				6	MAIN	0		咽頭炎	PHARYNGITIS	116	-	RECOVERING/RESOLVING	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	Yes/No
				7	MAIN	0		治癒不良	DELAY OF WOUND HEALING(BACK OF THIGH)	102	46	RECOVERED/RESOLVED	No	MILD	DOUBTFUL	NOT APPLICABLE	No	Yes	No/No
		814301	7[redacted]/ M	1	SCR	-		歯髄炎	PULPITIS	-4	8	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				2	SCR	-		上腹部痛	GASTRIC PAIN	-4	5	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				3	IND	100		鼻咽頭炎	COMMON COLD	31	1	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	Yes/No
				4	IND	100		鼻咽頭炎	COMMON COLD	37	1	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	Yes/No
				5	MAIN	100		鼻咽頭炎	COMMON COLD	56	12	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	Yes/No
				6	MAIN	0		潰瘍性大腸炎	WORSENING OF UC	72	42	RECOVERED/RESOLVED	Yes	MODERATE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				7	MAIN	0		鼻咽頭炎	COMMON COLD	73	6	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No
				8	MAIN	0		四肢痛	LEFT CALF ACHE	77	30	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No

表 2.7.6.5-9 重篤な有害事象を発現した症例の一覧（続き）

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				9	MAIN	0		痔核	WORSENING OF HEMORRHOIDS	80	39	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				10	MAIN	0		鼻咽頭炎	COMMON COLD	114	14	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No
				11	MAIN	0		眼部単純ヘルペス	HERPETIC KERATITIS	127	15	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No
				12	MAIN	0		帯状疱疹	SHINGLES	128	8	RECOVERED/RESOLVED	Yes	MODERATE	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No
				13	MAIN	100		潰瘍性大腸炎	WORSENING OF UC	59	14	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	DOSE NOT CHANGED	No	No	No/No
				14	MAIN	0		潰瘍性大腸炎	WORSENING OF UC	113	29	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				15	MAIN	0		帯状疱疹	SHINGLES	135	8	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No
				16	MAIN	0		上腹部痛	EPIGASTRALGIA	130	1	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				17	MAIN	0		背部痛	LUMBAGO	132	5	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				18	MAIN	0		ヘルペス後神経痛	POSTHERPETIC NEURALGIA	142	-	NOT RECOVERED/NOT RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
-	-	810103	1[redacted]/M	1	IND	100		潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	18	57	RECOVERED/RESOLVED	Yes	MODERATE	NOT RELATED	DRUG WITHDRAWN	No	Yes	No/No
				2	IND	100		鼻咽頭炎	COMMON COLD	14	7	RECOVERED/RESOLVED	No	MILD	DOUBTFUL	DOSE NOT CHANGED	No	Yes	Yes/No

表 2.7.6.5-9 重篤な有害事象を発現した症例の一覧（続き）

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				3	FUP	0		双極１型障害	BIPOLAR 1 DISORDER	80	73	RECOVERED/RESOLVED	Yes	SEVERE	DOUBTFUL	NOT APPLICABLE	No	Yes	No/No
				4	FUP	0		双極１型障害	BIPOLAR 1 DISORDER	78	3	RECOVERED/RESOLVED	No	MODERATE	DOUBTFUL	NOT APPLICABLE	No	Yes	No/No
				5	FUP	0		双極１型障害	BIPOLAR 1 DISORDER	152	-	RECOVERING/RESOLVING	No	MILD	DOUBTFUL	NOT APPLICABLE	No	Yes	No/No
				6	IND	100		潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	16	3	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	DOSE NOT CHANGED	No	No	No/No
				7	FUP	0		注入部位静脈炎	PHLEBITIS(DRIP INSERTION SITE)	19	41	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
		810107	5[redacted]/M	2	IND	100		潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	40	4	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	DOSE NOT CHANGED	No	Yes	No/No
				3	IND	100		潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	43	29	RECOVERED/RESOLVED	Yes	SEVERE	NOT RELATED	DRUG WITHDRAWN	No	Yes	No/No
				5	SCR	-		肛門周囲痛	ANAL PAIN	-9	94	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				6	FUP	0		注入部位静脈炎	PHLEBITIS(DRIP INSERTION SITE)	45	7	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
		810303	6[redacted]/M	1	SCR	-		大腸腺腫	ADENOMATOUS POLYP(CEACUM)	-6	2	RECOVERED/RESOLVED	Yes	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				2	FUP	0		潰瘍性大腸炎	AGGRAVATION OF UC	36	46	RECOVERED/RESOLVED	Yes	SEVERE	POSSIBLE	NOT APPLICABLE	No	Yes	No/No

表 2.7.6.5-9 重篤な有害事象を発現した症例の一覧（続き）

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
				3	IND	100		潰瘍性大腸炎	AGGRAVATION OF UC	35	2	RECOVERED/RESOLVED	No	SEVERE	POSSIBLE	DRUG WITHDRAWN	No	Yes	No/No
				4	FUP	0		サイトメガロウイルス感染	CYTOMEGALOVIRUS INFECTION	58	9	RECOVERED/RESOLVED	No	MILD	POSSIBLE	NOT APPLICABLE	No	Yes	Yes/No
				5	FUP	0		クロストリジウム・ディフィシレ感染	CLOSTRIDIUM DIFFICILE INFECTION	43	-	NOT RECOVERED/NOT RESOLVED	No	MODERATE	POSSIBLE	NOT APPLICABLE	No	Yes	Yes/No
		810402	5[redacted]/ M	1	FUP	0		潰瘍性大腸炎	EXACERBATION OF UC	71	31	RECOVERED/RESOLVED	Yes	MODERATE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				2	IND	100		潰瘍性大腸炎	EXACERBATION OF UC	47	25	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DRUG WITHDRAWN	No	Yes	No/No
				3	FUP	0		ざ瘡様皮膚炎	DERMATITIS ACNEIFORM	87	15	RECOVERED/RESOLVED	No	MILD	POSSIBLE	NOT APPLICABLE	No	No	No/No
		810702	7[redacted]/ M	1	FUP	0		潰瘍性大腸炎	ULCERATIVE COLITIS AGGRAVATED	65	32	RECOVERED/RESOLVED	Yes	SEVERE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				2	FUP	0		肝酵素上昇	HEPATIC ENZYME INCREASED	65	65	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
				3	FUP	0		白血球数減少	WHITE BLOOD CELL DECREASED	71	7	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
				4	FUP	0		潰瘍性大腸炎	ULCERATIVE COLITIS AGGRABVATED	58	8	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No

表 2.7.6.5-9 重篤な有害事象を発現した症例の一覧（続き）

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
				5	FUP	0		潰瘍性大腸炎	ULCERATIVE COLITIS AGGRAVATED	96	46	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				6	IND	100		鼻咽頭炎	COMMON COLD	17	23	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	Yes	Yes/No
		810802	2[redacted]/M	1	IND	100		潰瘍性大腸炎	EXACERBATION OF UC	30	96	RECOVERED/RESOLVED	Yes	SEVERE	NOT RELATED	DRUG WITHDRAWN	No	Yes	No/No
		811202	4[redacted]/M	1	IND	100		潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	42	47	RECOVERED/RESOLVED	Yes	MODERATE	NOT RELATED	DRUG WITHDRAWN	No	Yes	No/No
				2	SCR	-		発熱	FEVER	-13	3	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	Yes	Yes	No/No
		811501	5[redacted]/M	1	IND	200		上気道感染	UPPER RESPIRATORY TRACT INFECTION	8	5	RECOVERED/RESOLVED	No	MILD	NOT RELATED	DOSE NOT CHANGED	No	No	Yes/No
				2	FUP	0		細菌性肺炎	BACTERIAL PNEUMONIA	70	6	RECOVERED/RESOLVED	Yes	MODERATE	POSSIBLE	NOT APPLICABLE	No	Yes	Yes/No
				3	FUP	0		細菌性肺炎	BACTERIAL PNEUMONIA	66	5	RECOVERED/RESOLVED	No	MODERATE	POSSIBLE	NOT APPLICABLE	No	No	Yes/No
		811903	5[redacted]/M	1	SCR	-		大腸ポリープ	HYPERPLASTIC POLYP OF LARGE INTESTINE	-	9	RECOVERED/RESOLVED	Yes	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
		812002	4[redacted]/M	1	IND	200		貧血	WORSENING ANEMIA	15	43	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	DRUG WITHDRAWN	No	Yes	No/No
				2	FUP	0		サイトメガロウイルス感染	CYTOMEGALOVIRAL INFECTIONS	57	6	RECOVERED/RESOLVED	No	MODERATE	POSSIBLE	NOT APPLICABLE	No	No	Yes/No

表 2.7.6.5-9 重篤な有害事象を発現した症例の一覧（続き）

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
				3	FUP	0		サイトメガロウイルス感染	CYTOMEGALOVIRAL INFECTIONS	62	15	RECOVERED/RESOLVED	Yes	SEVERE	POSSIBLE	NOT APPLICABLE	No	Yes	Yes/No
				4	FUP	0		サイトメガロウイルス感染	CYTOMEGALOVIRAL INFECTIONS	76	10	RECOVERED/RESOLVED	No	MILD	POSSIBLE	NOT APPLICABLE	No	No	Yes/No
				5	FUP	0		鼻咽頭炎	COMMON COLD	112	16	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No
		812503	3[redacted]/ M	1	SCR	-		潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	-	35	RECOVERED/RESOLVED	Yes	SEVERE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
		812509	4[redacted]/ M	1	FUP	0		潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	50	31	RECOVERED/RESOLVED	Yes	MODERATE	POSSIBLE	NOT APPLICABLE	No	Yes	No/No
		812701	6[redacted]/ M	1	IND	200		痔核	EXTERNAL HAEMORRHOIDS	3	-	RECOVERING/RESOLVING	No	MILD	DOUBTFUL	DOSE NOT CHANGED	No	Yes	No/No
				2	IND	200		背部痛	LUMBAGO	5	18	RECOVERED/RESOLVED	No	MILD	DOUBTFUL	DOSE NOT CHANGED	No	No	No/No
				3	IND	100		サイトメガロウイルス性大腸炎	CYTOMEGALOVIRUS COLITIS SUSPICION	29	19	RECOVERED/RESOLVED	Yes	MODERATE	POSSIBLE	DRUG WITHDRAWN	No	Yes	Yes/No
				4	FUP	0		ヘモグロビン減少	HAEMOGLOBIN DECREASED	41	5	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				5	FUP	0		背部痛	LUMBAGO	78	15	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				6	FUP	0		血中マグネシウム減少	MAGNESIUM LOW	59	-	RECOVERING/RESOLVING	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No

表 2.7.6.5-9 重篤な有害事象を発現した症例の一覧（続き）

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
				7	FUP	0		廃用症候群	DISUSE SYNDROME	65	3	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
				8	FUP	0		過敏性腸症候群	IRRITABLE BOWEL SYNDROME	92	-	NOT RECOVERED/NOT RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
		812901	3[redacted]/F	1	SCR	-		潰瘍性大腸炎	UC AGGRAVATED	-	3	RECOVERED/RESOLVED	Yes	MODERATE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No

[a] SCR: screening phase, IND: induction phase, MAIN: maintenance phase, FUP: follow-up phase
Note: Adverse events were coded using MedDRA Version 18.1.

[LSAE_PMDA.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW68\RE_NDAJPKK\LSAE_PMDA.sas] 12MAY2016, 14:50

以下に，ゴリムマブの投与開始後に本試験で重篤な有害事象を発現した症例のうち，重篤な有害事象により治験薬投与を中止した症例及び治験担当医師により重篤な有害事象が感染症と判断された症例の詳細を示す。なお，本試験で死亡例はなかった。

(1) ランダム割付けされた被験者

a) プラセボ群

被験者識別コード：810703

■ **REASON FOR NARRATIVE SELECTION**

Subject has at least one SAE

■ **Demographics and Baseline Characteristics**

☐ Country: JPN

☐ Race: Asian

☐ Age (yrs): 3[redacted] ☐ Sex: M ☐ Planned treatment arm: Golimumab (open) - placebo (double blind) ☐ Baseline height (cm): 168.5 ☐ Baseline weight (kg): 57.9 ☐ Baseline bmi (kg/m^2): 20.4

■ **Disposition Information**

☐ End of induction/maintenance phase: 10mar2014 Discontinued Due to Adverse Event

☐ End of follow-up period: 03jul2014 Completed

■ **Fatal Adverse Events**

No Fatal Adverse Events reported

■ **Serious Adverse Events**

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
脳梗塞 (Cerebral infarction)	10mar14 21mar14	54 12	Y Moderate	Possible Drug withdrawn	Recovered/resolved

■ **Adverse Events Leading To Permanent Withdrawal**

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication	Outcome
脳梗塞 (Cerebral infarction)	10mar14 21mar14	54 12	Y	Y Moderate	Possible	Recovered/resolved

■ Other Adverse Events

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
鼻咽頭炎 (Common cold)	25feb14 09mar14	41 13	Y	N Mild	Not related Dose not changed	Recovered/resolved
齲歯 (Dental caries)	31jan14 03jul14	16 154	Y	N Mild	Not related Dose not changed	Recovered/resolved
潰瘍性大腸炎 (Ulcerative colitis aggravated)	19mar14 20apr14	63 33	Y	N Mild	Not related Not applicable	Recovered/resolved
脳梗塞 (Cerebral infarction)	04mar14 10mar14	48 7	Y	N Moderate	Possible Dose not changed	Recovered/resolved
脳梗塞 (Cerebral infarction)	21mar14 Ongoing	65 -	Y	N Mild	Possible Not applicable	Recovering/resolving

■ Medical History

Category	Verbatim Term
Other	結腸ポリープ

■ Study Medication

Phase	Planned Treatment	Actual Treatment	Dosing Start(Study Day)	Dosing End(Study Day)
Induction	Golimumab	Golimumab	16jan2014 (1)	27feb2014 (43)
Maintenance	Placebo (Double Blind)	Placebo	28feb2014 (44)	28feb2014 (44)

■ Drug History

Category	Medication	Use Period
UC Medication	Azathioprine	used >1 - <=2 years
UC Medication	Corticosteroids (excluding budesonide)	used <=1 year
UC Medication	Mesalamine	used >2 years
Antibiotics	Minocycline, amoxicillin	used <=1 year

■ Concomitant Medication

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
UC med. history (immunomodulators/5-ASA)	(Mesalamine)	13nov2013 (-64)	12dec2013 (-35)	-	2400 mg	daily oral
UC med. history (immunomodulators/5-ASA)	(Mesalamine)	13dec2013 (-34)	-	-	3600 mg	daily oral

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
UC medication history (other)	Clostridium butyricum combined drug	13nov2013 (-64)	-	-	6 tablet	daily oral
Concomitant therapy	(Colon polypectomy)	09jan2014 (-7)	09jan2014 (-7)	Concomitant disease	-	qd
Concomitant therapy	(Occupational therapy)	10mar2014 (54)	28apr2014 (103)	Adverse event	-	prn
Concomitant therapy	(Physiotherapy)	10mar2014 (54)	28apr2014 (103)	Adverse event	-	prn
Concomitant therapy	(Speech language hearing therapy)	10mar2014 (54)	17mar2014 (61)	Adverse event	-	prn
Concomitant therapy	(Treatment of dental caries)	31jan2014 (16)	30apr2014 (105)	Adverse event	-	prn
Concomitant therapy	Acetaminophen	15mar2014 (59)	15mar2014 (59)	Adverse event	300 mg	qd oral
Concomitant therapy	Acetaminophen	01apr2014 (76)	ongoing	Adverse event	300 mg	prn oral
Concomitant therapy	Acetated ringer	10mar2014 (54)	17mar2014 (61)	Adverse event	500-1500 ml	daily intravenous drip
Concomitant therapy	Aspirin	10mar2014 (54)	ongoing	Prophylaxis of recurrent cerebral infarction	100 mg	daily oral
Concomitant therapy	Barium sulfate	12mar2014 (56)	12mar2014 (56)	Videofluoroscopic examination of swallowing	200 g	daily oral
Concomitant therapy	Clostridium butyricum combined drug	prior to IC	20may2014 (125)	Ulcerative colitis	2 tablet	tid oral
Concomitant therapy	Clostridium butyricum combined drug	02jun2014 (138)	ongoing	Ulcerative colitis	2 tablet	tid oral
Concomitant therapy	D-sorbitol	12mar2014 (56)	12mar2014 (56)	Prevention of the constipation after taking bariconc mx	20 ml	daily oral
Concomitant therapy	Dimeticone	09jan2014 (-7)	09jan2014 (-7)	Endoscopy large bowel	240 mg	qd oral
Concomitant therapy	Esomeprazole magnesium hydrate	10mar2014 (54)	ongoing	Prevention of ulcers	10 mg	daily oral
Concomitant therapy	Flumazenil	09jan2014 (-7)	09jan2014 (-7)	Endoscopy large bowel	0.25 mg	daily intravenous
Concomitant therapy	Flunitrazepam	09jan2014 (-7)	09jan2014 (-7)	Endoscopy large bowel	0.5 mg	daily intravenous
Concomitant therapy	Gadodiamide hydrate	17mar2014 (61)	17mar2014 (61)	Mri and mra	10 ml	daily intravenous
Concomitant therapy	Glycerin	28feb2014 (44)	28feb2014 (44)	Endoscopy large bowel	150 ml	qd topical
Concomitant therapy	Initiation medium	10mar2014 (54)	10mar2014 (54)	Adverse event	500 ml	daily intravenous drip
Concomitant therapy	Loxoprofen sodium hydrate	08feb2014 (24)	08feb2014 (24)	Adverse event	60 mg	qd oral
Concomitant therapy	Mesalazine	prior to IC	20may2014 (125)	Ulcerative colitis	1200 mg	tid oral
Concomitant therapy	Mesalazine	02jun2014 (138)	ongoing	Ulcerative colitis	1200 mg	tid oral

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Ozagrel sodium	10mar2014 (54)	17mar2014 (61)	Adverse event	80-160 mg	daily intravenous drip
Concomitant therapy	Prednisolone	20mar2014 (64)	31mar2014 (75)	Adverse event	30 mg	daily oral
Concomitant therapy	Prednisolone	01apr2014 (76)	05apr2014 (80)	Adverse event	20 mg	daily oral
Concomitant therapy	Prednisolone	06apr2014 (81)	10apr2014 (85)	Adverse event	15 mg	daily oral
Concomitant therapy	Prednisolone	11apr2014 (86)	15apr2014 (90)	Adverse event	10 mg	daily oral
Concomitant therapy	Prednisolone	16apr2014 (91)	20apr2014 (95)	Adverse event	5 mg	daily oral
Concomitant therapy	Sodium picosulfate hydrate	08jan2014 (-8)	08jan2014 (-8)	Endoscopy large bowel	10 ml	qd oral
Concomitant therapy	Sodium/potassium combined drug	09jan2014 (-7)	09jan2014 (-7)	Endoscopy large bowel	137.155 g	qd oral
Concomitant therapy	Thiamine disulfide phosphate/b6/b12 combined drug	12mar2014 (56)	14mar2014 (58)	Vitamin supplementation	1 other	daily intravenous drip
UC surgeries/procedures	(Biopsy)	28feb2014 (44)	-	Ulcerative colitis	-	-

被験者識別コード：811701

■ **REASON FOR NARRATIVE SELECTION**

Subject has at least one SAE

■ **Demographics and Baseline Characteristics**

☐ Country: JPN

☐ Race: Asian

☐ Age (yrs): 3[redacted] ☐ Sex: F ☐ Planned treatment arm: Golimumab (open) - placebo (double blind) ☐ Baseline height (cm): 155.4 ☐ Baseline weight (kg): 58.4 ☐ Baseline bmi (kg/m^2): 24.2

■ **Disposition Information**

☐ End of induction/maintenance phase: 11mar2014 Discontinued Due to Lack of Efficacy

☐ End of follow-up period: 10jun2014 Completed

■ **Fatal Adverse Events**

No Fatal Adverse Events reported

■ Serious Adverse Events

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
喉頭炎 (Acute subglottic laryngitis)	04apr14 08apr14	262 5	Y Moderate	Possible Not applicable	Recovered/resolved

■ Adverse Events Leading To Permanent Withdrawal

No Adverse Events Leading To Permanent Withdrawal reported

■ Other Adverse Events

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
体重増加 (Weight gain)	17jul13 04apr14	1 262	Y	N Mild	Not related Dose not changed	Recovered/resolved
鼻咽頭炎 (Common cold)	18mar14 01apr14	245 15	Y	N Mild	Not related Not applicable	Recovered/resolved
喉頭炎 (Acute subglottic laryngitis)	08apr14 23may14	266 46	Y	N Moderate	Possible Not applicable	Recovered/resolved
全身性浮腫 (Generalized edema)	02aug13 12nov13	17 103	Y	N Mild	Not related Dose not changed	Recovered/resolved

■ Medical History

Category	Verbatim Term
Other	満月様顔貌

■ Study Medication

Phase	Planned Treatment	Actual Treatment	Dosing Start(Study Day)	Dosing End(Study Day)
Induction	Golimumab	Golimumab	17jul2013 (1)	22aug2013 (37)
Maintenance	Placebo (Double Blind)	Placebo	23aug2013 (38)	08jan2014 (176)
Maintenance	Placebo (Double Blind)	Golimumab(Dose Adj.)	09jan2014 (177)	04mar2014 (231)

■ Drug History

Category	Medication	Use Period
UC Medication	Corticosteroids (excluding budesonide)	used <=1 year
UC Medication	Mesalamine	used <=1 year

■ Concomitant Medication

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
UC med. history (immunomodulators/5-ASA)	(Mesalamine)	12mar2013 (-127)	-	-	3600 mg	daily oral
UC med. history (immunomodulators/5-ASA)	(Mesalamine)	02may2013 (-76)	20jun2013 (-27)	-	1 g	daily rectal
UC medication history (corticosteroids)	(Prednisolone)	31may2013 (-47)	13jun2013 (-34)	-	3 mg	daily oral
UC medication history (corticosteroids)	(Prednisolone)	21jun2013 (-26)	-	-	20 mg	daily oral
Concomitant therapy	Acetaminophen	25mar2014 (252)	25mar2014 (252)	Adverse event	600 mg	daily oral
Concomitant therapy	Adalimumab(genetical recombination)	25apr2014 (283)	25apr2014 (283)	Ulcerative colitis	160 mg	daily subcutaneous
Concomitant therapy	Adalimumab(genetical recombination)	09may2014 (297)	09may2014 (297)	Ulcerative colitis	80 mg	daily subcutaneous
Concomitant therapy	Clarithromycin	18apr2014 (276)	24apr2014 (282)	Adverse event	400 mg	daily oral
Concomitant therapy	Esomeprazole magnesium hydrate	prior to IC	09dec2013 (146)	Gastric mucosal protection	20 mg	daily oral
Concomitant therapy	Esomeprazole magnesium hydrate	04apr2014 (262)	24apr2014 (282)	Mucosal protection	20 mg	daily oral
Concomitant therapy	Glycerin	11mar2014 (238)	11mar2014 (238)	Colonoscopy preparation	120 ml	daily topical
Concomitant therapy	Hydrocortisone sodium succinate	04apr2014 (262)	08apr2014 (266)	Adverse event	300 mg	daily intravenous drip
Concomitant therapy	Levofloxacin hydrate	09apr2014 (267)	17apr2014 (275)	Adverse event	500 mg	daily oral
Concomitant therapy	Magnesium citrate	05jul2013 (-12)	05jul2013 (-12)	Preparation	100 g	daily oral
Concomitant therapy	Magnesium citrate	09jan2014 (177)	09jan2014 (177)	Colonoscopy preparation	100 g	daily oral
Concomitant therapy	Magnesium oxide	09jul2013 (-8)	11jul2013 (-6)	Constipation prophylactic	500 mg	daily oral
Concomitant therapy	Mesalazine	prior to IC	08may2014 (296)	Ulcerative colitis	3.6 g	daily oral
Concomitant therapy	Mesalazine	09may2014 (297)	ongoing	Ulcerative colitis	2.4 g	daily oral
Concomitant therapy	Mixed amino acid/carbohydrate/electrolyte/vitamin combined drug	07apr2014 (265)	07apr2014 (265)	Adverse event	1000 ml	daily intravenous drip
Concomitant therapy	Olopatadine hydrochloride	11apr2014 (269)	22may2014 (310)	Adverse event	10 mg	daily oral

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Prednisolone	prior to IC	08aug2013 (23)	Ulcerative colitis	20 mg	daily oral
Concomitant therapy	Prednisolone	09aug2013 (24)	22aug2013 (37)	Ulcerative colitis	15 mg	daily oral
Concomitant therapy	Prednisolone	23aug2013 (38)	06sep2013 (52)	Ulcerative colitis	12.5 mg	daily oral
Concomitant therapy	Prednisolone	07sep2013 (53)	19sep2013 (65)	Ulcerative colitis	10 mg	daily oral
Concomitant therapy	Prednisolone	20sep2013 (66)	14oct2013 (90)	Ulcerative colitis	7.5 mg	daily oral
Concomitant therapy	Prednisolone	15oct2013 (91)	11nov2013 (118)	Ulcerative colitis	5 mg	daily oral
Concomitant therapy	Prednisolone	12nov2013 (119)	09dec2013 (146)	Ulcerative colitis	2.5 mg	daily oral
Concomitant therapy	Prednisolone	11apr2014 (269)	17apr2014 (275)	Adverse event	30 mg	daily oral
Concomitant therapy	Scopolamine butylbromide	09jan2014 (177)	09jan2014 (177)	Preparation	20 mg	daily intramuscular
Concomitant therapy	Sodium picosulfate hydrate	05jul2013 (-12)	05jul2013 (-12)	Preparation	10 ml	daily oral
Concomitant therapy	Sodium picosulfate hydrate	23aug2013 (38)	23aug2013 (38)	Colonoscopy preparation	10 ml	daily oral
Concomitant therapy	Sodium picosulfate hydrate	09jan2014 (177)	09jan2014 (177)	Colonoscopy preparation	10 ml	daily oral
Concomitant therapy	Sodium/potassium combined drug	23aug2013 (38)	23aug2013 (38)	Colonoscopy preparation	137.155 g	daily oral
Concomitant therapy	Sulbactam sodium/ampicillin sodium	04apr2014 (262)	04apr2014 (262)	Adverse event	3.0 g	daily intravenous drip
Concomitant therapy	Sulbactam sodium/ampicillin sodium	05apr2014 (263)	07apr2014 (265)	Adverse event	4.5 g	daily intravenous drip
UC surgeries/procedures	(Other surgery)	20mar2014 (247)	-	Therapy for primary disease.	-	-
UC surgeries/procedures	(Other surgery)	25mar2014 (252)	-	Therapy for primary disease.	-	-
UC surgeries/procedures	(Other surgery)	28mar2014 (255)	-	Therapy for primary disease.	-	-
UC surgeries/procedures	(Other surgery)	01apr2014 (259)	-	Therapy for primary disease.	-	-
UC surgeries/procedures	(Other surgery)	08apr2014 (266)	-	Therapy for primary disease.	-	-
UC surgeries/procedures	(Other surgery)	11apr2014 (269)	-	Therapy for primary disease.	-	-
UC surgeries/procedures	(Other surgery)	15apr2014 (273)	-	Therapy for primary disease.	-	-

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
UC surgeries/procedures	(Other surgery)	18apr2014 (276)	-	Therapy for primary disease.	-	-
UC surgeries/procedures	(Other surgery)	22apr2014 (280)	-	Therapy for primary disease.	-	-
UC surgeries/procedures	(Other surgery)	25apr2014 (283)	-	Therapy for primary disease.	-	-

b) 100 mg 群

該当せず

(2) ランダム割付けされなかった被験者

被験者識別コード：810109

■ **REASON FOR NARRATIVE SELECTION**

Subject has at least one SAE

■ **Demographics and Baseline Characteristics**

☐ Country: JPN

☐ Race: Asian

☐ Age (yrs): 3[redacted] ☐ Sex: M ☐ Planned treatment arm: Golimumab (open) - golimumab (open) ☐ Baseline height (cm): 167.5 ☐ Baseline weight (kg): 59.4 ☐ Baseline bmi (kg/m^2): 21.2

■ **Disposition Information**

☐ End of induction/maintenance phase: 21apr2015 Completed

☐ End of follow-up period: 28jul2015 Completed

■ **Fatal Adverse Events**

No Fatal Adverse Events reported

■ **Serious Adverse Events**

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
帯状疱疹 (Herpes zoster(right forehead, right periocular))	16jul14 23jul14	142 8	Y Severe	Possible Dose not changed	Recovered/resolved

■ **Adverse Events Leading To Permanent Withdrawal**

No Adverse Events Leading To Permanent Withdrawal reported

■ **Other Adverse Events**

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
帯状疱疹 (Herpes zoster(right forehead, right periocular))	23jul14 26aug14	149 35	Y	N Moderate	Possible Dose not changed	Recovered/resolved
帯状疱疹 (Herpes zoster(right forehead, right periocular))	13jul14 16jul14	139 4	Y	N Moderate	Possible Dose not changed	Recovered/resolved

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
肛門周囲痛 (Anal pain)	03apr14 11nov14	38 223	Y	N Mild	Doubtful Dose not changed	Recovered/resolved
結膜炎 (Conjunctivitis)	10jul14 10aug14	136 32	Y	N Mild	Doubtful Dose not changed	Recovered/resolved
上気道感染 (Acute upper respiratory infection)	04mar14 05mar14	8 2	Y	N Mild	Doubtful Dose not changed	Recovered/resolved

■ Medical History

Category	Verbatim Term
Related UC	アフタ性口内炎
Other	アレルギー性鼻炎
Other	右足背部のしびれ感
Other	強膜炎

■ Study Medication

Phase	Planned Treatment	Actual Treatment	Dosing Start(Study Day)	Dosing End(Study Day)
Induction	Golimumab	Golimumab	25feb2014 (1)	02apr2014 (37)
Maintenance	Golimumab	Golimumab	03apr2014 (38)	07apr2015 (407)

■ Drug History

Category	Medication	Use Period
UC Medication	Corticosteroids (excluding budesonide)	used <=1 year
UC Medication	Mesalamine	used >2 years

■ Concomitant Medication

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
UC med. history (immunomodulators/5-ASA)	(Mesalamine)	12apr2011 (-1050)	-	-	3600 mg	daily oral
UC med. history (immunomodulators/5-ASA)	(Mesalamine)	27aug2013 (-182)	21jan2014 (-35)	-	1 g	other rectal
Concomitant therapy	Acetaminophen	04mar2014 (8)	05mar2014 (9)	Adverse event	200 mg	bid oral
Concomitant therapy	Aciclovir	16jul2014 (142)	22jul2014 (148)	Adverse event	250 mg	tid intravenous drip
Concomitant therapy	An extract obtained from inflammatory rabbit skin inoculated by vaccinia virus	16jul2014 (142)	22jul2014 (148)	Adverse event	3.6 units	qd intravenous drip

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Bepotastine besilate	04mar2014 (8)	05mar2014 (9)	Adverse event	10 mg	bid oral
Concomitant therapy	Diazepam	13feb2014 (-12)	13feb2014 (-12)	Colonoscopy	5 mg	qd intravenous
Concomitant therapy	Diazepam	03apr2014 (38)	03apr2014 (38)	Colonoscopy	5 mg	qd intravenous
Concomitant therapy	Diazepam	28may2014 (93)	28may2014 (93)	Colonoscopy	5 mg	qd intravenous
Concomitant therapy	Diazepam	28oct2014 (246)	28oct2014 (246)	Colonscopy	5 mg	qd intravenous
Concomitant therapy	Diazepam	21apr2015 (421)	21apr2015 (421)	Colonoscopy	5 mg	qd intravenous
Concomitant therapy	Dimethyl isopropylazulene	03apr2014 (38)	29jul2014 (155)	Adverse event	-	prn topical
Concomitant therapy	Dimeticone	13feb2014 (-12)	13feb2014 (-12)	Colonoscopy	10 ml	qd oral
Concomitant therapy	Dimeticone	03apr2014 (38)	03apr2014 (38)	Colonoscopy	10 ml	qd oral
Concomitant therapy	Dimeticone	28may2014 (93)	28may2014 (93)	Colonoscopy	10 ml	qd oral
Concomitant therapy	Dimeticone	28oct2014 (246)	28oct2014 (246)	Colonscopy	10 ml	qd oral
Concomitant therapy	Dimeticone	21apr2015 (421)	21apr2015 (421)	Colonoscopy	10 ml	qd oral
Concomitant therapy	Fluorometholone	14jul2014 (140)	16jul2014 (142)	Adverse event	1-2 drops	prn ophthalmic
Concomitant therapy	Gatifloxacin hydrate	14jul2014 (140)	10aug2014 (167)	Adverse event	1 drops	prn ophthalmic
Concomitant therapy	Gentamicin sulfate	16jul2014 (142)	22jul2014 (148)	Adverse event	-	prn topical
Concomitant therapy	Influenza ha vaccine	18nov2014 (267)	18nov2014 (267)	Influenza prevention	0.5 ml	qd subcutaneous
Concomitant therapy	Loxoprofen sodium hydrate	14jul2014 (140)	16jul2014 (142)	Adverse event	60 mg	tid oral
Concomitant therapy	Mecobalamin	14jul2014 (140)	16jul2014 (142)	Adverse event	500 mcg	tid oral
Concomitant therapy	Mecobalamin	16jul2014 (142)	04aug2014 (161)	Adverse event	500 mcg	tid oral
Concomitant therapy	Mesalazine	prior to IC	ongoing	Ulcerative colitis	1200 mg	tid oral
Concomitant therapy	Naproxen	16jul2014 (142)	21jul2014 (147)	Adverse event	100 mg	tid oral
Concomitant therapy	Pethidine hydrochloride	13feb2014 (-12)	13feb2014 (-12)	Colonoscopy	35 mg	qd intravenous
Concomitant therapy	Pethidine hydrochloride	03apr2014 (38)	03apr2014 (38)	Colonoscopy	35 mg	qd intravenous
Concomitant therapy	Pethidine hydrochloride	28may2014 (93)	28may2014 (93)	Colonoscopy	35 mg	qd intravenous
Concomitant therapy	Pethidine hydrochloride	28oct2014 (246)	28oct2014 (246)	Colonscopy	35 mg	qd intravenous
Concomitant therapy	Pethidine hydrochloride	21apr2015 (421)	21apr2015 (421)	Colonoscopy	35 mg	qd intravenous
Concomitant therapy	Pranlukast hydrate	04mar2014 (8)	05mar2014 (9)	Adverse event	225 mg	bid oral
Concomitant therapy	Rebamipide	14jul2014 (140)	16jul2014 (142)	Adverse event	100 mg	tid oral
Concomitant therapy	Scopolamine butylbromide	13feb2014 (-12)	13feb2014 (-12)	Colonoscopy	20 mg	qd intravenous
Concomitant therapy	Scopolamine butylbromide	03apr2014 (38)	03apr2014 (38)	Colonoscopy	20 mg	qd intravenous

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Scopolamine butylbromide	28may2014 (93)	28may2014 (93)	Colonoscopy	20 mg	qd intravenous
Concomitant therapy	Scopolamine butylbromide	28oct2014 (246)	28oct2014 (246)	Colonscopy	20 mg	qd intravenous
Concomitant therapy	Scopolamine butylbromide	21apr2015 (421)	21apr2015 (421)	Colonoscopy	20 mg	qd intravenous
Concomitant therapy	Sodium hyaluronate	17jul2014 (143)	10aug2014 (167)	Adverse event	1 drops	qid ophthalmic
Concomitant therapy	Sodium/potassium combined drug	13feb2014 (-12)	13feb2014 (-12)	Colonoscopy	137.155 g	qd oral
Concomitant therapy	Sodium/potassium combined drug	03apr2014 (38)	03apr2014 (38)	Colonoscopy	137.155 g	qd oral
Concomitant therapy	Sodium/potassium combined drug	28may2014 (93)	28may2014 (93)	Colonoscopy	137.155 g	qd oral
Concomitant therapy	Sodium/potassium combined drug	28oct2014 (246)	28oct2014 (246)	Colonscopy	137.155 g	qd oral
Concomitant therapy	Sodium/potassium combined drug	21apr2015 (421)	21apr2015 (421)	Colonoscopy	137.155 g	qd oral
Concomitant therapy	Valaciclovir hydrochloride	14jul2014 (140)	16jul2014 (142)	Adverse event	1000 mg	tid oral
Concomitant therapy	Vidarabine	14jul2014 (140)	16jul2014 (142)	Adverse event	other	prn topical
Concomitant therapy	Zanamivir hydrate	04mar2014 (8)	05mar2014 (9)	Influenza prevention	10 mg	qd respiratory (inhalation)

被験者識別コード：813705

■ **REASON FOR NARRATIVE SELECTION**

Subject has at least one SAE

■ **Demographics and Baseline Characteristics**

☐ Country: JPN

☐ Race: Asian

☐ Age (yrs): 7[redacted] ☐ Sex: M ☐ Planned treatment arm: Golimumab (open) - golimumab (open) ☐ Baseline height (cm): 159 ☐ Baseline weight (kg): 57.8 ☐ Baseline bmi (kg/m^2): 22.9

■ Disposition Information

□ End of induction/maintenance phase: 17jul2014 Discontinued Due to Lack of Efficacy

□ End of follow-up period: 17oct2014 Completed

■ Fatal Adverse Events

No Fatal Adverse Events reported

■ Serious Adverse Events

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
咽頭炎 (Pharyngitis)	30jul14 14aug14	101 16	Y Moderate	Possible Not applicable	Recovered/resolved
潰瘍性大腸炎 (Worsening of ulcerative colitis)	30jul14 06aug14	101 8	Y Moderate	Not related Not applicable	Recovered/resolved

■ Adverse Events Leading To Permanent Withdrawal

No Adverse Events Leading To Permanent Withdrawal reported

■ Other Adverse Events

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
上気道の炎症 (Upper respiratory inflammation)	28may14 02jul14	38 36	Y	N Mild	Possible Dose not changed	Recovered/resolved
咽頭炎 (Pharyngitis)	14aug14 Ongoing	116 -	Y	N Mild	Not related Not applicable	Recovering/resolving
咽頭炎 (Pharyngitis)	16jul14 30jul14	87 15	Y	N Mild	Possible Dose not changed	Recovered/resolved
膿痂疹 (Impetigo(back of thigh))	31jul14 14sep14	102 46	Y	N Mild	Not related Not applicable	Recovered/resolved
治癒不良 (Delay of wound healing(back of thigh))	31jul14 14sep14	102 46	Y	N Mild	Doubtful Not applicable	Recovered/resolved

■ Medical History

Category	Verbatim Term
Other	慢性胃炎
Other	頭痛

Category	Verbatim Term
Other	高脂血症
Other	不眠症
Other	下肢の倦怠感
Other	心膜炎
Other	老人性難聴
Other	副鼻腔炎

■ Study Medication

Phase	Planned Treatment	Actual Treatment	Dosing Start(Study Day)	Dosing End(Study Day)
Induction	Golimumab	Golimumab	21apr2014 (1)	27may2014 (37)
Maintenance	Golimumab	Golimumab	28may2014 (38)	02jul2014 (73)

■ Drug History

Category	Medication	Use Period
UC Medication	6 - mercaptopurine	used <=1 year
UC Medication	Corticosteroids (excluding budesonide)	used <=1 year
UC Medication	Mesalamine	used <=1 year
Antibiotics	Salfamethoxazole trimetoprim	used <=1 year

■ Concomitant Medication

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
UC med. history (immunomodulators/5-ASA)	(6 - mercaptopurine)	02oct2013 (-201)	-	-	20 mg	daily oral
UC medication history (corticosteroids)	(Prednisolone)	26feb2014 (-54)	-	-	10 mg	daily oral
UC medication history (other)	Clostridium butyricum	16oct2013 (-187)	-	-	60 mg	daily oral
UC medication history (other)	Dried ferrous sulfate	04sep2013 (-229)	-	-	105 mg	daily oral
Concomitant therapy	(Incision and drainage)	31jul2014 (102)	31jul2014 (102)	Adverse event	-	qd
Concomitant therapy	Acetated ringer's solution(with glucose)	30jul2014 (101)	05aug2014 (107)	Adverse event	500-1000 ml	daily intravenous
Concomitant therapy	Ambroxol hydrochloride	17jul2014 (88)	21jul2014 (92)	Adverse event	45 mg	daily oral
Concomitant therapy	Amoxicillin hydrate	31jul2014 (102)	06aug2014 (108)	Adverse event	750 mg	daily oral
Concomitant therapy	Betamethasone sodium phosphate	17jul2014 (88)	01aug2014 (103)	Adverse event	100 ml	qd rectal

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Betamethasone sodium phosphate	06aug2014 (108)	26sep2014 (159)	Ulcerative colitis	100 ml	prn rectal
Concomitant therapy	Carbocisteine	28may2014 (38)	01jun2014 (42)	Adverse event	1500 mg	daily oral
Concomitant therapy	Carbocisteine	25jun2014 (66)	29jun2014 (70)	Adverse event	1500 mg	daily oral
Concomitant therapy	Chikujountanto	04jun2014 (45)	10jun2014 (51)	Adverse event	7.5 g	daily oral
Concomitant therapy	Clarithromycin	17jul2014 (88)	21jul2014 (92)	Adverse event	400 mg	qd oral
Concomitant therapy	Clarithromycin	08sep2014 (141)	12sep2014 (145)	Adverse event	400 mg	daily oral
Concomitant therapy	Clostridium butyricum	prior to IC	ongoing	Ulcerative colitis	60 mg	qd oral
Concomitant therapy	Domiphen bromide	25jun2014 (66)	29jul2014 (100)	Adverse event	0.5 mg	prn topical
Concomitant therapy	Dried ferrous sulfate	prior to IC	ongoing	Ulcerative colitis	105 mg	qd oral
Concomitant therapy	Famotidine	prior to IC	ongoing	Concomitant disease	20 mg	qd oral
Concomitant therapy	Gentamicin sulfate	08sep2014 (141)	14sep2014 (147)	Adverse event	-	daily topical
Concomitant therapy	Glycerin	11apr2014 (-10)	11apr2014 (-10)	Endoscopy	120 ml	qd topical
Concomitant therapy	Glycerin	28may2014 (38)	28may2014 (38)	Endoscopy	120 ml	qd topical
Concomitant therapy	Glycerin	17jul2014 (88)	17jul2014 (88)	Endoscopy	120 ml	qd topical
Concomitant therapy	Ibuprofen	17jul2014 (88)	21jul2014 (92)	Adverse event	600 mg	daily oral
Concomitant therapy	Isoniazid	prior to IC	17jul2014 (88)	Prevention of tuberculosis	300 mg	qd oral
Concomitant therapy	Lactated ringers solution	30jul2014 (101)	30jul2014 (101)	Adverse event	500 ml	daily intravenous
Concomitant therapy	Levofloxacin hydrate	28may2014 (38)	01jun2014 (42)	Adverse event	500 mg	qd oral
Concomitant therapy	Levofloxacin hydrate	25jun2014 (66)	29jun2014 (70)	Adverse event	500 mg	qd oral
Concomitant therapy	Lidocaine hydrochloride	11apr2014 (-10)	11apr2014 (-10)	Endoscopy	1 ml	qd topical
Concomitant therapy	Lidocaine hydrochloride	28may2014 (38)	28may2014 (38)	Endoscopy	1 ml	qd topical
Concomitant therapy	Lidocaine hydrochloride	17jul2014 (88)	17jul2014 (88)	Endoscopy	1 ml	qd topical
Concomitant therapy	Lidocaine hydrochloride	31jul2014 (102)	06aug2014 (108)	As a lubricant during enema	30 ml	daily topical
Concomitant therapy	Lidocaine hydrochloride	06aug2014 (108)	ongoing	Lubricant enema	-	prn topical
Concomitant therapy	Maintenance medium	30jul2014 (101)	05aug2014 (107)	Adverse event	500-1000 ml	daily intravenous
Concomitant therapy	Mercaptopurine hydrate	prior to IC	29aug2014 (131)	Ulcerative colitis	20 mg	qd oral
Concomitant therapy	Mercaptopurine hydrate	30aug2014 (132)	ongoing	Ulcerative colitis	25 mg	daily oral
Concomitant therapy	Non-pyrine cold preparation	25jun2014 (66)	29jun2014 (70)	Adverse event	3 g	daily oral
Concomitant therapy	Povidone-iodine	25jun2014 (66)	29jul2014 (100)	Adverse event	other	prn topical

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Prednisolone	prior to IC	09may2014 (19)	Ulcerative colitis	10 mg	qd oral
Concomitant therapy	Prednisolone	10may2014 (20)	29aug2014 (131)	Ulcerative colitis	5 mg	daily oral
Concomitant therapy	Prednisolone	29aug2014 (131)	ongoing	Ulcerative colitis	2 g	prn rectal
Concomitant therapy	Prednisolone	30aug2014 (132)	19sep2014 (152)	Ulcerative colitis	4 mg	daily oral
Concomitant therapy	Prednisolone	20sep2014 (153)	ongoing	Ulcerative colitis	3 mg	daily oral
Concomitant therapy	Pyridoxal phosphate hydrate	prior to IC	17jul2014 (88)	Prevention of peripheral nerve by iscotin tablets	30 mg	qd oral
Concomitant therapy	Rebamipide	prior to IC	ongoing	Concomitant disease,prevention of nausea by fero-gladumet	100 mg	daily oral
Concomitant therapy	Rosuvastatin calcium	prior to IC	ongoing	Concomitant disease	2.5 mg	qd oral
Concomitant therapy	Sucralfate hydrate	29aug2014 (131)	ongoing	Prevention of proctitis by predonisolone	1 g	prn rectal
Concomitant therapy	Sulfadiazine silver	31jul2014 (102)	06aug2014 (108)	Adverse event	-	prn topical
Concomitant therapy	Tranexamic acid	17jul2014 (88)	21jul2014 (92)	Adverse event	750 mg	daily oral
UC surgeries/procedures	(Biopsy)	11apr2014 (-10)	-	Ulcerative colitis	-	-

被験者識別コード：814301

■ **REASON FOR NARRATIVE SELECTION**

Subject has at least one SAE

■ **Demographics and Baseline Characteristics**

☐ Country: JPN

☐ Race: Asian

☐ Age (yrs): 7[redacted] ☐ Sex: M ☐ Planned treatment arm: Golimumab (open) - golimumab (open) ☐ Baseline height (cm): 160.9 ☐ Baseline weight (kg): 66.6 ☐ Baseline bmi (kg/m^2): 25.7

■ **Disposition Information**

☐ End of induction/maintenance phase: 05mar2014 Discontinued Due to Lack of Efficacy

☐ End of follow-up period: 04jun2014 Completed

■ Fatal Adverse Events

No Fatal Adverse Events reported

■ Serious Adverse Events

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
潰瘍性大腸炎 (Worsening of uc)	06mar14 16apr14	72 42	Y Moderate	Not related Not applicable	Recovered/resolved
帯状疱疹 (Shingles)	01may14 08may14	128 8	Y Moderate	Not related Not applicable	Recovered/resolved

■ Adverse Events Leading To Permanent Withdrawal

No Adverse Events Leading To Permanent Withdrawal reported

■ Other Adverse Events

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
ヘルペス後神経痛 (Postherpetic neuralgia)	15may14 Ongoing	142 -	Y	N Mild	Not related Not applicable	Not recovered/not resolved
四肢痛 (Left calf ache)	11mar14 09apr14	77 30	Y	N Mild	Not related Not applicable	Recovered/resolved
眼部単純ヘルペス (Herpetic keratitis)	30apr14 14may14	127 15	Y	N Mild	Not related Not applicable	Recovered/resolved
鼻咽頭炎 (Common cold)	07mar14 12mar14	73 6	Y	N Mild	Not related Not applicable	Recovered/resolved
鼻咽頭炎 (Common cold)	18feb14 01mar14	56 12	Y	N Mild	Not related Dose not changed	Recovered/resolved
鼻咽頭炎 (Common cold)	30jan14 30jan14	37 1	Y	N Mild	Not related Dose not changed	Recovered/resolved
鼻咽頭炎 (Common cold)	17apr14 30apr14	114 14	Y	N Mild	Not related Not applicable	Recovered/resolved
鼻咽頭炎 (Common cold)	24jan14 24jan14	31 1	Y	N Mild	Not related Dose not changed	Recovered/resolved
帯状疱疹 (Shingles)	08may14 15may14	135 8	Y	N Moderate	Not related Not applicable	Recovered/resolved

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
痔核 (Worsening of hemorrhoids)	14mar14 21apr14	80 39	Y	N Mild	Not related Not applicable	Recovered/resolved
歯髄炎 (Pulpitis)	21dec13 28dec13	-4 8	-	N Mild	Not related Not applicable	Recovered/resolved
潰瘍性大腸炎 (Worsening of uc)	16apr14 14may14	113 29	Y	N Moderate	Not related Not applicable	Recovered/resolved
潰瘍性大腸炎 (Worsening of uc)	21feb14 06mar14	59 14	Y	N Moderate	Not related Dose not changed	Recovered/resolved
背部痛 (Lumbago)	05may14 09may14	132 5	Y	N Mild	Not related Not applicable	Recovered/resolved
上腹部痛 (Epigastralgia)	03may14 03may14	130 1	Y	N Mild	Not related Not applicable	Recovered/resolved
上腹部痛 (Gastric pain)	21dec13 25dec13	-4 5	-	N Mild	Not related Not applicable	Recovered/resolved

■ Medical History

Category	Verbatim Term
Other	痔核
Other	高脂血症
Other	高血圧
Other	心筋梗塞
Other	肩こり
Other	破傷風
Other	トリコフィトン感染症

■ Study Medication

Phase	Planned Treatment	Actual Treatment	Dosing Start(Study Day)	Dosing End(Study Day)
Induction	Golimumab	Golimumab	25dec2013 (1)	04feb2014 (42)
Maintenance	Golimumab	Golimumab	05feb2014 (43)	05feb2014 (43)

■ Drug History

Category	Medication	Use Period
UC Medication	Azathioprine	used >1 - <=2 years
UC Medication	Mesalamine	used >1 - <=2 years

■ Concomitant Medication

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
UC med. history (immunomodulators/5-ASA)	(Azathioprine)	28jun2012 (-545)	-	-	50 mg	daily oral
UC med. history (immunomodulators/5-ASA)	(Mesalamine)	06jun2012 (-567)	-	-	3600 mg	daily oral
UC medication history (other)	Clostridium butyricum combined drug	06jun2012 (-567)	-	-	9 tablet	daily oral
UC medication history (other)	Ferrous fumarate	04dec2013 (-21)	-	-	1 tablet	daily oral
Concomitant therapy	Acetaminophen	02may2014 (129)	14may2014 (141)	Adverse event	400 mg	prn oral
Concomitant therapy	Acetaminophen	15may2014 (142)	28may2014 (155)	Adverse event	1800 mg	daily oral
Concomitant therapy	Acetaminophen	29may2014 (156)	ongoing	Adverse event	2400 mg	daily oral
Concomitant therapy	Aciclovir	30apr2014 (127)	14may2014 (141)	Adverse event	-	fid ophthalmic
Concomitant therapy	Aciclovir	01may2014 (128)	07may2014 (134)	Adverse event	250 mg	tid intravenous drip
Concomitant therapy	Amlodipine besilate	25jan2014 (32)	ongoing	Concomitant disease	5 mg	qd oral
Concomitant therapy	An extract obtained from inflammatory rabbit skin inoculated by vaccinia virus	29may2014 (156)	ongoing	Adverse event	8 units	bid oral
Concomitant therapy	Analgesics, anti-itchings, astrigents and anti-inflammatory agents	prior to IC	ongoing	Concomitant disease	-	prn topical
Concomitant therapy	Antacids	25dec2013 (1)	25dec2013 (1)	Adverse event	other	qd oral
Concomitant therapy	Anti-dermoinfectives	prior to IC	31mar2014 (97)	Concomitant disease	-	prn topical
Concomitant therapy	Aspirin	prior to IC	ongoing	Concomitant disease	100 mg	qd oral
Concomitant therapy	Azathioprine	prior to IC	08apr2014 (105)	Ulcerative colitis	50 mg	qd oral
Concomitant therapy	Candesartan cilexetil/amlodipine besilate combined drug	prior to IC	23jan2014 (30)	Concomitant disease	1 tablet	qd oral
Concomitant therapy	Carbocisteine	26apr2014 (123)	29apr2014 (126)	Adverse event	250 mg	tid oral

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Cefcapene pivoxil hydrochloride hydrate	23apr2014 (120)	26apr2014 (123)	Adverse event	100 mg	tid oral
Concomitant therapy	Cefditoren pivoxil	26apr2014 (123)	29apr2014 (126)	Adverse event	100 mg	tid oral
Concomitant therapy	Clostridium butyricum combined drug	prior to IC	08jan2014 (15)	Ulcerative colitis	9 tablet	daily oral
Concomitant therapy	Clostridium butyricum combined drug	09jan2014 (16)	ongoing	Ulcerative colitis	6 tablet	daily oral
Concomitant therapy	Colibacillus vaccine/hydrocortisone	14mar2014 (80)	26mar2014 (92)	Adverse event	2 g	qd rectal
Concomitant therapy	Colibacillus vaccine/hydrocortisone	27mar2014 (93)	30mar2014 (96)	Adverse event	2 g	bid rectal
Concomitant therapy	Colibacillus vaccine/hydrocortisone	31mar2014 (97)	01apr2014 (98)	Adverse event	2 g	tid rectal
Concomitant therapy	Concentrated human red blood cells	25mar2014 (91)	25mar2014 (91)	Ulcerative colitis	2 units	qd intravenous drip
Concomitant therapy	Felbinac	05may2014 (132)	09may2014 (136)	Adverse event	1 patch	prn topical
Concomitant therapy	Ferrous fumarate	prior to IC	07jan2014 (14)	Ulcerative colitis	100 mg	qd oral
Concomitant therapy	Ferrous fumarate	12mar2014 (78)	23apr2014 (120)	Ulcerative colitis	100 mg	qd oral
Concomitant therapy	Glycerin	19dec2013 (-6)	19dec2013 (-6)	Colonoscopy	120 ml	qd rectal
Concomitant therapy	Glycerin	31jan2014 (38)	31jan2014 (38)	Colonoscopy	120 ml	qd rectal
Concomitant therapy	Glycerin	06mar2014 (72)	06mar2014 (72)	Colonoscopy	240 ml	qd rectal
Concomitant therapy	Ketoconazole	01apr2014 (98)	ongoing	Concomitant disease	-	prn topical
Concomitant therapy	Ketoprofen	11mar2014 (77)	14mar2014 (80)	Adverse event	1 patch	prn topical
Concomitant therapy	Lactated ringer's solution(with glucose)	08mar2014 (74)	18mar2014 (84)	Transfusion	500 ml	qd intravenous drip
Concomitant therapy	Lactated ringers solution	19dec2013 (-6)	19dec2013 (-6)	Colonoscopy	500 ml	qd intravenous drip
Concomitant therapy	Lactated ringers solution	31jan2014 (38)	31jan2014 (38)	Colonoscopy	500 ml	qd intravenous drip
Concomitant therapy	Lansoprazole	prior to IC	08apr2014 (105)	Prevention of gastritis	15 mg	qd oral
Concomitant therapy	Lansoprazole	09apr2014 (106)	ongoing	Prevention of gastritis	15 mg	qd oral

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Lidocaine hydrochloride/adrenaline	24dec2013 (-1)	28dec2013 (4)	Adverse event	1.8 ml	prn topical
Concomitant therapy	Loxoprofen sodium hydrate	23dec2013 (-2)	25dec2013 (1)	Adverse event	60 mg	prn oral
Concomitant therapy	Mecobalamin	29may2014 (156)	ongoing	Adverse event	250 mcg	tid oral
Concomitant therapy	Mesalazine	prior to IC	ongoing	Ulcerative colitis	1200 mg	tid oral
Concomitant therapy	Mixed amino acid/carbohydrate/electrolyte/vitamin combined drug	06mar2014 (72)	18mar2014 (84)	Transfusion	1000 ml	qd intravenous drip
Concomitant therapy	Nafamostat mesilate	10mar2014 (76)	31mar2014 (97)	Anticoagulation	50 mg	tiw intravenous drip
Concomitant therapy	Non-pyrine cold preparation	24jan2014 (31)	01mar2014 (67)	Adverse event	other	prn oral
Concomitant therapy	Non-pyrine cold preparation	08mar2014 (74)	12mar2014 (78)	Adverse event	other	qid oral
Concomitant therapy	Non-pyrine cold preparation	17apr2014 (114)	30apr2014 (127)	Adverse event	other	prn oral
Concomitant therapy	Olmesartan medoxomil	25jan2014 (32)	ongoing	Concomitant disease	20 mg	qd oral
Concomitant therapy	Paraphlebon/senna powder combined drug	01apr2014 (98)	21apr2014 (118)	Adverse event	2 tablet	tid oral
Concomitant therapy	Pethidine hydrochloride	19dec2013 (-6)	19dec2013 (-6)	Colonoscopy	35 mg	qd intravenous
Concomitant therapy	Pethidine hydrochloride	06mar2014 (72)	06mar2014 (72)	Colonoscopy	17.5 mg	qd intravenous
Concomitant therapy	Pethidine hydrochloride	25mar2014 (91)	25mar2014 (91)	Colonoscopy	35 mg	qd intravenous
Concomitant therapy	Prednisolone sodium phosphate	07mar2014 (73)	11mar2014 (77)	Ulcerative colitis	10 mg	qd rectal
Concomitant therapy	Prednisolone sodium phosphate	12mar2014 (78)	12mar2014 (78)	Ulcerative colitis	20 mg	qd rectal
Concomitant therapy	Pregabalin	02may2014 (129)	14may2014 (141)	Adverse event	25 mg	prn oral
Concomitant therapy	Pregabalin	15may2014 (142)	ongoing	Adverse event	75 mg	qd oral
Concomitant therapy	Rosuvastatin calcium	prior to IC	ongoing	Concomitant disease	2.5 mg	qd oral
Concomitant therapy	Scopolamine butylbromide	03may2014 (130)	03may2014 (130)	Adverse event	10 mg	prn oral
Concomitant therapy	Sodium/potassium combined drug	25mar2014 (91)	25mar2014 (91)	Colonoscopy	-	qd rectal
Concomitant therapy	Sodium/potassium combined drug	15apr2014 (112)	15apr2014 (112)	Colonoscopy	-	qd rectal
Concomitant therapy	Tacrolimus hydrate	26mar2014 (92)	28mar2014 (94)	Adverse event	3 mg	bid oral
Concomitant therapy	Tacrolimus hydrate	29mar2014 (95)	01apr2014 (98)	Adverse event	4.5 mg	bid oral

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Tacrolimus hydrate	01apr2014 (98)	08apr2014 (105)	Adverse event	5.5 mg	bid oral
Concomitant therapy	Tacrolimus hydrate	09apr2014 (106)	13apr2014 (110)	Adverse event	3.5 mg	bid oral
Concomitant therapy	Tacrolimus hydrate	14apr2014 (111)	02may2014 (129)	Adverse event	3.0 mg	bid oral
Concomitant therapy	Tacrolimus hydrate	02may2014 (129)	ongoing	Adverse event	2 mg	bid oral
Concomitant therapy	Thiamine disulfide phosphate/b6/b12 combined drug	08mar2014 (74)	18mar2014 (84)	Transfusion	other	qd intravenous drip
Concomitant therapy	Tipepidine hibenzate	26apr2014 (123)	29apr2014 (126)	Adverse event	10 mg	tid oral
Concomitant therapy	Tribenoside/lidocaine	01apr2014 (98)	21apr2014 (118)	Adverse event	2.4 g	bid rectal
Concomitant therapy	Vidarabine	01may2014 (128)	08may2014 (135)	Adverse event	-	prn topical
UC surgeries/procedures	(Other surgery)	10mar2014 (76)	-	Worsening of uc	-	-
UC surgeries/procedures	(Other surgery)	12mar2014 (78)	-	Worsening of uc	-	-
UC surgeries/procedures	(Other surgery)	14mar2014 (80)	-	Worsening of uc	-	-
UC surgeries/procedures	(Other surgery)	17mar2014 (83)	-	Worsening of uc	-	-
UC surgeries/procedures	(Other surgery)	19mar2014 (85)	-	Worsening of uc	-	-
UC surgeries/procedures	(Other surgery)	21mar2014 (87)	-	Worsening of uc	-	-
UC surgeries/procedures	(Other surgery)	24mar2014 (90)	-	Worsening of uc	-	-
UC surgeries/procedures	(Other surgery)	26mar2014 (92)	-	Worsening of uc	-	-
UC surgeries/procedures	(Other surgery)	28mar2014 (94)	-	Worsening of uc	-	-
UC surgeries/procedures	(Other surgery)	31mar2014 (97)	-	Worsening of uc	-	-

被験者識別コード：810103

■ **REASON FOR NARRATIVE SELECTION**

Subject has at least one SAE

■ **Demographics and Baseline Characteristics**

☐ Country: JPN

☐ Race: Asian

(74)

☐ Age (yrs): 1[redacted] ☐ Sex: M ☐ Planned treatment arm: Golimumab (open) ☐ Baseline height (cm): 169.4 ☐ Baseline weight (kg): 50.5 ☐ Baseline bmi (kg/m^2): 17.6

■ **Disposition Information**

☐ End of induction/maintenance phase: 29jul2013 Discontinued Due to Adverse Event

☐ End of follow-up period: 17dec2013 Completed

■ **Fatal Adverse Events**

No Fatal Adverse Events reported

■ **Serious Adverse Events**

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
潰瘍性大腸炎 (Exacerbation of ulcerative colitis)	29jul13 23sep13	18 57	Y Moderate	Not related Drug withdrawn	Recovered/resolved
双極 1 型障害 (Bipolar 1 disorder)	29sep13 10dec13	80 73	Y Severe	Doubtful Not applicable	Recovered/resolved

■ **Adverse Events Leading To Permanent Withdrawal**

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication	Outcome
潰瘍性大腸炎 (Exacerbation of ulcerative colitis)	29jul13 23sep13	18 57	Y	Y Moderate	Not related	Recovered/resolved

■ **Other Adverse Events**

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
双極 1 型障害 (Bipolar 1 disorder)	10dec13 Ongoing	152 -	Y	N Mild	Doubtful Not applicable	Recovering/resolving
双極 1 型障害 (Bipolar 1 disorder)	27sep13 29sep13	78 3	Y	N Moderate	Doubtful Not applicable	Recovered/resolved
注入部位静脈炎 (Phlebitis(drip insertion site))	30jul13 08sep13	19 41	Y	N Mild	Not related Not applicable	Recovered/resolved
鼻咽頭炎 (Common cold)	25jul13 31jul13	14 7	Y	N Mild	Doubtful Dose not changed	Recovered/resolved
潰瘍性大腸炎 (Exacerbation of ulcerative colitis)	27jul13 29jul13	16 3	Y	N Moderate	Not related Dose not changed	Recovered/resolved

■ Medical History

Category	Verbatim Term
Other	喉頭蓋炎
Other	腰椎椎間板ヘルニア

■ Study Medication

Phase	Planned Treatment	Actual Treatment	Dosing Start(Study Day)	Dosing End(Study Day)
Induction	Golimumab	Golimumab	12jul2013 (1)	25jul2013 (14)

■ Drug History

Category	Medication	Use Period
UC Medication	Azathioprine	used <=1 year
UC Medication	Corticosteroids (excluding budesonide)	used <=1 year
UC Medication	Mesalamine	used <=1 year
Antibiotics	Ciprofloxacin	used <=1 year
Antibiotics	Pazufloxacin mesilate	used <=1 year

■ Concomitant Medication

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
UC medication history (other)	(Leukocyt apheresis)	17may2013 (-56)	07jun2013 (-35)	-	-	biw
UC medication history (other)	Clostridium butyricum	06jun2013 (-36)	-	-	3 tablet	daily oral
UC medication history (other)	Dried ferrous sulfate	06jun2013 (-36)	-	-	105 mg	daily oral
Concomitant therapy	(Cooling)	03aug2013 (23)	23sep2013 (74)	Adverse event	-	prn
Concomitant therapy	Adalimumab(genetical recombination)	26aug2013 (46)	26aug2013 (46)	Adverse event	160 mg	qd subcutaneous
Concomitant therapy	Adalimumab(genetical recombination)	09sep2013 (60)	09sep2013 (60)	Adverse event	80 mg	qd subcutaneous
Concomitant therapy	Adalimumab(genetical recombination)	23sep2013 (74)	23sep2013 (74)	Adverse event	40 mg	qd subcutaneous
Concomitant therapy	Adalimumab(genetical recombination)	07oct2013 (88)	07oct2013 (88)	Ulcerative colitis	40 mg	qd subcutaneous
Concomitant therapy	Adalimumab(genetical recombination)	21oct2013 (102)	21oct2013 (102)	Ulcerative colitis	40 mg	qd subcutaneous
Concomitant therapy	Adalimumab(genetical recombination)	04nov2013 (116)	04nov2013 (116)	Ulcerative colitis	40 mg	qd subcutaneous
Concomitant therapy	Adalimumab(genetical recombination)	18nov2013 (130)	18nov2013 (130)	Ulcerative colitis	40 mg	qd subcutaneous
Concomitant therapy	Adalimumab(genetical recombination)	02dec2013 (144)	02dec2013 (144)	Ulcerative colitis	40 mg	qd subcutaneous
Concomitant therapy	Adalimumab(genetical recombination)	16dec2013 (158)	16dec2013 (158)	Ulcerative colitis	40 mg	qd subcutaneous

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Brotizolam	28sep2013 (79)	28sep2013 (79)	Adverse event	0.25 mg	qd oral
Concomitant therapy	Carbocisteine	26jul2013 (15)	31jul2013 (20)	Adverse event	500 mg	tid oral
Concomitant therapy	Clostridium butyricum	prior to IC	29sep2013 (80)	Ulcerative colitis	1 tablet	tid oral
Concomitant therapy	Diazepam	12jul2013 (1)	12jul2013 (1)	Colonoscopy	5 mg	qd intravenous
Concomitant therapy	Diazepam	23aug2013 (43)	23aug2013 (43)	Colonoscopy	5 mg	qd intravenous
Concomitant therapy	Diazepam	20sep2013 (71)	20sep2013 (71)	Colonoscopy	5 mg	qd intravenous
Concomitant therapy	Dimeticone	12jul2013 (1)	12jul2013 (1)	Colonoscopy	10 ml	qd oral
Concomitant therapy	Dimeticone	23aug2013 (43)	23aug2013 (43)	Colonoscopy	10 ml	qd oral
Concomitant therapy	Dimeticone	20sep2013 (71)	20sep2013 (71)	Colonoscopy	10 ml	qd oral
Concomitant therapy	Fexofenadine hydrochloride	26jul2013 (15)	31jul2013 (20)	Adverse event	60 mg	bid oral
Concomitant therapy	Iron compounds and preparations(including organo-iron compounds)	prior to IC	ongoing	Ulcerative colitis	105 mg	qd oral
Concomitant therapy	Lactomin	30sep2013 (81)	ongoing	Ulcerative colitis	1 g	tid oral
Concomitant therapy	Lithium carbonate	15oct2013 (96)	10dec2013 (152)	Adverse event	300-800 mg	daily oral
Concomitant therapy	Lithium carbonate	10dec2013 (152)	ongoing	Adverse event	300-800 mg	daily oral
Concomitant therapy	Loxoprofen sodium hydrate	26jul2013 (15)	31jul2013 (20)	Adverse event	60 mg	prn oral
Concomitant therapy	Magnesium citrate	19sep2013 (70)	19sep2013 (70)	Colonoscopy	100 g	qd oral
Concomitant therapy	Methylprednisolone sodium succinate	29jul2013 (18)	31jul2013 (20)	Adverse event	500 mg	qd intravenous
Concomitant therapy	Non-pyrine cold preparation	26jul2013 (15)	31jul2013 (20)	Adverse event	1 g	tid oral
Concomitant therapy	Olanzapine	28sep2013 (79)	29sep2013 (80)	Adverse event	2.5-30 mg	qd oral
Concomitant therapy	Olanzapine	29sep2013 (80)	10dec2013 (152)	Adverse event	2.5-30 mg	qd oral
Concomitant therapy	Olanzapine	10dec2013 (152)	ongoing	Adverse event	2.5-30 mg	qd oral
Concomitant therapy	Pazufloxacin mesilate	29jul2013 (18)	02aug2013 (22)	Adverse event	500 mg	bid intravenous
Concomitant therapy	Pethidine hydrochloride	12jul2013 (1)	12jul2013 (1)	Colonoscopy	35 mg	qd intravenous
Concomitant therapy	Pethidine hydrochloride	23aug2013 (43)	23aug2013 (43)	Colonoscopy	35 mg	qd intravenous
Concomitant therapy	Pethidine hydrochloride	20sep2013 (71)	20sep2013 (71)	Colonoscopy	35 mg	qd intravenous
Concomitant therapy	Prednisolone	11sep2013 (62)	17sep2013 (68)	Adverse event	20 mg	qd oral
Concomitant therapy	Prednisolone	18sep2013 (69)	23sep2013 (74)	Adverse event	15 mg	qd oral
Concomitant therapy	Prednisolone	24sep2013 (75)	15oct2013 (96)	Ulcerative colitis	0-15 mg	qd oral
Concomitant therapy	Prednisolone sodium succinate	01aug2013 (21)	14aug2013 (34)	Adverse event	50 mg	qd intravenous

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Prednisolone sodium succinate	15aug2013 (35)	26aug2013 (46)	Adverse event	40 mg	qd intravenous
Concomitant therapy	Prednisolone sodium succinate	27aug2013 (47)	03sep2013 (54)	Adverse event	30 mg	qd intravenous
Concomitant therapy	Prednisolone sodium succinate	04sep2013 (55)	10sep2013 (61)	Adverse event	20 mg	qd intravenous
Concomitant therapy	Scopolamine butylbromide	12jul2013 (1)	12jul2013 (1)	Colonoscopy	20 mg	qd intravenous
Concomitant therapy	Scopolamine butylbromide	23aug2013 (43)	23aug2013 (43)	Colonoscopy	20 mg	qd intravenous
Concomitant therapy	Scopolamine butylbromide	20sep2013 (71)	20sep2013 (71)	Colonoscopy	20 mg	qd intravenous
Concomitant therapy	Sodium rabeprazole	03aug2013 (23)	ongoing	Prevention of gastritis	10 mg	qd oral
Concomitant therapy	Sodium/potassium combined drug	12jul2013 (1)	12jul2013 (1)	Colonoscopy	137.155 g	qd oral
Concomitant therapy	Sodium/potassium combined drug	23aug2013 (43)	23aug2013 (43)	Colonoscopy	137.155 g	qd oral
Concomitant therapy	Sodium/potassium combined drug	20sep2013 (71)	20sep2013 (71)	Colonoscopy	137.155 g	qd oral
Concomitant therapy	Sulfamethoxazole/trimethoprim	31jul2013 (20)	23sep2013 (74)	Adverse event	1 tablet	qd oral
Concomitant therapy	Sulfamethoxazole/trimethoprim	24sep2013 (75)	ongoing	Ulcerative colitis	1 tablet	qd oral
Concomitant therapy	Tropicamide/phenylephrine hydrochloride	01aug2013 (21)	01aug2013 (21)	Ophthalmologic examination	0.6 ml	qd ophthalmic
UC surgeries/procedures	(Biopsy)	15nov2013 (127)	-	Ulceration colitis	-	-
UC surgeries/procedures	(Colonoscopy)	20sep2013 (71)	-	Confirmation of the curative effect	-	-
UC surgeries/procedures	(Colonoscopy)	15nov2013 (127)	-	Condition confirmation of the ulcerative colitis	-	-

被験者識別コード：810107

■ **REASON FOR NARRATIVE SELECTION**

Subject has at least one SAE

■ **Demographics and Baseline Characteristics**

☐ Country: JPN

☐ Race: Asian

☐ Age (yrs): 5[redacted] ☐ Sex: M ☐ Planned treatment arm: Golimumab (open) ☐ Baseline height (cm): 165.1 ☐ Baseline weight (kg): 68.8 ☐ Baseline bmi (kg/m^2): 25.2

■ Disposition Information

☐ End of induction/maintenance phase: 18mar2014 Discontinued Due to Lack of Efficacy

☐ End of follow-up period: 29may2014 Completed

■ Fatal Adverse Events

No Fatal Adverse Events reported

■ Serious Adverse Events

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
潰瘍性大腸炎 (Exacerbation of ulcerative colitis)	18mar14 15apr14	43 29	Y Severe	Not related Drug withdrawn	Recovered/resolved

■ Adverse Events Leading To Permanent Withdrawal

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication	Outcome
潰瘍性大腸炎 (Exacerbation of ulcerative colitis)	18mar14 15apr14	43 29	Y	Y Severe	Not related	Recovered/resolved

■ Other Adverse Events

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
潰瘍性大腸炎 (Exacerbation of ulcerative colitis)	15mar14 18mar14	40 4	Y	N Moderate	Not related Dose not changed	Recovered/resolved
注入部位静脈炎 (Phlebitis(drip insertion site))	20mar14 26mar14	45 7	Y	N Mild	Not related Not applicable	Recovered/resolved
肛門周囲痛 (Anal pain)	26jan14 29apr14	-9 94	-	N Mild	Not related Not applicable	Recovered/resolved

■ Medical History

Category	Verbatim Term
Other	頭痛
Other	逆流性食道炎

■ Study Medication

Phase	Planned Treatment	Actual Treatment	Dosing Start(Study Day)	Dosing End(Study Day)
Induction	Golimumab	Golimumab	04feb2014 (1)	18feb2014 (15)

■ Drug History

Category	Medication	Use Period
UC Medication	Azathioprine	used >1 - <=2 years
UC Medication	Corticosteroids (excluding budesonide)	used <=1 year
UC Medication	Mesalamine	used <=1 year
UC Medication	Sulfasalazine	used <=1 year

■ Concomitant Medication

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
UC med. history (immunomodulators/5-ASA)	(Azathioprine)	26jul2012 (-558)	-	-	75 mg	daily oral
UC medication history (corticosteroids)	(Betamethasone)	31jan2013 (-369)	14jan2014 (-21)	-	3 mg	other rectal
UC medication history (other)	Clostridium butyricum	19jun2012 (-595)	-	-	3 tablet	daily oral
Concomitant therapy	Antipyretics, analgesics and anti-inflammatory agents	prior to IC	19feb2014 (16)	Concomitant disease	2 tablet	prn oral
Concomitant therapy	Azathioprine	prior to IC	ongoing	Ulcerative colitis	75 mg	qd oral
Concomitant therapy	Bifidobacterium	30jan2014 (-5)	03feb2014 (-1)	Ulcerative colitis	1 g	tid oral
Concomitant therapy	Celecoxib	15mar2014 (40)	17mar2014 (42)	Adverse event	100 mg	prn oral
Concomitant therapy	Clostridium butyricum	prior to IC	ongoing	Ulcerative colitis	1 tablet	tid oral
Concomitant therapy	Colibacillus vaccine/hydrocortisone	19mar2014 (44)	29apr2014 (85)	Adverse event	2 g	prn rectal
Concomitant therapy	Diazepam	04feb2014 (1)	04feb2014 (1)	Colonoscopy	5 mg	qd intravenous
Concomitant therapy	Diazepam	18mar2014 (43)	18mar2014 (43)	Colonoscopy	5 mg	qd intravenous
Concomitant therapy	Diazepam	08apr2014 (64)	08apr2014 (64)	Colonoscopy	10 mg	qd intravenous
Concomitant therapy	Dimethyl isopropylazulene	04mar2014 (29)	17mar2014 (42)	Adverse event	-	prn topical
Concomitant therapy	Dimeticone	04feb2014 (1)	04feb2014 (1)	Colonoscopy	10 ml	qd oral
Concomitant therapy	Flurbiprofen axetil	22mar2014 (47)	22mar2014 (47)	Adverse event	50 mg	qd intravenous
Concomitant therapy	Hydrocortisone sodium succinate	19mar2014 (44)	19mar2014 (44)	Adverse event	200 mg	qd intravenous drip
Concomitant therapy	Hydrocortisone sodium succinate	02apr2014 (58)	02apr2014 (58)	Adverse event	200 mg	qd intravenous drip
Concomitant therapy	Hydrocortisone sodium succinate	01may2014 (87)	01may2014 (87)	Ulcerative colitis	200 mg	qd intravenous drip

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Infliximab(genetical recombination)	19mar2014 (44)	19mar2014 (44)	Adverse event	400 mg	qd intravenous drip
Concomitant therapy	Infliximab(genetical recombination)	02apr2014 (58)	02apr2014 (58)	Adverse event	400 mg	qd intravenous drip
Concomitant therapy	Infliximab(genetical recombination)	01may2014 (87)	01may2014 (87)	Ulcerative colitis	400 mg	qd intravenous drip
Concomitant therapy	Iopamidol	19mar2014 (44)	19mar2014 (44)	Computeed tomography	100 ml	qd intravenous
Concomitant therapy	Magnesium citrate	18mar2014 (43)	18mar2014 (43)	Colonoscopy	100 g	qd oral
Concomitant therapy	Magnesium citrate	08apr2014 (64)	08apr2014 (64)	Colonosopy	100 g	qd oral
Concomitant therapy	Methylprednisolone sodium succinate	18mar2014 (43)	18mar2014 (43)	Adverse event	500 mg	qd intravenous drip
Concomitant therapy	Mixed amino acid/carbohydrate/electrolyte/vitamin combined drug	18mar2014 (43)	20mar2014 (45)	Adverse event	1000 ml	qd intravenous drip
Concomitant therapy	Mixed amino acid/carbohydrate/electrolyte/vitamin combined drug	21mar2014 (46)	22mar2014 (47)	Adverse event	500 ml	qd intravenous drip
Concomitant therapy	Pazufloxacin mesilate	18mar2014 (43)	18mar2014 (43)	Adverse event	500 mg	qd intravenous drip
Concomitant therapy	Pazufloxacin mesilate	19mar2014 (44)	22mar2014 (47)	Adverse event	500 mg	bid intravenous drip
Concomitant therapy	Pethidine hydrochloride	04feb2014 (1)	04feb2014 (1)	Colonoscopy	35 mg	qd intravenous
Concomitant therapy	Pethidine hydrochloride	18mar2014 (43)	18mar2014 (43)	Colonoscopy	35 mg	qd intravenous
Concomitant therapy	Pethidine hydrochloride	08apr2014 (64)	08apr2014 (64)	Colonoscopy	35 mg	qd intravenous
Concomitant therapy	Prednisolone sodium phosphate	10apr2014 (66)	15apr2014 (71)	Adverse event	20 mg	qd rectal
Concomitant therapy	Prednisolone sodium phosphate	16apr2014 (72)	01may2014 (87)	Ulcerative colitis	20 mg	qd rectal
Concomitant therapy	Prednisolone sodium phosphate	02may2014 (88)	29may2014 (115)	Ulcerative colitis	20 mg	tiw rectal
Concomitant therapy	Scopolamine butylbromide	04feb2014 (1)	04feb2014 (1)	Colonoscopy	20 mg	qd intravenous
Concomitant therapy	Scopolamine butylbromide	18mar2014 (43)	18mar2014 (43)	Colonoscopy	20 mg	qd intravenous
Concomitant therapy	Scopolamine butylbromide	08apr2014 (64)	08apr2014 (64)	Colonoscopy	20 mg	qd intravenous
Concomitant therapy	Sodium rabeprazole	20mar2014 (45)	14apr2014 (70)	Reflux esophagitis	10 mg	qd oral
Concomitant therapy	Sodium/potassium combined drug	04feb2014 (1)	04feb2014 (1)	Colonoscopy	137.155 g	qd oral
Concomitant therapy	Tribenoside/lidocaine	30jan2014 (-5)	01mar2014 (26)	Adverse event	1 units	prn rectal

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
UC surgeries/procedures	(Cat scan)	19mar2014 (44)	-	Exacerbation of ulcerative colitis	-	-
UC surgeries/procedures	(Colonoscopy)	08apr2014 (64)	-	Confirmation of the curative effect	-	-

被験者識別コード：810802

■ **REASON FOR NARRATIVE SELECTION**

Subject has at least one SAE

■ **Demographics and Baseline Characteristics**

☐ Country: JPN

☐ Race: Asian

☐ Age (yrs): 2[redacted] ☐ Sex: M ☐ Planned treatment arm: Golimumab (open) ☐ Baseline height (cm): 165.2 ☐ Baseline weight (kg): 43.9 ☐ Baseline bmi (kg/m^2): 16.1

■ **Disposition Information**

☐ End of induction/maintenance phase: 05nov2013 Discontinued Due to Adverse Event

☐ End of follow-up period: 08feb2014 Completed

■ **Fatal Adverse Events**

No Fatal Adverse Events reported

■ **Serious Adverse Events**

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
潰瘍性大腸炎 (Exacerbation of uc)	05nov13 08feb14	30 96	Y Severe	Not related Drug withdrawn	Recovered/resolved

■ Adverse Events Leading To Permanent Withdrawal

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication	Outcome
潰瘍性大腸炎 (Exacerbation of uc)	05nov13 08feb14	30 96	Y	Y Severe	Not related	Recovered/resolved

■ Other Adverse Events

No Other Adverse Events reported

■ Medical History

No Medical History reported

■ Study Medication

Phase	Planned Treatment	Actual Treatment	Dosing Start(Study Day)	Dosing End(Study Day)
Induction	Golimumab	Golimumab	07oct2013 (1)	26oct2013 (20)

■ Drug History

Category	Medication	Use Period
UC Medication	Corticosteroids (excluding budesonide)	used <=1 year
UC Medication	Mesalamine	used >1 - <=2 years

■ Concomitant Medication

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
UC med. history (immunomodulators/5-ASA)	(Mesalamine)	08sep2012 (-394)	-	-	3.6 g	daily oral
UC medication history (other)	Timepidium bromide hydrate	22dec2012 (-289)	-	-	90 mg	daily oral
Concomitant therapy	Berberine chloride hydrate/geranium herb extract	19nov2013 (44)	27dec2013 (82)	Ulcerative colitis	3 tablet	daily oral
Concomitant therapy	Clostridium butyricum	19nov2013 (44)	ongoing	Ulcerative colitis	3 g	daily oral
Concomitant therapy	Flumazenil	02oct2013 (-5)	02oct2013 (-5)	Treatment of endoscope	0.25 mg	prn intravenous
Concomitant therapy	Flumazenil	06nov2013 (31)	06nov2013 (31)	Treatment of endoscope	0.25 mg	prn intravenous
Concomitant therapy	Flunitrazepam	06nov2013 (31)	06nov2013 (31)	Treatment of endoscope	0.2 mg	prn intravenous
Concomitant therapy	Influenza ha vaccine	06dec2013 (61)	06dec2013 (61)	Vaccination	0.5 ml	other subcutaneous

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Lactated ringers solution(with d-sorbitol)	05nov2013 (30)	05nov2013 (30)	Transfusion	500 ml	daily intravenous drip
Concomitant therapy	Lidocaine hydrochloride	02oct2013 (-5)	02oct2013 (-5)	Treatment of endoscope	other	prn topical
Concomitant therapy	Lidocaine hydrochloride	06nov2013 (31)	06nov2013 (31)	Treatment of endoscope	other	prn topical
Concomitant therapy	Mercaptopurine hydrate	09nov2013 (34)	18nov2013 (43)	Adverse event	15 mg	qd oral
Concomitant therapy	Mercaptopurine hydrate	19nov2013 (44)	ongoing	Adverse event	30 mg	qd oral
Concomitant therapy	Mesalazine	prior to IC	ongoing	Ulcerative colitis	3.6 g	daily oral
Concomitant therapy	Midazolam	02oct2013 (-5)	02oct2013 (-5)	Treatment of endoscope	2.5 mg	prn intravenous
Concomitant therapy	Pentazocine	11nov2013 (36)	12nov2013 (37)	Adverse event	15 mg	prn intravenous
Concomitant therapy	Prednisolone	19nov2013 (44)	23nov2013 (48)	Adverse event	40 mg	daily oral
Concomitant therapy	Prednisolone	24nov2013 (49)	29nov2013 (54)	Adverse event	35 mg	daily oral
Concomitant therapy	Prednisolone	30nov2013 (55)	13dec2013 (68)	Adverse event	30 mg	daily oral
Concomitant therapy	Prednisolone	14dec2013 (69)	27dec2013 (82)	Adverse event	20 mg	daily oral
Concomitant therapy	Prednisolone	28dec2013 (83)	10jan2014 (96)	Adverse event	15 mg	daily oral
Concomitant therapy	Prednisolone	11jan2014 (97)	24jan2014 (110)	Adverse event	10 mg	daily oral
Concomitant therapy	Prednisolone	25jan2014 (111)	ongoing	Adverse event	5 mg	daily oral
Concomitant therapy	Prednisolone acetate	07nov2013 (32)	12nov2013 (37)	Adverse event	50 mg	qd intravenous drip
Concomitant therapy	Prednisolone acetate	13nov2013 (38)	16nov2013 (41)	Adverse event	50 mg	daily intravenous
Concomitant therapy	Prednisolone acetate	17nov2013 (42)	18nov2013 (43)	Adverse event	40 mg	daily intravenous
Concomitant therapy	Scopolamine butylbromide	02oct2013 (-5)	02oct2013 (-5)	Treatment of endoscope	20 mg	prn intravenous
Concomitant therapy	Scopolamine butylbromide	06nov2013 (31)	06nov2013 (31)	Treatment of endoscope	20 mg	prn intravenous
Concomitant therapy	Sodium rabeprazole	07nov2013 (32)	ongoing	Prevention of gastritis	10 mg	qd oral
Concomitant therapy	Sodium/potassium combined drug	02oct2013 (-5)	02oct2013 (-5)	Treatment of endoscope	274.31 g	prn oral
Concomitant therapy	Timepidium bromide hydrate	prior to IC	ongoing	Ulcerative colitis	90-120 mg	daily oral
UC surgeries/procedures	(Biopsy)	02oct2013 (-5)	-	Ulceractive colitis	-	-
UC surgeries/procedures	(Biopsy)	06nov2013 (31)	-	Ulceractive colitis	-	-

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
UC surgeries/procedures	(Cat scan)	07nov2013 (32)	-	Ulceractive colitis	-	-

被験者識別コード：811202

■ **REASON FOR NARRATIVE SELECTION**

Subject has at least one SAE

■ **Demographics and Baseline Characteristics**

☐ Country: JPN

☐ Race: Asian

☐ Age (yrs): 4[redacted] ☐ Sex: M ☐ Planned treatment arm: Golimumab (open) ☐ Baseline height (cm): 163.5 ☐ Baseline weight (kg): 58.4 ☐ Baseline bmi (kg/m^2): 21.8

■ **Disposition Information**

☐ End of induction/maintenance phase: 06jan2014 Discontinued Due to Adverse Event

☐ End of follow-up period: 24mar2014 Completed

■ **Fatal Adverse Events**

No Fatal Adverse Events reported

■ **Serious Adverse Events**

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
潰瘍性大腸炎 (Exacerbation of ulcerative colitis)	06jan14 21feb14	42 47	Y Moderate	Not related Drug withdrawn	Recovered/resolved

■ **Adverse Events Leading To Permanent Withdrawal**

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication	Outcome
潰瘍性大腸炎 (Exacerbation of ulcerative colitis)	06jan14 21feb14	42 47	Y	Y Moderate	Not related	Recovered/resolved

■ Other Adverse Events

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
発熱 (Fever)	13nov13 15nov13	-13 3	-	N Mild	Not related Not applicable	Recovered/resolved

■ Medical History

Category	Verbatim Term
Other	肛門周囲膿瘍
Other	花粉症

■ Study Medication

Phase	Planned Treatment	Actual Treatment	Dosing Start(Study Day)	Dosing End(Study Day)
Induction	Golimumab	Golimumab	26nov2013 (1)	10dec2013 (15)

■ Drug History

Category	Medication	Use Period
UC Medication	Corticosteroids (excluding budesonide)	used <=1 year
UC Medication	Mesalamine	used <=1 year

■ Concomitant Medication

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
UC med. history (immunomodulators/5-ASA)	(Mesalamine)	09sep2013 (-78)	-	-	4000 mg	daily oral
UC medication history (other)	Clostridium butyricum	09sep2013 (-78)	-	-	6 g	daily oral
UC medication history (other)	Saireito	09sep2013 (-78)	-	-	8.1 g	daily oral
Concomitant therapy	Acetated ringer	06jan2014 (42)	07jan2014 (43)	Adverse event	500 ml	daily intravenous drip
Concomitant therapy	Acetated ringer's solution(with glucose)	06jan2014 (42)	10jan2014 (46)	Adverse event	500-1000 ml	daily intravenous drip
Concomitant therapy	Acetated ringer's solution(with glucose)	30jan2014 (66)	30jan2014 (66)	Adverse event	500 ml	qd intravenous drip
Concomitant therapy	Aluminum hydroxide gel/magnesium hydroxide	13nov2013 (-13)	13nov2013 (-13)	Colon fiber	10 ml	qd topical

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Aluminum hydroxide gel/magnesium hydroxide	10jan2014 (46)	10jan2014 (46)	Colon fiber	10 ml	qd topical
Concomitant therapy	Antibiotics-resistant lactic acid bacteriae	09jan2014 (45)	12feb2014 (79)	Adverse event	3 g	daily oral
Concomitant therapy	Azathioprine	06feb2014 (73)	ongoing	Adverse event	75 mg	qd oral
Concomitant therapy	Ceftazidime hydrate	06jan2014 (42)	06jan2014 (42)	Adverse event	2 g	daily intravenous drip
Concomitant therapy	Ceftazidime hydrate	07jan2014 (43)	08jan2014 (44)	Adverse event	3 g	daily intravenous drip
Concomitant therapy	Ceftazidime hydrate	09jan2014 (45)	09jan2014 (45)	Adverse event	1 g	daily intravenous drip
Concomitant therapy	Clostridium butyricum	prior to IC	ongoing	Ulcerative colitis	6-9 g	daily oral
Concomitant therapy	Dimeticone	13nov2013 (-13)	13nov2013 (-13)	Colon fiber	10 ml	qd topical
Concomitant therapy	Enteral nutrition	22jan2014 (58)	13feb2014 (80)	Adverse event	80 g	qd oral
Concomitant therapy	Famotidine	06jan2014 (42)	17feb2014 (84)	Adverse event	20-40 mg	daily intravenous drip
Concomitant therapy	Famotidine	20feb2014 (87)	ongoing	Adverse event	40 mg	daily oral
Concomitant therapy	Ferric oxide,saccharated	10jan2014 (46)	10feb2014 (77)	Adverse event	40-80 mg	daily intravenous drip
Concomitant therapy	Ferric oxide,saccharated	12feb2014 (79)	17feb2014 (84)	Adverse event	80 mg	daily intravenous drip
Concomitant therapy	Flurbiprofen axetil	08jan2014 (44)	14jan2014 (50)	Adverse event	50 mg	prn intravenous drip
Concomitant therapy	Ganciclovir	10jan2014 (46)	15jan2014 (51)	Adverse event	250-500 mg	daily intravenous drip
Concomitant therapy	Iopamidol	06jan2014 (42)	06jan2014 (42)	Cat scan	100 ml	qd intravenous
Concomitant therapy	Lidocaine hydrochloride	13nov2013 (-13)	13nov2013 (-13)	Colon fiber	other	qd topical
Concomitant therapy	Lidocaine hydrochloride	10jan2014 (46)	10jan2014 (46)	Colon fiber	other	qd topical
Concomitant therapy	Lidocaine hydrochloride	05feb2014 (72)	05feb2014 (72)	Colon fiber	other	qd topical
Concomitant therapy	Loxoprofen sodium hydrate	14nov2013 (-12)	15nov2013 (-11)	Adverse event	60 mg	prn oral
Concomitant therapy	Magnesium citrate	05feb2014 (72)	05feb2014 (72)	Colon fiber	17 g	qd oral

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Maintenance medium	13nov2013 (-13)	13nov2013 (-13)	Colon fiber	200 ml	qd intravenous
Concomitant therapy	Maintenance medium	06jan2014 (42)	10jan2014 (46)	Adverse event	500-1000 ml	daily intravenous drip
Concomitant therapy	Maintenance medium	30jan2014 (66)	17feb2014 (84)	Adverse event	500 ml	qd intravenous drip
Concomitant therapy	Manganese chloride/zinc sulfate hydrate combined drug	11jan2014 (47)	30jan2014 (66)	Adverse event	2 ml	daily intravenous drip
Concomitant therapy	Meropenem hydrate	09jan2014 (45)	10jan2014 (46)	Adverse event	1.5 g	daily intravenous drip
Concomitant therapy	Meropenem hydrate	11jan2014 (47)	14jan2014 (50)	Adverse event	2.0 g	daily intravenous drip
Concomitant therapy	Mesalazine	prior to IC	10jan2014 (46)	Ulcerative colitis	4000 mg	daily oral
Concomitant therapy	Mesalazine	10jan2014 (46)	ongoing	Adverse event	3600 mg	daily oral
Concomitant therapy	Mesalazine	06feb2014 (73)	09feb2014 (76)	Adverse event	1 g	qd rectal
Concomitant therapy	Mesalazine	11feb2014 (78)	11feb2014 (78)	Adverse event	1 g	qd rectal
Concomitant therapy	Metoclopramide hydrochloride	13nov2013 (-13)	13nov2013 (-13)	Colon fiber	10 mg	qd intravenous
Concomitant therapy	Metoclopramide hydrochloride	06jan2014 (42)	17feb2014 (84)	Adverse event	20-10 mg	daily intravenous drip
Concomitant therapy	Metoclopramide hydrochloride	05feb2014 (72)	05feb2014 (72)	Colon fiber	10 mg	qd intravenous
Concomitant therapy	Mixed amino acid/carbohydrate/electrolyte combined drug	08jan2014 (44)	10jan2014 (46)	Adverse event	1000 ml	daily intravenous drip
Concomitant therapy	Mixed amino acid/carbohydrate/electrolyte combined drug	31jan2014 (67)	16feb2014 (83)	Adverse event	1000 ml	qd intravenous drip
Concomitant therapy	Mixed amino acid/carbohydrate/electrolyte combined drug	18feb2014 (85)	19feb2014 (86)	Adverse event	1000 ml	daily intravenous drip
Concomitant therapy	Mixed amino acid/carbohydrate/electrolyte/vitamin combined drug	11jan2014 (47)	11jan2014 (47)	Adverse event	903 ml	daily intravenous drip
Concomitant therapy	Mixed amino acid/carbohydrate/electrolyte/vitamin combined drug	11jan2014 (47)	11jan2014 (47)	Adverse event	1003 ml	daily intravenous drip

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Mixed amino acid/carbohydrate/electrolyte/vitamin combined drug	12jan2014 (48)	30jan2014 (66)	Adverse event	2006 ml	daily intravenous drip
Concomitant therapy	Monoammonium glycyrrhizinate/glycine/l-cysteine combined drug	29jan2014 (65)	16feb2014 (83)	Adverse event	60-40 ml	daily intravenous drip
Concomitant therapy	Nafamostat mesilate	14jan2014 (50)	13feb2014 (80)	Adverse event	70 mg	biw intravenous
Concomitant therapy	Naloxone hydrochloride	13nov2013 (-13)	13nov2013 (-13)	Colon fiber	0.2 mg	qd intravenous
Concomitant therapy	Panthenol	06jan2014 (42)	07jan2014 (43)	Adverse event	100 mg	daily intravenous drip
Concomitant therapy	Panthenol	11jan2014 (47)	16feb2014 (83)	Adverse event	100-200 mg	daily intravenous drip
Concomitant therapy	Panthenol	18feb2014 (85)	19feb2014 (86)	Adverse event	100 mg	daily intravenous drip
Concomitant therapy	Pethidine hydrochloride	13nov2013 (-13)	13nov2013 (-13)	Colon fiber	35 mg	qd intravenous
Concomitant therapy	Pethidine hydrochloride	10jan2014 (46)	10jan2014 (46)	Colon fiber	35 mg	qd intravenous
Concomitant therapy	Pethidine hydrochloride	05feb2014 (72)	05feb2014 (72)	Colon fiber	35 mg	qd intravenous
Concomitant therapy	Prednisolone sodium phosphate	10jan2014 (46)	30jan2014 (66)	Adverse event	60 ml	qd rectal
Concomitant therapy	Rebamipide	14nov2013 (-12)	15nov2013 (-11)	Adverse event	100 mg	prn oral
Concomitant therapy	Saireito	prior to IC	ongoing	Ulcerative colitis	8.1 g	daily oral
Concomitant therapy	Scopolamine butylbromide	13nov2013 (-13)	13nov2013 (-13)	Colon fiber	10 mg	qd intravenous
Concomitant therapy	Scopolamine butylbromide	05feb2014 (72)	05feb2014 (72)	Colon fiber	10 mg	qd intravenous
Concomitant therapy	Sodium alginate	13nov2013 (-13)	13nov2013 (-13)	Colon fiber	10 ml	qd topical
Concomitant therapy	Sodium alginate	10jan2014 (46)	10jan2014 (46)	Colon fiber	10 ml	qd topical
Concomitant therapy	Sodium/potassium/ascorbic acid combined drug	13nov2013 (-13)	13nov2013 (-13)	Colon fiber	2 l	qd oral
Concomitant therapy	Soybean oil	14jan2014 (50)	28jan2014 (64)	Adverse event	250 ml	daily intravenous drip
Concomitant therapy	Thiamine disulfide phosphate/b6/b12 combined drug	06jan2014 (42)	10jan2014 (46)	Adverse event	1 other	daily intravenous drip

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Thiamine disulfide phosphate/b6/b12 combined drug	30jan2014 (66)	17feb2014 (84)	Adverse event	1 other	qd intravenous drip
Concomitant therapy	Thrombin	13nov2013 (-13)	13nov2013 (-13)	Colon fiber	20000 units	qd topical
Concomitant therapy	Thrombin	10jan2014 (46)	10jan2014 (46)	Colon fiber	20000 units	qd topical
UC surgeries/procedures	(Biopsy)	10jan2014 (46)	-	Exacerbation of ulcerative colitis	-	-
UC surgeries/procedures	(Cat scan)	06jan2014 (42)	-	Exacerbation of ulcerative colitis	-	-
UC surgeries/procedures	(Colonoscopy)	10jan2014 (46)	-	Leukocytapheresis exacerbation of ulcerative colitis	-	-
UC surgeries/procedures	(Colonoscopy)	05feb2014 (72)	-	Leukocytapheresis exacerbation of ulcerative colitis	-	-
UC surgeries/procedures	(Other surgery)	14jan2014 (50)	-	Exacerbation of ulcerative colitis	-	-
UC surgeries/procedures	(Other surgery)	17jan2014 (53)	-	Exacerbation of ulcerative colitis	-	-
UC surgeries/procedures	(Other surgery)	21jan2014 (57)	-	Exacerbation of ulcerative colitis	-	-
UC surgeries/procedures	(Other surgery)	24jan2014 (60)	-	Exacerbation of ulcerative colitis	-	-
UC surgeries/procedures	(Other surgery)	28jan2014 (64)	-	Exacerbation of ulcerative colitis	-	-
UC surgeries/procedures	(Other surgery)	31jan2014 (67)	-	Exacerbation of ulcerative colitis	-	-
UC surgeries/procedures	(Other surgery)	04feb2014 (71)	-	Exacerbation of ulcerative colitis	-	-
UC surgeries/procedures	(Other surgery)	07feb2014 (74)	-	Exacerbation of ulcerative colitis	-	-
UC surgeries/procedures	(Other surgery)	10feb2014 (77)	-	Exacerbation of ulcerative colitis	-	-
UC surgeries/procedures	(Other surgery)	13feb2014 (80)	-	Exacerbation of ulcerative colitis	-	-
UC surgeries/procedures	(Tpn)	10jan2014 (46)	30jan2014 (66)	Exacerbation of ulcerative colitis	-	-

被験者識別コード：811501

■ **REASON FOR NARRATIVE SELECTION**

Subject has at least one SAE

■ **Demographics and Baseline Characteristics**

☐ Country: JPN

☐ Race: Asian

☐ Age (yrs): 5[redacted] ☐ Sex: M ☐ Planned treatment arm: Golimumab (open) ☐ Baseline height (cm): 169 ☐ Baseline weight (kg): 60.8 ☐ Baseline bmi (kg/m^2): 21.3

■ **Disposition Information**

☐ End of induction/maintenance phase: 05jun2013 Discontinued Due to Lack of Efficacy

☐ End of follow-up period: 02sep2013 Completed

■ **Fatal Adverse Events**

No Fatal Adverse Events reported

■ **Serious Adverse Events**

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
細菌性肺炎 (Bacterial pneumonia)	17jul13 22jul13	70 6	Y Moderate	Possible Not applicable	Recovered/resolved

■ **Adverse Events Leading To Permanent Withdrawal**

No Adverse Events Leading To Permanent Withdrawal reported

■ **Other Adverse Events**

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
上気道感染 (Upper respiratory tract infection)	16may13 20may13	8 5	Y	N Mild	Not related Dose not changed	Recovered/resolved
細菌性肺炎 (Bacterial pneumonia)	13jul13 17jul13	66 5	Y	N Moderate	Possible Not applicable	Recovered/resolved

■ **Medical History**

Category	Verbatim Term
Other	高血圧

■ Study Medication

Phase	Planned Treatment	Actual Treatment	Dosing Start(Study Day)	Dosing End(Study Day)
Induction	Golimumab	Golimumab	09may2013 (1)	20may2013 (12)

■ Drug History

Category	Medication	Use Period
UC Medication	Azathioprine	used <=1 year
UC Medication	Corticosteroids (excluding budesonide)	used <=1 year
UC Medication	Mesalamine	used >1 - <=2 years
UC Medication	Tacrolimus	used <=1 year

■ Concomitant Medication

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
UC med. history (immunomodulators/5-ASA)	(Mesalamine)	29nov2012 (-161)	15apr2013 (-24)	-	500 mg	daily rectal
UC med. history (immunomodulators/5-ASA)	(Mesalamine)	06mar2013 (-64)	-	-	4000 mg	daily oral
UC medication history (other)	Clostridium butyricum combined drug	04oct2012 (-217)	-	-	3 tablet	daily oral
Concomitant therapy	Clostridium butyricum combined drug	prior to IC	ongoing	Ulcerative colitis	3 tablet	daily oral
Concomitant therapy	Dimeticone	09may2013 (1)	09may2013 (1)	Endoscopy	3 ml	prn oral
Concomitant therapy	Garenoxacin mesilate hydrate	22jul2013 (75)	28jul2013 (81)	Prevention of bacterial pneumonia	400 mg	qd oral
Concomitant therapy	Glycerin	09may2013 (1)	09may2013 (1)	Endoscopy	60 ml	prn topical
Concomitant therapy	Imidapril hydrochloride	prior to IC	ongoing	Concomitant disease	5 mg	qd oral
Concomitant therapy	Infliximab(genetical recombination)	12jun2013 (35)	12jun2013 (35)	Ulcerative colitis	300 mg	qd intravenous drip
Concomitant therapy	Infliximab(genetical recombination)	26jun2013 (49)	26jun2013 (49)	Ulcerative colitis	300 mg	qd intravenous drip
Concomitant therapy	Infliximab(genetical recombination)	24jul2013 (77)	24jul2013 (77)	Ulcerative colitis	300 mg	qd intravenous drip
Concomitant therapy	Lidocaine	09may2013 (1)	09may2013 (1)	Endoscopy	30 ml	prn topical
Concomitant therapy	Mesalazine	prior to IC	ongoing	Ulcerative colitis	4000 mg	daily oral
Concomitant therapy	Piperacillin sodium	17jul2013 (70)	19jul2013 (72)	Adverse event	2 g	bid intravenous drip
Concomitant therapy	Prednisolone	05jun2013 (28)	12jun2013 (35)	Ulcerative colitis	40 mg	qd oral

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Prednisolone	13jun2013 (36)	26jun2013 (49)	Ulcerative colitis	30 mg	qd oral
Concomitant therapy	Prednisolone	27jun2013 (50)	10jul2013 (63)	Ulcerative colitis	20 mg	qd oral
Concomitant therapy	Prednisolone	11jul2013 (64)	24jul2013 (77)	Ulcerative colitis	15 mg	qd oral
Concomitant therapy	Prednisolone	25jul2013 (78)	31jul2013 (84)	Ulcerative colitis	10 mg	qd oral
Concomitant therapy	Prednisolone	01aug2013 (85)	14aug2013 (98)	Ulcerative colitis	5 mg	qd oral
Concomitant therapy	Sulfamethoxazole/trimethoprim	17jul2013 (70)	21jul2013 (74)	Adverse event	4 tablet	bid oral
Concomitant therapy	Sulfamethoxazole/trimethoprim	22jul2013 (75)	28jul2013 (81)	Prevention of bacterial pneumonia	4 tablet	bid oral

被験者識別コード：812002

■ **REASON FOR NARRATIVE SELECTION**

Subject has at least one SAE

■ **Demographics and Baseline Characteristics**

☐ Country: JPN

☐ Race: Asian

☐ Age (yrs): 4[redacted] ☐ Sex: M ☐ Planned treatment arm: Golimumab (open) ☐ Baseline height (cm): 167.2 ☐ Baseline weight (kg): 60.7 ☐ Baseline bmi (kg/m^2): 21.7

■ **Disposition Information**

☐ End of induction/maintenance phase: 16jul2014 Discontinued Due to Adverse Event

☐ End of follow-up period: 22oct2014 Completed

■ **Fatal Adverse Events**

No Fatal Adverse Events reported

■ Serious Adverse Events

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
サイトメガロウイルス感染 (Cytomegaloviral infections)	18aug14 01sep14	62 15	Y Severe	Possible Not applicable	Recovered/resolved

■ Adverse Events Leading To Permanent Withdrawal

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication	Outcome
貧血 (Worsening anemia)	02jul14 13aug14	15 43	Y	N Moderate	Not related	Recovered/resolved

■ Other Adverse Events

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
鼻咽頭炎 (Common cold)	07oct14 22oct14	112 16	Y	N Mild	Not related Not applicable	Recovered/resolved
サイトメガロウイルス感染 (Cytomegaloviral infections)	01sep14 10sep14	76 10	Y	N Mild	Possible Not applicable	Recovered/resolved
サイトメガロウイルス感染 (Cytomegaloviral infections)	13aug14 18aug14	57 6	Y	N Moderate	Possible Not applicable	Recovered/resolved

■ Medical History

Category	Verbatim Term
Other	鉄欠乏性貧血

■ Study Medication

Phase	Planned Treatment	Actual Treatment	Dosing Start(Study Day)	Dosing End(Study Day)
Induction	Golimumab	Golimumab	18jun2014 (1)	02jul2014 (15)

■ Drug History

Category	Medication	Use Period
UC Medication	Azathioprine	used <=1 year
UC Medication	Corticosteroids (excluding budesonide)	used <=1 year
UC Medication	Mesalamine	used >2 years
UC Medication	Tacrolimus	used <=1 year

■ **Concomitant Medication**

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
UC med. history (immunomodulators/5-ASA)	(Azathioprine)	04dec2013 (-196)	-	-	50 mg	daily oral
UC med. history (immunomodulators/5-ASA)	(Mesalamine)	09oct2013 (-252)	-	-	4000 mg	daily oral
UC med. history (immunomodulators/5-ASA)	(Mesalamine)	23apr2014 (-56)	20may2014 (-29)	-	1 g	daily rectal
UC medication history (corticosteroids)	(Prednisolone)	07nov2013 (-223)	-	-	5 mg	daily oral
UC medication history (corticosteroids)	(Prednisolone)	23apr2014 (-56)	20may2014 (-29)	-	20 mg	daily rectal
UC medication history (other)	(Granulocyte monocyte adosorption apheress)	23apr2014 (-56)	31may2014 (-18)	-	-	other
Concomitant therapy	Acetaminophen	30jul2014 (43)	30jul2014 (43)	Preparation of injection	0.5 g	daily oral
Concomitant therapy	Acetaminophen	13aug2014 (57)	13aug2014 (57)	Preparation of injection	0.5 g	daily oral
Concomitant therapy	Acetaminophen	10sep2014 (85)	10sep2014 (85)	Paration of injection	0.5 g	daily oral
Concomitant therapy	Azathioprine	prior to IC	18aug2014 (62)	Ulcerative colitis	50 mg	daily oral
Concomitant therapy	Azathioprine	10sep2014 (85)	30sep2014 (105)	Ulcerative colitis	50 mg	daily oral
Concomitant therapy	Azathioprine	01oct2014 (106)	ongoing	Ulcerative colitis	100 mg	daily oral
Concomitant therapy	Clarithromycin	07oct2014 (112)	11oct2014 (116)	Adverse event	400 mg	daily oral
Concomitant therapy	Diphenhydramine hydrochloride	30jul2014 (43)	30jul2014 (43)	Preparation of injection	30 mg	daily oral
Concomitant therapy	Diphenhydramine hydrochloride	13aug2014 (57)	13aug2014 (57)	Preparation of injection	30 mg	daily oral
Concomitant therapy	Diphenhydramine hydrochloride	10sep2014 (85)	10sep2014 (85)	Paration of injection	30 mg	daily oral
Concomitant therapy	Flumazenil	04jun2014 (-14)	04jun2014 (-14)	Colonoscopy preparation	0.25 mg	daily intravenous
Concomitant therapy	Flumazenil	30jul2014 (43)	30jul2014 (43)	Colonoscopy preparation	0.25 mg	daily intravenous
Concomitant therapy	Flumazenil	01oct2014 (106)	01oct2014 (106)	Colonoscopy preparation	0.25 mg	daily intravenous
Concomitant therapy	Ganciclovir	18aug2014 (62)	01sep2014 (76)	Adverse event	600 mg	daily intravenous
Concomitant therapy	Hydrocortisone sodium succinate	30jul2014 (43)	30jul2014 (43)	Preparation of injection	100 mg	daily intravenous
Concomitant therapy	Hydrocortisone sodium succinate	13aug2014 (57)	13aug2014 (57)	Preparation of injection	100 mg	daily intravenous

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Hydrocortisone sodium succinate	10sep2014 (85)	10sep2014 (85)	Paration of injection	100 mg	daily intravenous
Concomitant therapy	Infliximab(genetical recombination)	30jul2014 (43)	30jul2014 (43)	Ulcerative colitis	300 mg	daily intravenous
Concomitant therapy	Infliximab(genetical recombination)	13aug2014 (57)	13aug2014 (57)	Ulcerative colitis	300 mg	daily intravenous
Concomitant therapy	Infliximab(genetical recombination)	10sep2014 (85)	10sep2014 (85)	Ulcerative colitis	300 mg	daily intravenous
Concomitant therapy	Loxoprofen sodium hydrate	07oct2014 (112)	11oct2014 (116)	Adverse event	60 mg	prn oral
Concomitant therapy	Maintenance medium	18aug2014 (62)	21aug2014 (65)	Nutritional support	2000 ml	daily intravenous
Concomitant therapy	Mesalazine	prior to IC	21oct2014 (126)	Ulcerative colitis	4000 mg	daily oral
Concomitant therapy	Mesalazine	01oct2014 (106)	ongoing	Ulcerative colitis	1 g	daily rectal
Concomitant therapy	Midazolam	04jun2014 (-14)	04jun2014 (-14)	Colonoscopy preparation	3.75 mg	daily intravenous
Concomitant therapy	Midazolam	30jul2014 (43)	30jul2014 (43)	Colonoscopy preparation	3.75 mg	daily intravenous
Concomitant therapy	Midazolam	01oct2014 (106)	01oct2014 (106)	Colonoscopy preparation	3.75 mg	daily intravenous
Concomitant therapy	Non-pyrine cold preparation	07oct2014 (112)	11oct2014 (116)	Adverse event	3 g	daily oral
Concomitant therapy	Prednisolone	prior to IC	12aug2014 (56)	Ulcerative colitis	5 mg	daily oral
Concomitant therapy	Prednisolone	13aug2014 (57)	09sep2014 (84)	Ulcerative colitis	3 mg	daily oral
Concomitant therapy	Scopolamine butylbromide	04jun2014 (-14)	04jun2014 (-14)	Colonoscopy preparation	20 mg	daily intravenous
Concomitant therapy	Scopolamine butylbromide	30jul2014 (43)	30jul2014 (43)	Colonoscopy preparation	20 mg	daily intravenous
Concomitant therapy	Scopolamine butylbromide	01oct2014 (106)	01oct2014 (106)	Colonoscopy preparation	20 mg	daily intravenous
Concomitant therapy	Sodium ferrous citrate	16jul2014 (29)	ongoing	Adverse event	200 mg	daily oral
Concomitant therapy	Sodium gualenate hydrate	07oct2014 (112)	11oct2014 (116)	Adverse event	- other	prn topical
Concomitant therapy	Sodium gualenate hydrate/l-glutamine	07oct2014 (112)	11oct2014 (116)	Adverse event	1.5 g	daily oral
Concomitant therapy	Sodium/potassium combined drug	04jun2014 (-14)	04jun2014 (-14)	Colonoscopy preparation	137.155 g	daily oral
Concomitant therapy	Sodium/potassium combined drug	30jul2014 (43)	30jul2014 (43)	Colonoscopy preparation	137.155 g	daily oral
Concomitant therapy	Sodium/potassium combined drug	01oct2014 (106)	01oct2014 (106)	Colonoscopy preparation	137.155 g	daily oral

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Thiamine disulfide phosphate/b6/b12 combined drug	18aug2014 (62)	20aug2014 (64)	Nutritional support	208.13 mg	daily intravenous
UC surgeries/procedures	(Biopsy)	04jun2014 (-14)	-	Ulcerative colitis	-	-
UC surgeries/procedures	(Biopsy)	30jul2014 (43)	-	Ulcerative colitis	-	-
UC surgeries/procedures	(Biopsy)	01oct2014 (106)	-	Ulcerative colitis	-	-
UC surgeries/procedures	(Colonoscopy)	01oct2014 (106)	-	Ulcerative colitis	-	-
UC surgeries/procedures	(Other surgery)	16jul2014 (29)	-	Therapy for primary disease	-	-
UC surgeries/procedures	(Other surgery)	19jul2014 (32)	-	Therapy for primary disease	-	-
UC surgeries/procedures	(Other surgery)	23jul2014 (36)	-	Therapy for primary disease	-	-
UC surgeries/procedures	(Other surgery)	26jul2014 (39)	-	Therapy for primary disease	-	-
UC surgeries/procedures	(Other surgery)	02aug2014 (46)	-	Therapy for primary disease	-	-
UC surgeries/procedures	(Other surgery)	07aug2014 (51)	-	Therapy for primary disease	-	-
UC surgeries/procedures	(Other surgery)	09aug2014 (53)	-	Therapy for primary disease	-	-
UC surgeries/procedures	(Other surgery)	16aug2014 (60)	-	Therapy for primary disease	-	-

被験者識別コード：812701

■ **REASON FOR NARRATIVE SELECTION**

Subject has at least one SAE

■ **Demographics and Baseline Characteristics**

☐ Country: JPN

☐ Race: Asian

☐ Age (yrs): 6[redacted] ☐ Sex: M ☐ Planned treatment arm: Golimumab (open) ☐ Baseline height (cm): 171.5 ☐ Baseline weight (kg): 69.5 ☐ Baseline bmi (kg/m^2): 23.6

■ **Disposition Information**

☐ End of induction/maintenance phase: 22may2013 Discontinued Due to Adverse Event

☐ End of follow-up period: 04sep2013 Completed

■ **Fatal Adverse Events**

No Fatal Adverse Events reported

■ **Serious Adverse Events**

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
サイトメガロウイルス性大腸炎 (Cytomegalovirus colitis suspicion)	22may13 09jun13	29 19	Y Moderate	Possible Drug withdrawn	Recovered/resolved

■ **Adverse Events Leading To Permanent Withdrawal**

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication	Outcome
サイトメガロウイルス性大腸炎 (Cytomegalovirus colitis suspicion)	22may13 09jun13	29 19	Y	Y Moderate	Possible	Recovered/resolved

■ **Other Adverse Events**

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
過敏性腸症候群 (Irritable bowel syndrome)	24jul13 Ongoing	92 -	Y	N Mild	Not related Not applicable	Not recovered/not resolved
痔核 (External haemorrhoids)	26apr13 Ongoing	3 -	Y	N Mild	Doubtful Dose not changed	Recovering/resolving
ヘモグロビン減少 (Haemoglobin decreased)	03jun13 07jun13	41 5	Y	N Moderate	Not related Not applicable	Recovered/resolved
廃用症候群 (Disuse syndrome)	27jun13 29jun13	65 3	Y	N Mild	Not related Not applicable	Recovered/resolved
血中マグネシウム減少 (Magnesium low)	21jun13 Ongoing	59 -	Y	N Mild	Not related Not applicable	Recovering/resolving
背部痛 (Lumbago)	10jul13 24jul13	78 15	Y	N Mild	Not related Not applicable	Recovered/resolved

Preferred AE Term(MedDRA v18.1) (Reported AE Term)	Start AE End AE	Onset Day Duration (days)	TEAE	Serious AE Severity/Intensity	Relatedness to Study Medication Action Taken on Study Medication	Outcome
背部痛 (Lumbago)	28apr13 15may13	5 18	Y	N Mild	Doubtful Dose not changed	Recovered/resolved

■ Medical History

Category	Verbatim Term
Other	萎縮性胃炎
Other	慢性 B 型肝炎
Other	逆流性食道炎

■ Study Medication

Phase	Planned Treatment	Actual Treatment	Dosing Start(Study Day)	Dosing End(Study Day)
Induction	Golimumab	Golimumab	24apr2013 (1)	08may2013 (15)

■ Drug History

Category	Medication	Use Period
UC Medication	Corticosteroids (excluding budesonide)	used <=1 year
UC Medication	Mesalamine	used >2 years

■ Concomitant Medication

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
UC med. history (immunomodulators/5-ASA)	(Mesalamine)	13feb2013 (-70)	-	-	4.0 g	daily oral
UC medication history (corticosteroids)	(Betamethasone)	13feb2013 (-70)	12mar2013 (-43)	-	1.0 mg	daily rectal
UC medication history (other)	Clostridium butyricum	13feb2013 (-70)	-	-	60 mg	daily oral
Concomitant therapy	Acetated ringer's solution(with glucose)	22may2013 (29)	22may2013 (29)	Adverse event	500 ml	prn intravenous drip
Concomitant therapy	Aluminum hydroxide gel/magnesium hydroxide	03jul2013 (71)	07jul2013 (75)	Adverse event	3.6 g	daily oral
Concomitant therapy	Azathioprine	08jul2013 (76)	03sep2013 (133)	Ulcerative colitis	25 mg	qd oral
Concomitant therapy	Azathioprine	04sep2013 (134)	ongoing	Ulcerative colitis	25 mg	qd oral
Concomitant therapy	Clostridium butyricum	prior to IC	09jul2013 (77)	Ulcerative colitis	60 mg	daily oral
Concomitant therapy	Clostridium butyricum	10jul2013 (78)	ongoing	Ulcerative colitis	80 mg	bid oral
Concomitant therapy	Colibacillus vaccine/hydrocortisone	08jul2013 (76)	ongoing	Adverse event	other	qd topical
Concomitant therapy	Enteral nutrition	09jun2013 (47)	10jun2013 (48)	Nutritional supplement	80 g	daily oral

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
Concomitant therapy	Enteral nutrition	11jun2013 (49)	28jun2013 (66)	Nutritional supplement	200 ml	qd oral
Concomitant therapy	Esomeprazole magnesium hydrate	prior to IC	ongoing	Concomitant disease	10 mg	qd oral
Concomitant therapy	Ferric oxide,saccharated	03jun2013 (41)	03jun2013 (41)	Adverse event	40 mg	prn intravenous drip
Concomitant therapy	Ganciclovir	29may2013 (36)	09jun2013 (47)	Adverse event	350-700 mg	daily intravenous drip
Concomitant therapy	Indometacin	10jul2013 (78)	23jul2013 (91)	Adverse event	70 mg	qd topical
Concomitant therapy	Lidocaine hydrochloride	10jun2013 (48)	ongoing	Endoscopy	other	qd topical
Concomitant therapy	Magnesium oxide	21jun2013 (59)	22jun2013 (60)	Adverse event	660 mg	qd oral
Concomitant therapy	Magnesium oxide	08jul2013 (76)	ongoing	Adverse event	0-0.33 g	prn oral
Concomitant therapy	Maintenance medium	02jun2013 (40)	19jun2013 (57)	Prophylaxis against dehydration	500 ml	qd intravenous drip
Concomitant therapy	Maintenance medium	26jun2013 (64)	26jun2013 (64)	Prophylaxis against dehydration	500 ml	qd intravenous drip
Concomitant therapy	Mesalazine	prior to IC	22may2013 (29)	Ulcerative colitis	4.0 g	daily oral
Concomitant therapy	Mesalazine	22may2013 (29)	29may2013 (36)	Ulcerative colitis	1200 mg	bid oral
Concomitant therapy	Mesalazine	30may2013 (37)	09jul2013 (77)	Ulcerative colitis	1200 mg	tid oral
Concomitant therapy	Mesalazine	24jun2013 (62)	ongoing	Ulcerative colitis	1 g	qd rectal
Concomitant therapy	Mesalazine	10jul2013 (78)	ongoing	Ulcerative colitis	1600 mg	bid oral
Concomitant therapy	Sulfamethoxazole/trimethoprim	10jun2013 (48)	ongoing	Pneumocystis carinii prophylaxis	1 tablet	bid oral
Concomitant therapy	Tacrolimus hydrate	08jun2013 (46)	09jun2013 (47)	Ulcerative colitis	1.5 mg	daily oral
Concomitant therapy	Tacrolimus hydrate	10jun2013 (48)	11jun2013 (49)	Ulcerative colitis	4 mg	daily oral
Concomitant therapy	Tacrolimus hydrate	12jun2013 (50)	13jun2013 (51)	Ulcerative colitis	11 mg	daily oral
Concomitant therapy	Tacrolimus hydrate	14jun2013 (52)	20jun2013 (58)	Ulcerative colitis	13 mg	daily oral
Concomitant therapy	Tacrolimus hydrate	21jun2013 (59)	26jun2013 (64)	Ulcerative colitis	5.5 mg	daily oral
Concomitant therapy	Tacrolimus hydrate	27jun2013 (65)	30jul2013 (98)	Ulcerative colitis	10 mg	daily oral
Concomitant therapy	Tacrolimus hydrate	31jul2013 (99)	ongoing	Ulcerative colitis	4.5 mg	daily oral
Concomitant therapy	Tribenoside/lidocaine	08may2013 (15)	14may2013 (21)	Adverse event	other	bid topical
Concomitant therapy	Trimebutine maleate	24jul2013 (92)	ongoing	Adverse event	300 mg	daily oral
UC surgeries/procedures	(Other surgery)	03jun2013 (41)	-	Uc	-	-
UC surgeries/procedures	(Other surgery)	07jun2013 (45)	-	Uc	-	-
UC surgeries/procedures	(Other surgery)	10jun2013 (48)	-	Uc	-	-

Category	Concomitant Therapy	Start Date(Study Day)	End Date(Study Day)	Reason for Administration	Dose	Frequency/Route
UC surgeries/procedures	(Other surgery)	13jun2013 (51)	-	Uc	-	-
UC surgeries/procedures	(Other surgery)	17jun2013 (55)	-	Uc	-	-
UC surgeries/procedures	(Other surgery)	24jun2013 (62)	-	Uc	-	-