ウパシタ静注透析用25μgシリンジ
ウパシタ静注透析用50μgシリンジ
ウパシタ静注透析用100μgシリンジ
ウパシタ静注透析用150μgシリンジ
ウパシタ静注透析用200μgシリンジ
ウパシタ静注透析用250μgシリンジ
ウパシタ静注透析用300μgシリンジ

第2部（モジュール2）

2.7.3 臨床的有効性

株式会社三和化学研究所

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略号一覧表

略号	略号内容
BAP	Bone specific alkaline phosphatase　骨型アルカリフォスファターゼ
CaSR	Calcium-sensing receptor　カルシウム感知受容体
CKD-MBD	CKD-mineral and bone disorder　慢性腎臓病に伴う骨・ミネラル代謝異常
FAS	Full analysis set　最大の解析対象集団
HD	Hemodialysis　血液透析
HDF	Hemodiafiltration　血液透析濾過
iFGF23	intact fibroblast growth factor 23　インタクト線維芽細胞増殖因子 23
iPTH	intact parathyroid hormone　インタクト副甲状腺ホルモン
P1NP	type I procollagen N-terminal propeptide　I 型プロコラーゲン架橋 N-プロペプチド
PPS	Per protocol set　治験実施計画書に適合した対象集団
PTH	Parathyroid hormone　副甲状腺ホルモン
QTcF	Corrected QT interval with Fridericia method　Fridericia による補正 QT
SHPT	Secondary hyperparathyroidism　二次性副甲状腺機能亢進症
TRACP-5b	Tartrate-resistant acid phosphatase-5b　酒石酸抵抗性酸性フォスファターゼ
whole-PTH	whole parathyroid hormone　ホール副甲状腺ホルモン

2.7.3 臨床的有効性の概要

2.7.3.1 背景及び概観

2.7.3.1.1 試験の概観

SK-1403 について，臨床的有効性及び安全性を検討した試験の概略を表 2.7.3－1 に示した。全ての試験は国内で実施され，全て評価資料とした。

表 2.7.3－1 維持血液透析下の SHPT 患者を対象に臨床的有効性及び安全性を検討した試験の概略

試験番号	目的	デザイン	投与期間	例数	主要評価項目	添付資料番号
AJ1002 （第 II 相用量調整試験）	治療第 I 期 有効性及び安全性の検討 治療第 II 期 長期投与の安全性及び有効性の検討	多施設共同 非盲検 非対照 個体内用量調整	52 週間 治療第 I 期 18 週間 治療第 II 期 34 週間	目標 60 例 登録 58 例	18 週時の血清 iPTH 濃度が 60 pg/mL 以上 240 pg/mL 以下を達成した被験者の割合	5.3.5.2-1
AJ1003 （第 III 相長期投与試験）	長期投与の安全性及び有効性の検討	多施設共同 非盲検 非対照 個体内用量調整	52 週間	目標 160 例 登録 157 例	設定なし	5.3.5.2-2
AJ1004 （第 III 相比較試験）	プラセボを対照とした優越性の検証及び安全性の検討	多施設共同 ランダム化 プラセボ対照 二重盲検 並行群間比較 個体内用量調整	24 週間	目標 150 例 SK-1403 群 100 例 プラセボ群 50 例 登録 154 例 SK-1403 群 103 例 プラセボ群 51 例*	治療期 22，23，24 週時における血清 iPTH 濃度平均値が 60 pg/mL 以上 240 pg/mL 以下を達成した被験者の割合	5.3.5.1-1

*：1 例は割付後未投与のため、投与例数は 50 例

2.7.3.1.2 試験デザイン

臨床的有効性及び安全性を検討した表 2.7.3－1 の 3 試験において，対象は維持血液透析下の二次性副甲状腺機能亢進症（以下，SHPT）患者とした。また，SK-1403 は血清インタクト副甲状腺ホルモン（以下，iPTH）濃度及び血清補正 Ca 濃度が管理目標範囲内に維持されるように個体内で用量調整を行う薬剤であることから，これら 3 試験は個体内用量調整で試験を実施した。主要な有効性評価項目は 3 試験とも，血清 iPTH 濃度が管理目標（60 pg/mL 以上 240 pg/mL）を達成した被験者の割合とした。

第 II 相用量調整試験である AJ1002 試験は，有効性及び安全性の検討を目的に，非対照，非盲検で実施した。試験スケジュールを図 2.7.3－1 に示した。投与期間を 52 週間とし，治

療第 I 期は，開始用量及び用量調整方法を検討することを目的に実施した。主要評価項目は 18 週時における血清 iPTH 濃度が管理目標を達成した被検者の割合とした。治療第 II 期では，長期投与した場合の安全性及び有効性を評価するため，治療第 I 期を完遂した症例に対して SK-1403 を 34 週間継続投与した。

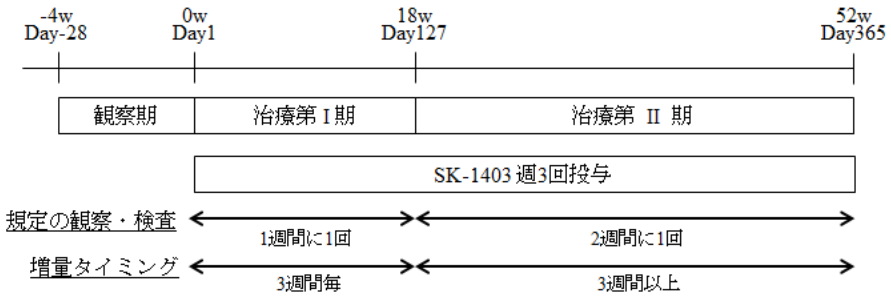


図 2.7.3－1　試験スケジュール（AJ1002 試験）

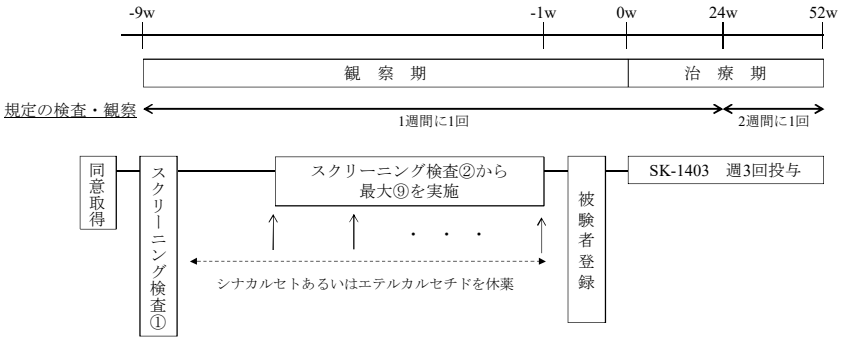
［資料 5.3.5.2-1 表 9-1 から引用］

第 III 相長期投与試験である AJ1003 試験は, SK-1403 を 52 週間投与した時の安全性及び有効性の検討を目的に，非対照，非盲検で実施した。試験スケジュールについて図 2.7.3－2 に示した。

前治療において，シナカルセト塩酸塩（以下，シナカルセト）あるいはエテルカルセチド塩酸塩（以下，エテルカルセチド）が投与されている場合は，観察期のスクリーニング検査①を実施後に休薬を開始した。スクリーニング検査①で対象基準に合致している場合は翌週より治験薬の投与を開始した。対象基準に合致しなかった場合には，対象基準に合致するまで追加でスクリーニング検査②以降を実施し（スクリーニング検査②は最大 8 回実施可），対象基準に合致したことを確認した翌週より治験薬の投与を開始することとした。

前治療において，シナカルセトあるいはエテルカルセチドが投与されていない場合は，スクリーニング検査①及び②（治験薬投与開始の 2 週間前及び 1 週間前）の連続した 2 回の検査両方で対象基準に合致することを確認した後，翌週より治験薬の投与を開始することとした。

（A）前治療においてシナカルセトあるいはエテルカルセチドが投与されている場合



（B）前治療においてシナカルセトあるいはエテルカルセチドが投与されていない場合

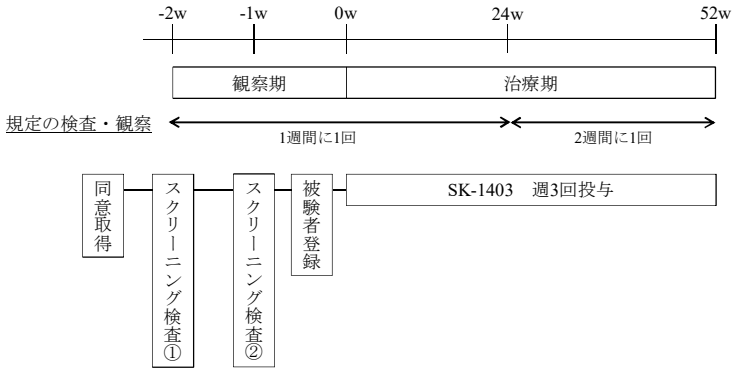


図 2.7.3－2　試験スケジュール（AJ1003 試験）

［資料 5.3.5.2-2 図 9-1 及び図 9-2 から引用］

第 III 相比較試験である AJ1004 試験は，有効性におけるプラセボに対する優越性の検証及び安全性の検討を目的に，ランダム割付，二重盲検，並行群間比較により実施した。試験スケジュールを図 2.7.3－3 に示した。SK-1403 又はプラセボを 24 週間投与し，主要評価項目は血清 iPTH 濃度平均値（22，23，24 週 3 時点の平均値）が管理目標を達成した被験者の割合とした。0 週において各投与群の血清 iPTH 濃度及び血清補正 Ca 濃度に群間の偏りを最小限にするため，治験薬投与開始 1 週間前の血清 iPTH 濃度（500 pg/mL 以上，500 pg/mL 未満）及び血清補正 Ca 濃度（9.0 mg/dL 以上，9.0 mg/dL 未満）を因子とした最小化法により動的割付を行った。

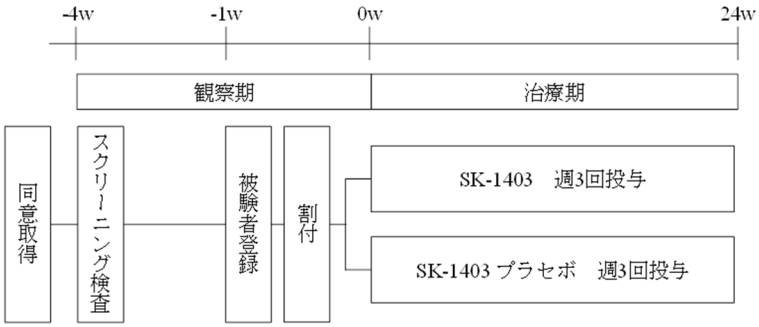


図 2.7.3－3　試験スケジュール（AJ1004 試験）

［資料 5.3.5.1-1 図 9-1 から引用］

2.7.3.1.3 対象

表 2.7.3－2 に各試験の主な選択基準を示した。

対象疾患は，3 試験とも週 3 回の血液透析又は血液透析濾過を施行中の慢性腎不全患者とした。「慢性腎臓病に伴う骨・ミネラル代謝異常の診療ガイドライン（2012）」（以下，CKD-MBD ガイドライン）［3］で，血清 iPTH 濃度の管理目標は 60 pg/mL 以上 240 pg/mL 以下，血清補正 Ca 濃度の管理目標は 8.4～10.0 mg/dL と設定されている。このことから，3 試験とも透析前血清 iPTH 濃度が 240 pg/mL を超える患者を対象とした。また，カルシウム感知受容体（以下，CaSR）活性化作用により血清 Ca 濃度が低下することから，血清補正 Ca 濃度が 8.4 mg/dL 以上の患者を対象とした。

表 2.7.3－2 各試験の主な選択基準

試験番号	AJ1002	AJ1003	AJ1004
対象疾患	週 3 回の血液透析又は血液透析濾過を施行中の慢性腎不全患者	週 3 回の血液透析又は血液透析濾過を施行中の慢性腎不全患者	週 3 回の血液透析又は血液透析濾過を施行中の慢性腎不全患者
血清 iPTH 濃度	連続 2 週間の透析前血清 iPTH 濃度の平均値が 240 pg/mL を超える患者	前治療としてシナカルセトあるいはエテルカルセチドの投与を受けており，休薬開始後，治験薬投与開始 1 週間前の透析前血清 iPTH 濃度が 240 pg/mL を超える患者（休薬期間は 1 週間以上 9 週間以下） 前治療としてシナカルセトあるいはエテルカルセチドの投与を受けておらず，治験薬投与開始 2 週間前及び 1 週間前の透析前血清 iPTH 濃度がともに 240 pg/mL を超える患者	連続 2 週間の透析前血清 iPTH 濃度が 240 pg/mL を超える患者
血清補正 Ca 濃度	透析前血清補正 Ca 濃度が 8.4 mg/dL 以上の患者	前治療としてシナカルセトあるいはエテルカルセチドの投与を受けており，休薬開始後，治験薬投与開始 1 週間前の透析前血清補正 Ca 濃度が 8.4 mg/dL 以上の患者（休薬期間は 1 週間以上 9 週間以下） 前治療としてシナカルセトあるいはエテルカルセチドの投与を受けておらず，治験薬投与開始 1 週間前の血清補正 Ca 濃度が 8.4 mg/dL 以上の患者	透析前血清補正 Ca 濃度が 8.4 mg/dL 以上の患者

各試験の対象患者の違いは，主に前治療における CaSR 作動薬の使用状況である（CaSR 作動薬使用の有無及びその wash out 期間）。

表 2.7.3－3 に，各試験における CaSR 作動薬（シナカルセト，エテルカルセチド及びエボカルセト）の前治療に関する除外基準を示した。AJ1002 試験及び AJ1004 試験では，CaSR 作動薬の持越し効果を排除するため，スクリーニング検査前にシナカルセトは 2 週間以上，エテルカルセチドは少なくとも 8 週間以上使用していない患者を対象とした。AJ1003 試験で

は，患者の多くが既に CaSR 作動薬を使用している臨床実態を考慮し，シナカルセトあるいはエテルカルセチドを使用している患者については，SK-1403 の投与開始までに 1 週以上休薬しており，血清 iPTH 濃度と血清補正 Ca 濃度が選択基準内の患者を対象としたが（表 2.7.3－2），休薬開始後 8 週間を経過しても選択基準を満たさない場合は対象から除外した。AJ1002 試験開始時には発売されていなかったエボカルセトについては，AJ1002 試験では基準を設定していないが，エボカルセト発売以降に実施した AJ1003 試験及び AJ1004 試験ではスクリーニング検査前 1 週間以内に使用していない患者を対象とした。

表 2.7.3－3　各試験の CaSR 作動薬前治療に関する除外基準

試験番号	AJ1002	AJ1003	AJ1004
シナカルセト	スクリーニング検査前 2 週間以内にシナカルセトの投与を受けた患者	スクリーニング検査前 2 週間以内にシナカルセトの用法・用量を変更した患者（新規投与を含む） シナカルセトによる治療を受けている患者で，シナカルセトの休薬期間が 8 週間を経過してもスクリーニング検査時の最大透析間隔後の透析前血清 iPTH 濃度が 240 pg/mL 以下又は最大透析間隔後の透析前血清補正 Ca 濃度が 8.4 mg/dL 未満の患者	スクリーニング検査前 2 週間以内にシナカルセトの投与を受けた患者
エテルカルセチド	スクリーニング検査前 12 週間以内にエテルカルセチドの投与を受けた患者	スクリーニング検査前 4 週間以内にエテルカルセチドの用法・用量を変更した患者（新規投与を含む） エテルカルセチドによる治療を受けている患者で，エテルカルセチドの休薬期間が 8 週間を経過してもスクリーニング検査時の最大透析間隔後の透析前血清 iPTH 濃度が 240 pg/mL 以下又は最大透析間隔後の透析前血清補正 Ca 濃度が 8.4 mg/dL 未満の患者	スクリーニング検査前 8 週間以内にエテルカルセチドの投与を受けた患者
エボカルセト		スクリーニング検査前 1 週間以内にエボカルセトの投与を受けた患者	スクリーニング検査前 1 週間以内にエボカルセトの投与を受けた患者

2.7.3.1.4　有効性評価項目

各試験の有効性評価項目を表 2.7.3－4 に示した。

有効性に関する主要評価項目は AJ1002 試験及び AJ1004 試験で設定し，血清 iPTH 濃度の管理目標である 60 pg/mL 以上 240 pg/mL 以下を達成した被験者の割合とした。なお，AJ1002 試験は治療期 18 週時の血清 iPTH 濃度，AJ1004 試験は治療期 22，23，24 週時の血清 iPTH 濃度平均値で評価した。AJ1003 試験においては主要評価項目を設定しなかったが，各時点における血清 iPTH 濃度が 60 pg/mL 以上 240 pg/mL 以下を達成した被験者の割合を評価項目に

設定した。

有効性のその他の評価項目としては，全ての試験で血清 iPTH 濃度の変化率が-30%又は-50%以下を達成した被験者の割合，SHPT 又は骨・ミネラル代謝異常の評価に使われる各種検査値［血清 iPTH 濃度，血清補正 Ca 濃度，イオン化 Ca（AJ1002 試験では設定せず），血清 P 濃度, 血清補正 Ca×P 積, 血清 whole-PTH 濃度, インタクト線維芽細胞増殖因子（iFGF23），骨型アルカリフォスファターゼ（BAP），1 型プロコラーゲン-N-ペプチド（total P1NP）及び骨型酒石酸抵抗性酸性フォスファターゼ-5b（TRACP-5b）］の測定値及び変化率を設定した。変化率は特に記載のない限りベースラインを 0 週時の測定値とし算出した。また，AJ1003 試験においては副甲状腺体積を設定した。

表 2.7.3－4　各試験の有効性評価項目

AJ1002*	AJ1003	AJ1004
主要評価項目		
治療期 18 週時における血清 iPTH 濃度が 60 pg/mL 以上 240 pg/mL 以下を達成した被験者の割合（治療第 I 期）	設定なし	治療期 22，23，24 週時における血清 iPTH 濃度平均値が 60 pg/mL 以上 240 pg/mL 以下を達成した被験者の割合
その他の評価項目		
・治療期 16，17，18 週時における血清 iPTH 濃度平均値が 60 pg/mL 以上 240 pg/mL 以下を達成した被験者の割合（治療第 I 期） ・治療期 18 週時における血清 iPTH 濃度の変化率が-30%，-50%以下を達成したそれぞれの被験者の割合（治療第 I 期） ・最終投与量別及び最大投与量別の各時点における血清 iPTH の測定値及び変化率（治療第 I 期） ・最終投与量別及び最大投与量別の各時点における血清補正 Ca 濃度及び変化率（治療第 I 期） ・各時点における血清 iPTH 濃度が 60 pg/mL 以上 240 pg/mL 以下を達成した被験者の割合 ・各時点における下記項目の測定値及び変化率 血清 iPTH 濃度，血清補正 Ca 濃度，血清 P 濃度，血清補正 Ca×P 積，血清 whole-PTH 濃度，iFGF23，BAP，total P1NP，TRACP-5b	・各時点における血清 iPTH 濃度が 60 pg/mL 以上 240 pg/mL 以下を達成した被験者の割合 ・各時点における血清 iPTH 濃度の変化率が-30%，-50%以下を達成したそれぞれの被験者の割合 ・各時点における下記項目の測定値及び変化率 血清 iPTH 濃度，血清補正 Ca 濃度，イオン化 Ca，血清 P 濃度，血清補正 Ca×P 積，血清 whole-PTH 濃度, iFGF23, BAP, total P1NP，TRACP-5b ・各時点における副甲状腺体積	・各時点における血清 iPTH 濃度が 60 pg/mL 以上 240 pg/mL 以下を達成した被験者の割合 ・治療期 22，23，24 週時における血清 iPTH 濃度平均値の変化率**が-30%，-50%以下を達成したそれぞれの被験者の割合 ・各時点における血清 iPTH 濃度の変化率が-30%，-50%以下を達成したそれぞれの被験者の割合 ・各時点における下記項目の測定値及び変化率 血清 iPTH 濃度，血清補正 Ca 濃度，イオン化 Ca，血清 P 濃度，血清補正 Ca×P 積，血清 whole-PTH 濃度, iFGF23, BAP, total P1NP，TRACP-5b

*：有効性評価は治療第 I 期終了時と治療第 II 期終了時の 2 回実施した。治療第 I 期の記載がある評価項目については治療第 I 期終了時のみ解析を実施した。

**：治験薬投与開始 2 週間前，1 週間前及び治療期 0 週の血清 iPTH 濃度平均値をベースラインとして算出した。

2.7.3.1.5　用法・用量

SK-1403 は被験者ごとに用量を調整して投与される薬剤である。各試験の用法・用量及び用量調整基準について表 2.7.3－5 に示した。全ての試験で用法・用量，目標血清 iPTH 濃度（60～240 pg/mL），用量調整段階（25 μg から 300 μg までの 7 段階）及び休薬基準（血清補正 Ca 濃度が 7.5 mg/dL 未満若しくは医師が休薬を必要と判断）は同一である。

開始用量については，AJ1001 試験（第 I/II 相試験）の結果に基づき，AJ1002 試験では 50 μg とした。AJ1003 及び AJ1004 試験では，AJ1002 試験の結果を踏まえて，投与初期における血清補正 Ca 濃度の過度の低下（7.5 mg/dL 未満）を抑制するため，治験薬投与開始 1 週間前の血清補正 Ca 濃度が 9.0 mg/dL 未満の場合は開始用量を 25 μg とし，9.0 mg/dL 以上の場合は 50 μg とした。

用量調整基準のうち，増量の基準については，AJ1001 試験において血清 iPTH 濃度及び血清補正 Ca 濃度が SK-1403 投与後 1～2 週間で安定したことを踏まえ，全ての試験で増量時まで同一用量を 3 週間以上維持し，増量直近の血清補正 Ca 濃度が 8.4 mg/dL 以上である場合に増量可とした（2.7.2.2.3.2（2））。さらに，AJ1002 試験治療第 I 期及び AJ1004 試験では，血清 iPTH 濃度が管理目標を達成した被験者の割合を主要評価項目としていることから，増量直近の血清 iPTH 濃度が 240 pg/mL を超えていることを増量基準に設定した。減量の基準はいずれの試験も医師が必要と判断した場合とし，さらに AJ1002 試験治療第 I 期及び AJ1004 試験では血清 iPTH 濃度が 2 週連続して 60 pg/mL 未満の場合に減量することとした。

表 2.7.3−5　用法・用量及び用量調整基準

試験番号	AJ1002	AJ1003	AJ1004
用法・用量	週 3 回，血液透析終了後，透析回路静脈側に 25～300 μg の範囲で投与		
目標血清 iPTH 濃度	60～240 pg/mL	60～240 pg/mL （目安として 150 pg/mL）	60～240 pg/mL
用量調整段階	25 μg，50 μg，100 μg，150 μg，200 μg，250 μg，300 μg の 7 段階 増量及び減量は 1 段階		
開始用量	50 μg	-1 週の血清補正 Ca 濃度が 9.0 mg/dL 未満の場合 25 μg 9.0 mg/dL 以上の場合 50 μg	
増量基準 （全て満たした場合）	治療第 I 期 増量タイミングは 3 週間隔 ・同一用量を 3 週間以上維持 ・1 週前の血清 iPTH 濃度が 240 pg/mL を超え，かつ血清補正 Ca 濃度が 8.4 mg/dL 以上 ・安全性に問題がないと判断 治療第 II 期 増量タイミングは 3 週間以上 ・同一用量を 3 週間以上維持 ・直近の血清補正 Ca 濃度が 8.4 mg/dL 以上 ・安全性に問題がないと判断	・同一用量を 3 週間以上維持 ・直近の血清補正 Ca 濃度が 8.4 mg/dL 以上 ・安全性に問題がないと判断	・同一用量を 3 週間以上維持 ・直近の血清 iPTH 濃度が 240 pg/mL を超え，かつ血清補正 Ca 濃度が 8.4 mg/dL 以上 ・安全性に問題がないと判断
減量基準 （いずれか該当する場合）	治療第 I 期 ・血清 iPTH 濃度が 2 週連続して 60 pg/mL 未満 ・減量が必要と判断 治療第 II 期 ・減量が必要と判断 25 μg 投与中の場合は休薬	・減量が必要と判断 25 μg 投与中の場合は休薬	・血清 iPTH 濃度が 2 週連続して 60 pg/mL 未満 ・減量が必要と判断 25 μg 投与中の場合は休薬
休薬基準 （いずれか該当する場合）	・血清補正 Ca 濃度が 7.5 mg/dL 未満 ・休薬が必要と判断 投与再開は血清補正 Ca 濃度が 8.4 mg/dL 以上		

2.7.3.1.6　治験薬の投与期間

AJ1002 試験の治療第 I 期の投与期間については，SK-1403　50 μg より投与を開始し，増量基準に従って最大用量 300 μg まで増量が必要となった場合に 18 週間の投与期間が必要であることから，18 週間とした。治療第 II 期の投与期間は長期安全性を評価するため治療第 I 期と合わせて 52 週間となるように 34 週間とした。AJ1003 試験の投与期間は，長期投与での安全性を評価するため 52 週間とした。AJ1004 試験の投与期間は，SK-1403　25 μg から投与を開始し，最大用量 300 μg まで増量が必要となった場合に 21 週間の評価期間が必要であるため及び 6 か月の長期投与での安全性を評価するために 24 週間とした。

2.7.3.1.7　併用薬剤及び併用療法

併用制限薬及びその制限条件を表 2.7.3－6 に示した。

観察期は，全ての試験でカルシウム製剤及びリン吸着薬並びに活性型ビタミン D 製剤の用法・用量の変更又は新規投与開始について，被験者の適格性に影響を及ぼす可能性があるため不可とした。

治療期は, CKD-MBD ガイドラインにて血清 PTH 濃度管理に優先して血清 P 濃度及び血清補正 Ca 濃度を管理することが推奨されていることから，全ての試験でカルシウム製剤及びリン吸着薬の用法・用量の変更又は新規投与開始を可とした。活性型ビタミン D 製剤については，AJ1002 試験の治療第 I 期及び AJ1004 試験において，原則として用法・用量の変更又は新規投与開始を不可としたが，救済治療に該当するような特定の条件を満たした場合には用法・用量の変更又は新規投与開始を可とした。AJ1002 試験の治療第 II 期及び AJ1003 試験においては，市販後の臨床使用実態を考慮し活性型ビタミン D 製剤の用法・用量の変更又は新規投与開始を可とした。

併用禁止薬及び併用禁止開始時期を表 2.7.3－7 に示した。各薬剤の併用禁止開始時期はそれぞれの半減期及び効果持続期間を考慮して設定した。

透析条件［透析方法（血液透析から血液透析濾過への変更等），ダイアライザー，透析液，処方透析時間，処方血液流量，処方透析液流量］については，観察期は変更禁止とし，治療期は原則変更禁止とした。AJ1003 試験の治療期については市販後の臨床使用実態を考慮し変更可とした。

表 2.7.3－6　併用制限薬及び制限条件

試験番号	AJ1002	AJ1003	AJ1004
カルシウム製剤及びリン吸着薬	観察期 用法・用量の変更又は新規投与開始を禁止 治療期 用法・用量の変更又は新規投与開始は可 以下の場合，カルシウム製剤（Ca 含有リン吸着薬を含む）の増量又は新規投与を考慮 ・血清補正 Ca 濃度が目安として 8.4 mg/dL 未満 ・症候性の低 Ca 血症が発現	観察期 用法・用量の変更又は新規投与開始禁止 治療期 用法・用量の変更又は新規投与開始は可 以下の場合，カルシウム製剤（Ca 含有リン吸着薬を含む）の増量又は新規投与を考慮 ・血清補正 Ca 濃度が目安として 8.4 mg/dL 未満 ・症候性の低 Ca 血症が発現 血清補正 Ca 濃度が高値の場合（目安として 11.0 mg/dL），カルシウム製剤（Ca 含有リン吸着薬を含む）の減量又は中止を考慮	観察期 用法・用量の変更又は新規投与開始を禁止 治療期 用法・用量の変更又は新規投与開始は可 以下の場合，カルシウム製剤（Ca 含有リン吸着薬を含む）の増量又は新規に投与開始を考慮 ・血清補正 Ca 濃度が目安として 8.4 mg/dL 未満 ・症候性の低 Ca 血症が発現
活性型ビタミン D 製剤	観察期 用法・用量の変更又は新規投与開始を禁止 治療第 I 期 用法・用量の変更又は新規投与開始を禁止 以下の場合でカルシウム製剤の増量又は新規投与を行っても改善が認められない場合，増量又は新規投与可 ・血清補正 Ca 濃度が 7.5 mg/dL 未満 ・症候性の低 Ca 血症が発現 血清補正 Ca 濃度が高値の場合（目安として 11.0 mg/dL），減量又は中止は可（なお，減量後又は中止後に，減量前又は中止前の用量まで戻すことも可） 治療期 II 期 用法・用量の変更又は新規投与開始は可	観察期 用法・用量の変更又は新規投与開始禁止 治療期 用法・用量の変更又は新規投与開始は可 以下の場合，活性型ビタミン D 製剤の増量又は新規投与を考慮 ・血清補正 Ca 濃度が目安として 8.4 mg/dL 未満 ・症候性の低 Ca 血症が発現 血清補正 Ca 濃度が高値の場合（目安として 11.0 mg/dL），活性型ビタミン D 製剤の減量又は中止を考慮	観察期 用法・用量の変更又は新規投与開始を禁止 治療期 用法・用量の変更又は新規投与開始を禁止 以下の場合，用法・用量の変更又は新規投与開始は可 血清 iPTH 濃度高値 ・3 週以降の血清 iPTH 濃度が 0 週の 2 倍以上 ・12 週以降の血清 iPTH 濃度が 0 週の 1.5 倍以上 血清補正 Ca 濃度低値 以下の場合でカルシウム製剤の増量又は新規投与を行っても改善が認められない場合 ・血清補正 Ca 濃度が 7.5 mg/dL 未満（治験薬休薬） ・症候性の低 Ca 血症が発現 血清補正 Ca 濃度が高値の場合（目安として 11.0 mg/dL），減量又は中止は可（なお，減量後又は中止後に血清補正 Ca 濃度が 8.4～10.0 mg/dL となり，必要と判断された場合，減量前又は中止前の用量までの範囲に戻すことは可）

表 2.7.3－7　併用禁止薬及び併用禁止開始時期

併用禁止開始時期*	AJ1002	AJ1003	AJ1004
スクリーニング検査時から		シナカルセト，エテルカルセチド	
スクリーニング検査前1週間から		エボカルセト	エボカルセト
スクリーニング検査前2週間から	シナカルセト，エストロゲンホルモン剤，合成エストロゲン製剤，選択的エストロゲン受容体モジュレーター，カルシトニン製剤	エストロゲンホルモン剤，合成エストロゲン製剤，選択的エストロゲン受容体モジュレーター，カルシトニン製剤	シナカルセト，エストロゲンホルモン剤，合成エストロゲン製剤，選択的エストロゲン受容体モジュレーター，カルシトニン製剤
スクリーニング検査前8週間から			エテルカルセチド
スクリーニング検査前12週間から	エテルカルセチド		
スクリーニング検査前24週間から	ビスホスホネート製剤，抗 RANKL モノクローナル抗体，副甲状腺ホルモン製剤（テリパラチド）	ビスホスホネート製剤，抗 RANKL モノクローナル抗体，副甲状腺ホルモン製剤（テリパラチド），抗スクレロスチンモノクローナル抗体	ビスホスホネート製剤，抗 RANKL モノクローナル抗体，副甲状腺ホルモン製剤（テリパラチド），抗スクレロスチンモノクローナル抗体
スクリーニング検査前52週間から		ゾレドロン酸水和物注射液（リクラスト点滴静注液）	ゾレドロン酸水和物注射液（リクラスト点滴静注液）
過去の使用	ゾレドロン酸水和物注射液（リクラスト点滴静注液）		

*：スクリーニング検査から SK-1403 投与までの期間は，AJ1002 試験及び AJ1004 試験では最短 1 週間，AJ1003 試験ではシナカルセトあるいはエテルカルセチドによる治療を受けている場合は最短 1 週間，受けていない場合は最短 2 週間

2.7.3.1.8　解析方法

(1) 解析集団

全ての試験において，有効性評価のための主要解析対象集団は最大の解析対象集団である FAS とした。ただし，主要評価項目の副次解析として治験実施計画書に適合した対象集団である PPS を対象とした解析も実施した。

(2) 欠測値に関する取り扱い

全ての試験において，治療期 0 週時のデータが欠測の場合は観察期のデータで補完した。治療期 0 週時以外の欠測値については補完しなかった。

なお，AJ1004 試験における主要評価項目の解析では，以下に該当する被験者は主要評価項目を達成しなかった被験者として取り扱うこととし，解析対象に加えた。

・治療期 22，23，24 週時の血清 iPTH 濃度のデータが 1 点もない被験者
・血清 iPTH 濃度高値のため救済治療として活性型ビタミン D 製剤の用法・用量の変更，あるいは新規に投与開始された被験者

(3) 主な有効性の解析方法

1) 血清 iPTH 濃度の管理目標を達成した被験者の割合

全ての試験で管理目標を達成した被験者の割合及び両側 95%信頼区間を算出した。比較試験である AJ1004 試験は，各投与群の管理目標を達成した被験者の割合について，投与群間の差及び両側 95%信頼区間を算出するとともに Fisher の直接確率検定を用いて群間比較を行った。また，管理目標を達成した被験者の割合を目的変数として，Logistic 回帰分析で影響因子の検討を行い，選択された影響因子により層別した Mantel-Haenszel 検定を行って主要評価項目に対する影響を検討した。

2) 他の有効性評価項目

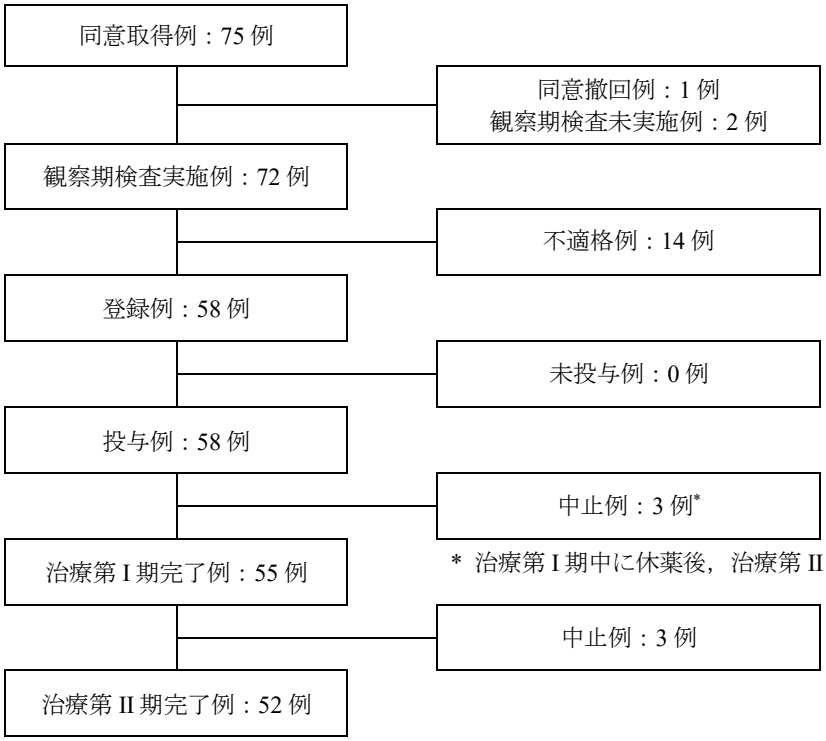
血清 iPTH 濃度の変化率が-30%，-50%以下を達成したそれぞれの被験者の割合及び両側 95%信頼区間を算出した。各評価項目の測定値及びベースラインからの変化率に関しては要約統計量を算出した。また，各項目の測定値について，AJ1004 試験は繰り返しのある二元配置分散分析を行い，AJ1003 試験は繰り返しのない二元配置分散分析を行った。

2.7.3.2 個々の試験結果の要約

2.7.3.2.1 AJ1002 試験（第 II 相用量調整試験）［資料 5.3.5.2-1］

2.7.3.2.1.1 被験者の内訳

被験者の内訳を図 2.7.3－4 に示した。



* 治療第 I 期中に休薬後，治療第 II 期で中止判断された 2 例を含む

図 2.7.3－4 被験者の内訳

［資料 5.3.5.2-1 図 10-2 から改変引用］

75 例から同意を取得し，そのうち 72 例で観察期検査を実施した。観察期検査で 14 例が不適格となり，58 例が登録された。登録後に治験薬の投与に至らなかった未投与症例はなく，58 例全例に SK-1403 が投与された。中止症例は 6 例あり，完了症例は 52 例であった。中止症例の内訳は，有害事象の発現により治験責任医師又は治験分担医師によって治験の継続が困難であると判断された症例が 3 例，継続した治験薬の休薬が 6 週間を超えた症例が 1 例，治験責任医師又は治験分担医師の医学的判断により治験中止の必要性を認めた症例が 2 例であった。

2.7.3.2.1.2 主要評価項目（治療第Ⅰ期）

治療期 18 週時における血清 iPTH 濃度が 60 pg/mL 以上 240 pg/mL 以下を達成した被験者の割合（目標達成率）を表 2.7.3－8 に示した。目標達成率は 57.9%（33 例/57 例）［95%信頼区間：44.1% - 70.9%］であった。

表 2.7.3－8　治療期 18 週時の血清 iPTH 濃度　目標達成率（治療第Ⅰ期）

	血清 iPTH 濃度目標			
対象被験者数	達成	未達成	目標達成率	95%信頼区間
57	33	24	57.9%	44.1% - 70.9%

［資料 5.3.5.2-1 表 14.2.1-1 から改変引用］

2.7.3.2.1.3　副次評価項目

（1）治療第Ⅰ期

治療期 18 週時における血清 iPTH 濃度のベースライン（治療期 0 週時測定値，以下本項中同じ）からの変化率が-30%又は-50%以下を達成した被験者の割合はそれぞれ，68.4%（39 例/57 例）［95%信頼区間：54.8% - 80.1%］及び 47.4%（27 例/57 例）［95%信頼区間：34.0% - 61.0%］であった。

治療期 16，17，18 週時における血清 iPTH 濃度平均値の目標達成率は，57.9%（33 例/57 例）［95%信頼区間：44.1% - 70.9%］であった。

治療期 18 週時における最終投与量別（0 μg，25 μg，50 μg，100 μg，150 μg，200 μg，250 μg 及び 300 μg）の血清 iPTH 濃度は，それぞれ 158.3 ± 132.1 pg/mL（4 例），166.2 ± 82.1 pg/mL（9 例），171.8 ± 94.9 pg/mL（16 例），253.0 ± 131.4 pg/mL（5 例），196.4 ± 84.9 pg/mL（8 例），307.7 ± 111.7 pg/mL（3 例），476.7 ± 204.5 pg/mL（3 例）及び 346.3 ± 146.2 pg/mL（9 例）であった。また，ベースラインからの血清 iPTH 濃度変化率は，それぞれ-51.2 ± 37.4%, -42.9 ± 24.4%, -27.5 ± 60.1%, -39.9 ± 27.0%, -50.3 ± 34.1%, -45.6 ± 20.3%, -42.7 ± 20.7%及び-27.9 ± 25.2%であった。

治療期 18 週時における最大投与量別（50 μg，100 μg，150 μg，200 μg，250 μg 及び 300 μg）の血清 iPTH 濃度は，それぞれ 164.5 ± 92.4 pg/mL（28 例），256.3 ± 117.8 pg/mL（6 例），196.4 ± 84.9 pg/mL（8 例），307.7 ± 111.7 pg/mL（3 例），476.7 ± 204.5 pg/mL（3 例）及び 346.3 ± 146.2 pg/mL（9 例）であった。また，ベースラインからの血清 iPTH 濃度変化率は，それぞれ-36.2 ± 49.2%，-36.1 ± 25.9%，-50.3 ± 34.1%，-45.6 ± 20.3%，-42.7 ± 20.7%及び-27.9 ± 25.2%であった。

治療期 18 週時における最終投与量別（0 μg，25 μg，50 μg，100 μg，150 μg，200 μg，250 μg 及び 300 μg）の血清補正 Ca 濃度は，それぞれ 9.33 ± 0.83 mg/dL（4 例），8.13 ± 0.32 mg/dL（9 例），8.68 ± 0.59 mg/dL（15 例），8.54 ± 0.18 mg/dL（5 例），8.74 ± 0.43 mg/dL（8 例），8.17 ± 0.35 mg/mL（3 例），8.37 ± 0.15 mg/dL（3 例）及び 8.54 ± 0.61 mg/dL（9 例）であった。また，ベースラインからの血清補正 Ca 濃度変化率は，それぞれ 4.8 ± 8.3%, -7.2 ± 3.2%，-8.7 ± 4.5%，-11.5 ± 3.4%，-10.4 ± 3.8%，-16.7 ± 2.3%，-17.8 ± 5.6%及び-17.6 ± 6.1%であった。

治療期 18 週時における最大投与量別（50 μg，100 μg，150 μg，200 μg，250 μg 及び 300 μg）の血清補正 Ca 濃度は，それぞれ 8.63 ± 0.66 mg/dL（27 例），8.42 ± 0.34 mg/dL（6 例），8.74 ± 0.43 mg/dL（8 例），8.17 ± 0.35 mg/dL（3 例），8.37 ± 0.15 mg/dL（3 例）及び 8.54 ± 0.61 mg/dL（9 例）であった。また，ベースラインからの血清補正 Ca 濃度変化率は，それぞれ-6.1 ± 6.6%，-11.5 ± 3.0%，-10.4 ± 3.8%，-16.7 ± 2.3%，-17.8 ± 5.6%及び-17.6 ± 6.1%であった。

(2) 治療第 I 期と治療第 II 期

各検査時点における血清 iPTH 濃度の目標達成率の推移を表 2.7.3－9 に示した。治療期 6 週で 50%を超え，その後徐々に増加して治療期 18 週で 58.9%（33 例/56 例），34 週で 69.8%（37 例/53 例）及び 52 週で 80.8%（42 例/52 例）であった。

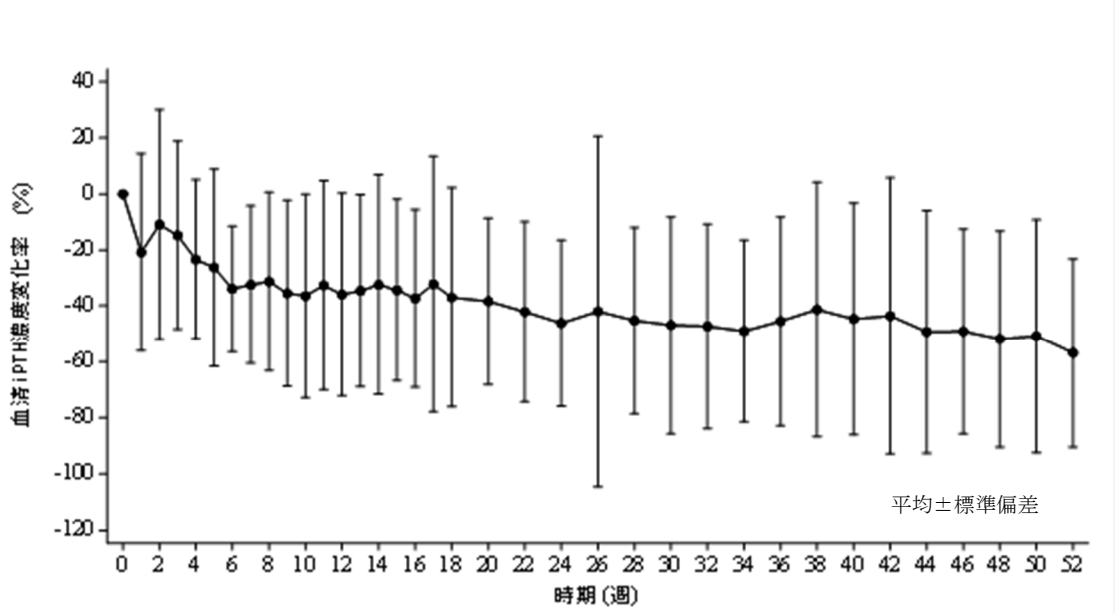
表 2.7.3－9 各検査時点における血清 iPTH 濃度の目標達成率の推移

時期	対象被験者数	血清 iPTH 濃度目標		目標達成率	95%信頼区間
		達成	未達成		
0 週	58	11	47	19.0%	9.9% - 31.4%
1 週	58	24	34	41.4%	28.6% - 55.1%
2 週	58	20	38	34.5%	22.5% - 48.1%
3 週	58	23	35	39.7%	27.0% - 53.4%
4 週	57	19	38	33.3%	21.4% - 47.1%
5 週	57	26	31	45.6%	32.4% - 59.3%
6 週	57	33	24	57.9%	44.1% - 70.9%
7 週	57	32	25	56.1%	42.4% - 69.3%
8 週	57	29	28	50.9%	37.3% - 64.4%
9 週	57	29	28	50.9%	37.3% - 64.4%
10 週	57	31	26	54.4%	40.7% - 67.6%
11 週	57	30	27	52.6%	39.0% - 66.0%
12 週	57	29	28	50.9%	37.3% - 64.4%
13 週	57	32	25	56.1%	42.4% - 69.3%
14 週	57	31	26	54.4%	40.7% - 67.6%
15 週	57	34	23	59.6%	45.8% - 72.4%
16 週	55	32	23	58.2%	44.1% - 71.3%
17 週	56	30	26	53.6%	39.7% - 67.0%
18 週	56	33	23	58.9%	45.0% - 71.9%
20 週	54	32	22	59.3%	45.0% - 72.4%
22 週	53	37	16	69.8%	55.7% - 81.7%
24 週	54	38	16	70.4%	56.4% - 82.0%
26 週	51	35	16	68.6%	54.1% - 80.9%
28 週	53	39	14	73.6%	59.7% - 84.7v
30 週	53	36	17	67.9%	53.7% - 80.1%
32 週	53	38	15	71.7%	57.7% - 83.2%
34 週	53	37	16	69.8%	55.7% - 81.7%
36 週	53	39	14	73.6%	59.7% - 84.7%
38 週	53	36	17	67.9%	53.7% - 80.1%
40 週	53	37	16	69.8%	55.7% - 81.7%
42 週	53	32	21	60.4%	46.0% - 73.5%
44 週	53	42	11	79.2%	65.9% - 89.2%
46 週	53	39	14	73.6%	59.7% - 84.7%
48 週	52	41	11	78.8%	65.3% - 88.9%
50 週	50	40	10	80.0%	66.3% - 90.0%
52 週	52	42	10	80.8%	67.5% - 90.4%

［資料 5.3.5.2-1 表 14.2.11-1 から改変引用］

18 週の目標達成率については，2.7.3.2.1.2 主要評価項目の解析結果（57.9%，33 例/57 例）と対象被験者数が 1 例少なく異なっている。この違いは，治療第 I 期と治療第 II 期の解析におけるデータの取り扱いで，中止症例の中止時データは最終投与時データとするという規定により，治療第 I 期中に休薬後，治療第 II 期に中止判断された 2 例（図 2.7.3－4）について，休薬開始後のデータは不採用としていることによる（治療第 I 期の解析では休薬中のため採用）。ただし，この 2 例のうち，1 例は最終投与の時期から 18 週データを採用となっているため，主要評価の 57 例と比較し 1 例少なくなっている。

血清 iPTH 濃度変化率の推移を図 2.7.3－5 に示した。血清 iPTH 濃度（変化率）は，治療期 0 週に 407.3 ± 233.7 pg/mL であったのに対し，治療期 18 週，34 週及び 52 週ではそれぞれ 234.4 ± 138.6 pg/mL（-37.0 ± 39.2%），177.5 ± 92.1 pg/mL（-49.0 ± 32.4%）及び 144.6 ± 68.3 pg/mL（-56.9 ± 33.6%）であり，SK-1403 の投与開始後徐々に低下した。



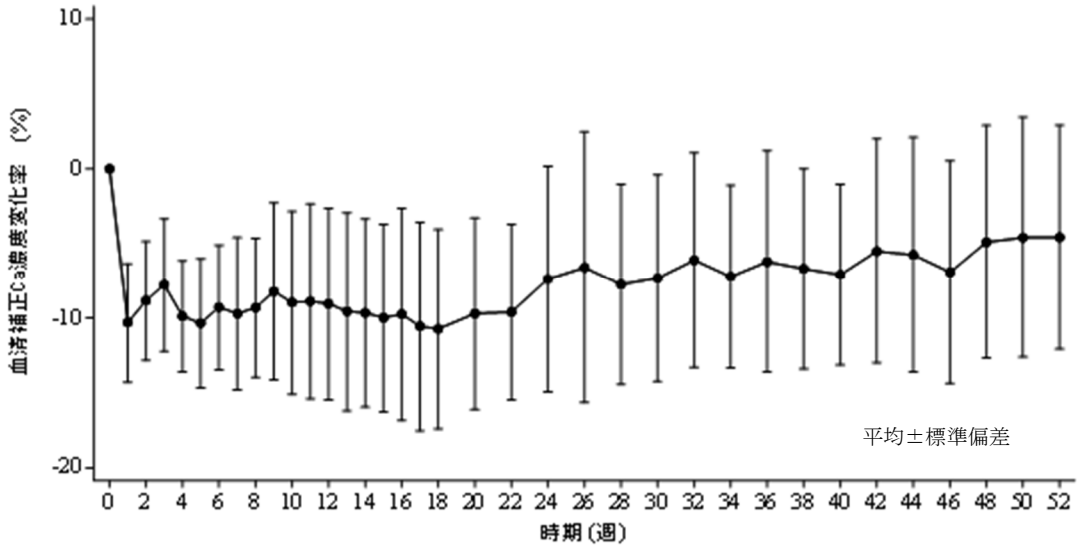
週	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
症例数	58	58	58	57	57	57	57	57	57	57	57	57	57	57	57	55	56	56	54	53	54	51	53	53	53	53	53	53	53	53	53	53	52	50	52

図 2.7.3－5　血清 iPTH 濃度変化率の推移

［資料 5.3.5.2-1 図 14.2.4-1 から改変引用］

血清 whole-PTH 濃度（変化率）は，治療期 0 週に 222.99 ± 110.58 pg/mL であったのに対し，治療期 18 週，34 週及び 52 週ではそれぞれ 146.07 ± 96.40 pg/mL（-30.9 ± 41.3%），111.95 ± 68.01 pg/mL（-43.4 ± 38.3%）及び 80.04 ± 49.49 pg/mL（-58.4 ± 33.4%）であり，SK-1403 の投与開始後徐々に低下した。

血清補正 Ca 濃度変化率の推移について図 2.7.3－6 に示した。血清補正 Ca 濃度（変化率）は治療期 0 週の 9.56 ± 0.68 mg/dL から治療期 1 週で 8.58 ± 0.77 mg/dL（-10.3 ± 4.0%）と SK-1403 の投与開始早期から低下が認められたが，治療期 1 週以降はさらに低下することなくほぼ一定に推移し，治療期 18 週は 8.55 ± 0.56 mg/dL（-10.7 ± 6.7%）であった。治療第 II 期（18 週以降）では，血清補正 Ca 濃度は緩やかに上昇し，治療期 34 週及び 52 週では 8.86 ± 0.58 mg/dL（-7.2 ± 6.1%）及び 9.13 ± 0.81 mg/dL（-4.6 ± 7.5%）であった。

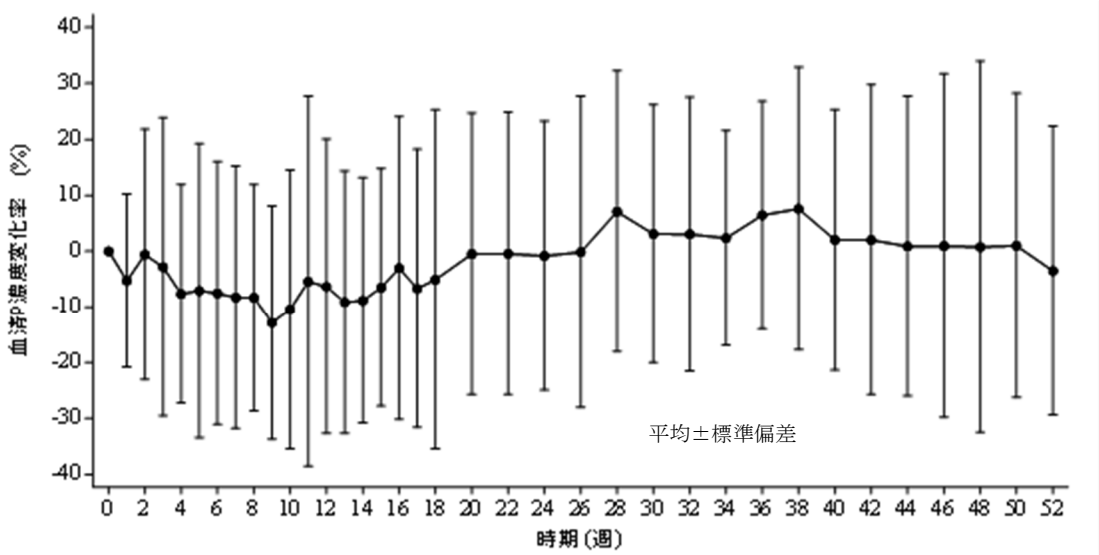


週	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
症例数	58	57	57	57	57	57	57	57	57	56	57	57	57	57	57	55	56	55	53	52	54	53	52	53	53	53	53	53	53	53	52	52	51	50	52

図 2.7.3－6　血清補正 Ca 濃度変化率の推移

［資料 5.3.5.2-1 図 14.2.4-1 から改変引用］

血清 P 濃度変化率の推移を図 2.7.3－7 に示した。血清 P 濃度（変化率）は治療期 0 週で 5.33 ± 1.13 mg/dL であったのに対し, 治療期 18 週, 34 週及び 52 週でそれぞれ 4.98 ± 1.63 mg/dL (-5.1 ± 30.4%), 5.31 ± 1.30 mg/dL (2.4 ± 19.2%) 及び 4.93 ± 1.35 mg/dL (-3.5 ± 25.8%) であった。治療第 I 期に低下がみられたものの，治療第 II 期においてはベースラインに対し大きな変化はなかった。



週	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
症例数	58	58	58	57	57	57	57	57	57	57	57	57	57	57	57	55	56	56	53	53	54	53	53	53	53	53	53	53	53	53	53	53	52	50	52

図 2.7.3－7　血清 P 濃度変化率の推移

［資料 5.3.5.2-1 図 14.2.4-1 から改変引用］

血清補正 Ca×P 積（変化率）は，治療期 0 週に 51.095 ± 12.274 であったのに対し，治療期 18 週，34 週及び 52 週ではそれぞれ，42.537 ± 14.703（-16.5 ± 26.7%），47.136 ± 12.221（-4.9 ± 19.6%）及び 44.968 ± 12.576（-7.7 ± 26.8%）であった。治療第 I 期には低下が認められたが，治療第 II 期にはその低下率が小さくなった。

iFGF23 は, 治療期 0 週に 13509.7 ± 18201.7 pg/mL であったのに対し, 治療期 18 週, 34 週及び 52 週ではそれぞれ 8787.9 ± 13323.7 pg/mL, 9575.7 ± 15152.5 pg/mL 及び 8885.4 ± 11806.7 と低下した。

骨形成の指標である BAP は, 投与初期には上昇がみられ, 治療期 0 週に 18.23 ± 13.22 µg/L であったのに対し，治療期 6 週で最大の 20.99 ± 14.14 µg/L を示した後，治療期 18 週，34 週及び 52 週では 16.21 ± 11.17 µg/L，11.29 ± 5.74 µg/L 及び 11.23 ± 5.60 µg/L と低下が認められた。同じく骨形成の指標である total P1NP は治療期 0 週に 402.32 ± 288.35 ng/mL であったのに対し, 治療期 18 週, 34 週及び 52 週では 266.75 ± 221.01 ng/mL, 212.22 ± 148.06 ng/mL 及び 236.53 ± 191.65 ng/mL と低下が認められた。骨吸収の指標である TRACP-5b は治療期 0 週に 755.9 ± 413.3 mU/dL であったのに対し，治療期 18 週，34 週及び 52 週では 480.0 ± 264.4 mU/dL，413.8 ± 270.8 mU/dL 及び 405.3 ± 205.1 mU/dL と低下が認められた。

2.7.3.2.2 AJ1003 試験（第 III 相長期投与試験）[資料 5.3.5.2-2]

2.7.3.2.2.1 被験者の内訳

被験者の内訳を図 2.7.3－8 に示した。

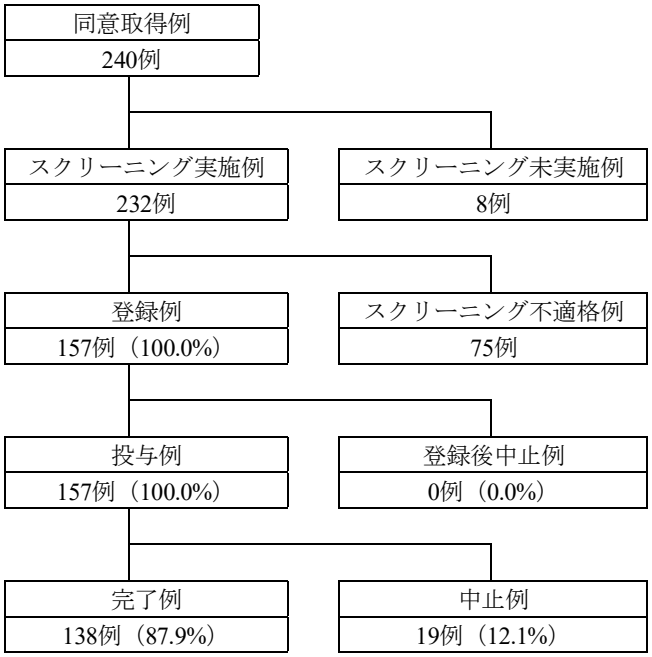


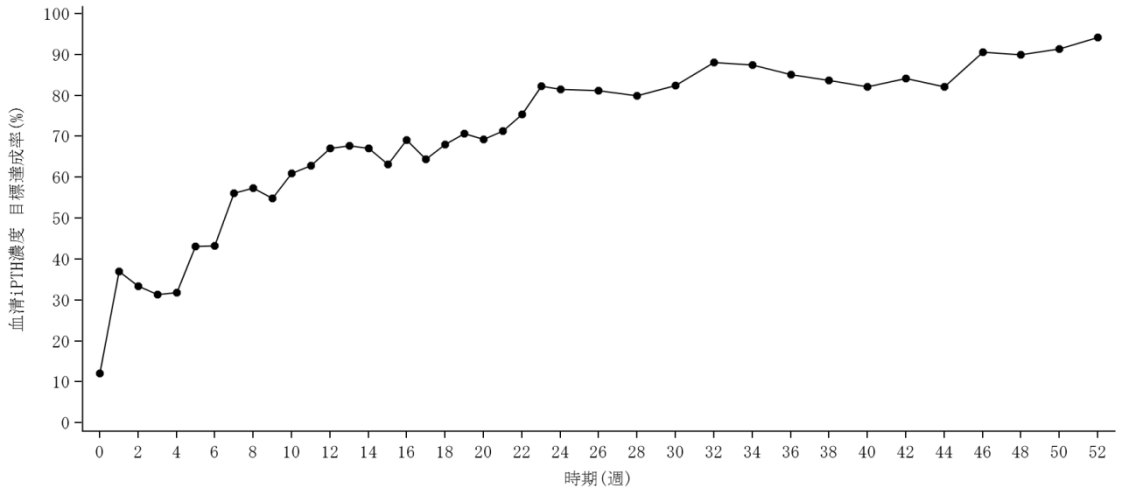
図 2.7.3－8 症例の内訳

[資料 5.3.5.2-2 図 10-1 から改変引用]

240 例から同意を取得し，そのうち 232 例でスクリーニングを実施した。スクリーニングで 75 例が不適格となり，157 例が登録された。登録後に治験薬の投与に至らなかった症例はなく，投与症例は 157 例であった。中止症例は 19 例（12.1%）あり，完了症例は 138 例（87.9%）であった。中止症例の内訳は，継続した治験薬の休薬が規定の期間を超えた症例が 1 例（0.6%），有害事象の発現により治験責任医師又は治験分担医師によって治験の継続が困難であると判断された症例が 4 例（2.5%），被験者から治験中止の申し出があった症例が 6 例（3.8%），治験責任医師又は治験分担医師の医学的判断により治験中止の必要性を認めた症例が 5 例（3.2%），効果がないため中止された症例が 2 例（1.3%），その他の理由により中止された症例が 1 例（0.6%）であった。

2.7.3.2.2.2 有効性評価

血清 iPTH 濃度が 60 pg/mL 以上 240 pg/mL 以下を達成した被験者の割合（目標達成率）の推移を図 2.7.3－9 に示した。投与期間を通して増加傾向が認められ，治療期 24 週及び 52 週でそれぞれ 81.5%（119 例/146 例）［95%信頼区間：74.2% - 87.4%］，94.2%（131 例/139 例）［95%信頼区間：89.0% - 97.5%］であった。



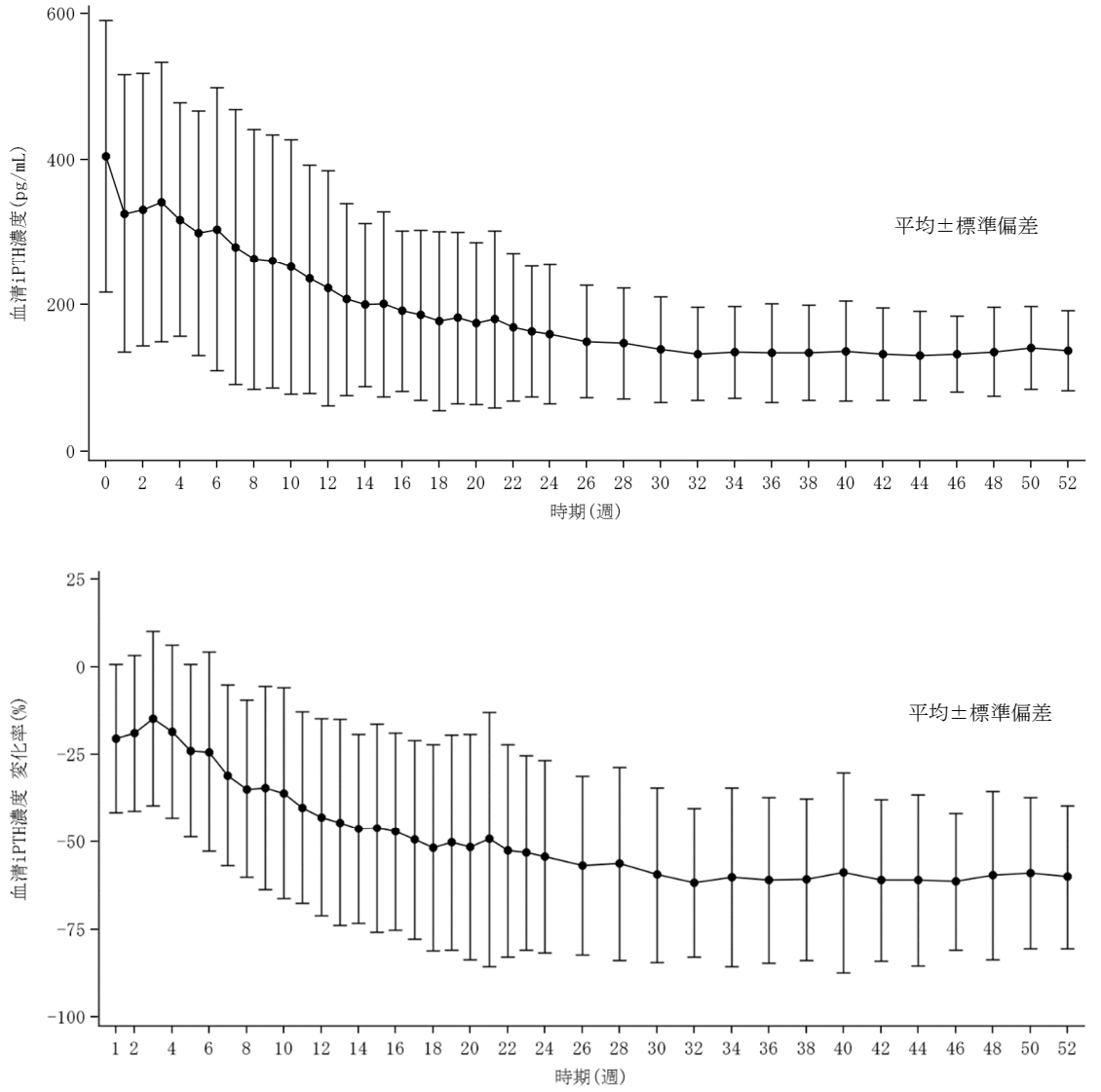
週	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
症例数	157	157	156	153	154	153	155	155	155	155	154	151	153	152	152	152	152	152	150	150	150	150	146	147	146	144	144	143	143	143	141	141	140	139	140	138	140	140	139

図 2.7.3－9 血清 iPTH 濃度 目標達成率の推移

［資料 5.3.5.2-2 図 14.2.1-1 から改変引用］

各時点における血清 iPTH 濃度のベースラインからの変化率が-30%又は-50%以下を達成した被験者の割合について，-30%以下の達成割合は，治療期 1 週で 31.2%（49 例/157 例）［95%信頼区間：24.1% - 39.1%］から徐々に増加し，治療期 12 週，24 週，36 週及び 52 週でそれぞれ 67.8%（103 例/152 例）［95%信頼区間：59.7% - 75.1%］，82.9%（121 例/146 例）［95%信頼区間：75.8% - 88.6%］，92.2%（130 例/141 例）［95%信頼区間：86.5% - 96.0%］及び 89.9%（125 例/139 例）［95%信頼区間：83.7% - 94.4%］であった。-50%以下の達成割合は，治療期 1 週で 7.6%（12 例/157 例）［95%信頼区間：4.0% - 13.0%］から徐々に増加し，治療期 12 週，24 週，36 週及び 52 週でそれぞれ 44.7%（68 例/152 例）［95%信頼区間：36.7% - 53.0%］，61.6%（90 例/146 例）［95%信頼区間：53.2% - 69.6%］，73.8%（104 例/141 例）［95%信頼区間：65.7% - 80.8%］及び 73.4%（102 例/139 例）［95%信頼区間：65.2% - 80.5%］であった。

血清 iPTH 濃度測定値及び変化率の推移を図 2.7.3－10 に示した。血清 iPTH 濃度（変化率）は治療期 0 週, 12 週, 24 週, 36 週及び 52 週でそれぞれ 404.1 ± 186.7 pg/mL, 223.4 ± 161.5 pg/mL（-43.0 ± 28.2%）, 160.2 ± 95.1 pg/mL（-54.3 ± 27.5%）, 134.5 ± 67.3 pg/mL（-61.0 ± 23.7%）及び 137.1 ± 54.6 pg/mL（-60.1 ± 20.4%）と徐々に低下した。二元配置分散分析の結果，推移について統計学的に有意な差が認められた（p<0.001）。



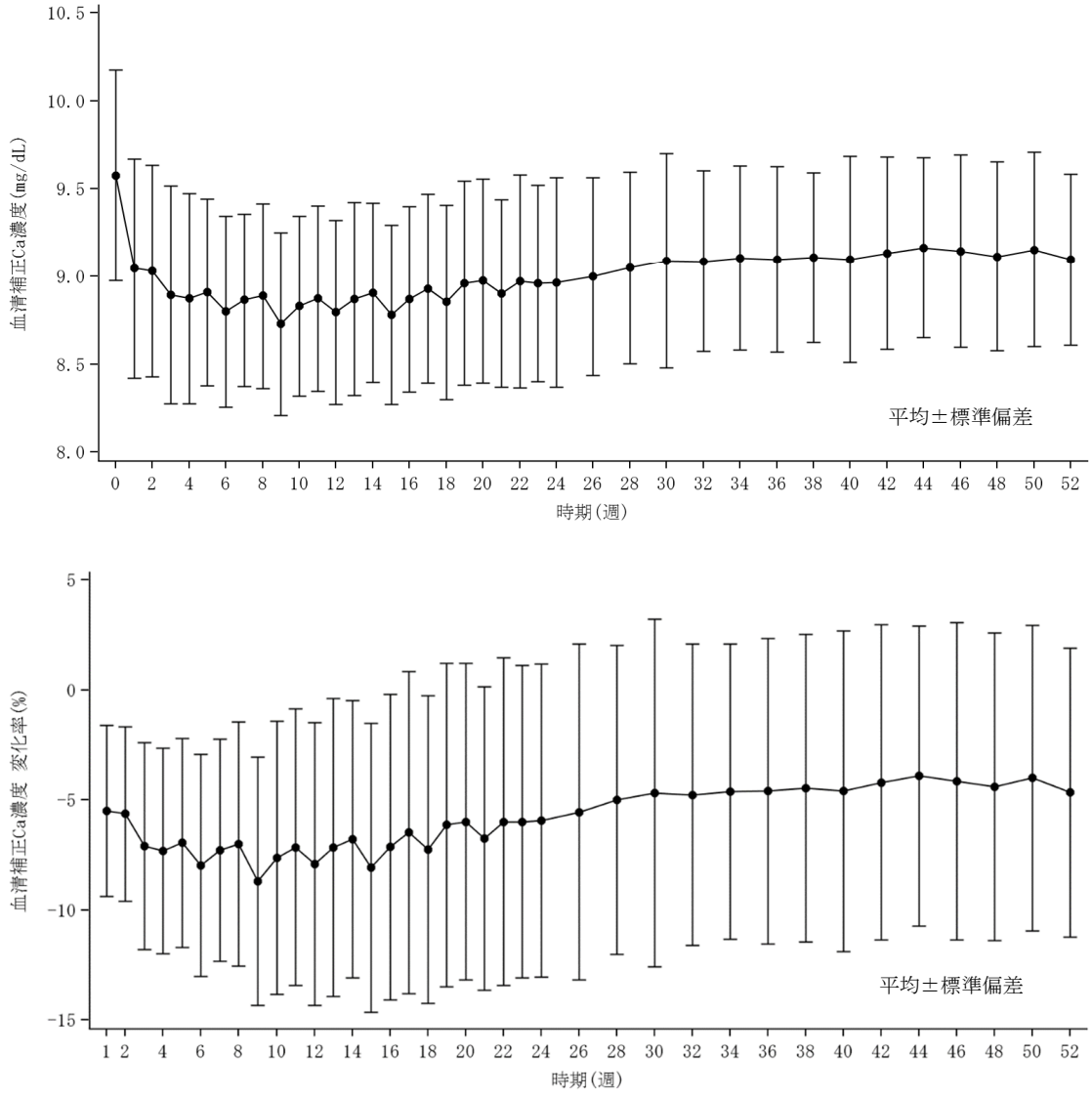
週	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
症例数	157	157	156	153	154	153	155	155	155	155	154	151	153	152	152	152	152	152	150	150	150	150	146	147	146	144	144	143	143	143	141	141	140	139	140	138	140	140	139

図 2.7.3－10　血清 iPTH 濃度の測定値及び変化率の推移

［資料 5.3.5.2-2 図 14.2.2-1 及び図 14.2.2-2 から改変引用］

血清 whole-PTH 濃度（変化率）も血清 iPTH と同様に，治療期 0 週，12 週，24 週，36 週及び 52 週でそれぞれ 251.9 ± 117.20 pg/mL, 128.88 ± 93.59 pg/mL（-47.8 ± 25.3%）, 91.32 ± 62.59 pg/mL（-59.0 ± 23.8%），84.29 ± 51.16 pg/mL（-61.5 ± 23.5%）及び 88.78 ± 37.92 pg/mL（-58.7 ± 21.4%）と投与開始後から徐々に低下した。二元配置分散分析の結果，推移について統計学的に有意な差が認められた（p<0.001）。

血清補正 Ca 濃度測定値及び変化率の推移を図 2.7.3－11 に示した。血清補正 Ca 濃度（変化率）は治療期 0 週，1 週，12 週，24 週，36 週及び 52 週でそれぞれ 9.57 ± 0.60 mg/dL，9.04 ± 0.62 mg/dL（-5.5 ± 3.9%），8.80 ± 0.53 mg/dL（-7.9 ± 6.4%），8.97 ± 0.60 mg/dL（-5.9 ± 7.1%），9.10 ± 0.53 mg/dL（-4.6 ± 6.9%）及び 9.10 ± 0.49 mg/dL（-4.7 ± 6.6%）と投与開始 1 週後に低下した後，ほぼ一定の推移を示した。二元配置分散分析の結果，推移について統計学的に有意な差が認められた（p<0.001）。



週	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
症例数	157	157	156	153	154	153	155	155	155	155	154	151	153	152	152	152	152	152	150	150	150	150	146	147	146	144	144	143	143	143	141	141	140	139	138	138	140	140	139

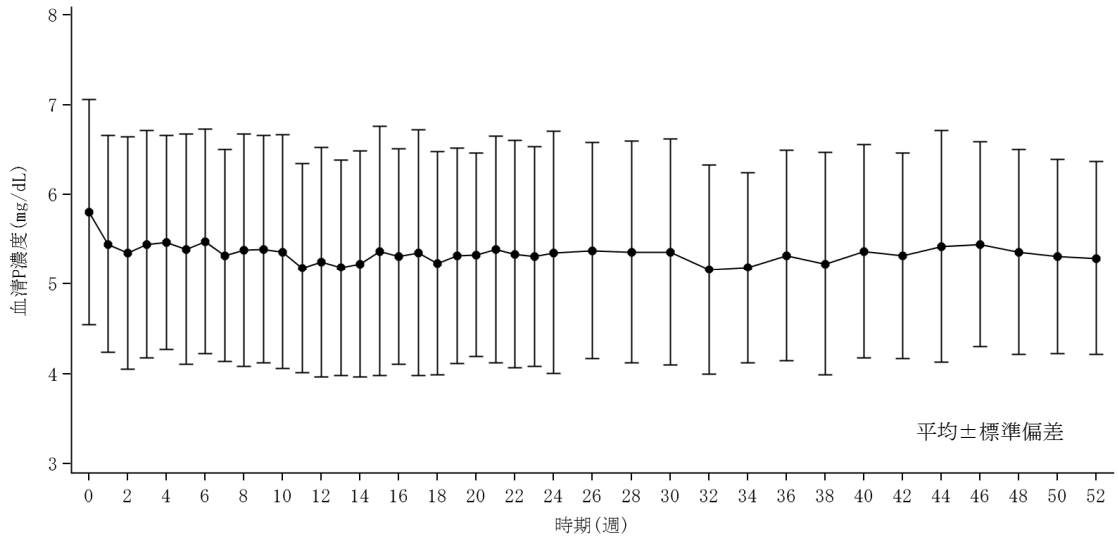
図 2.7.3－11　血清補正 Ca 濃度の測定値及び変化率の推移

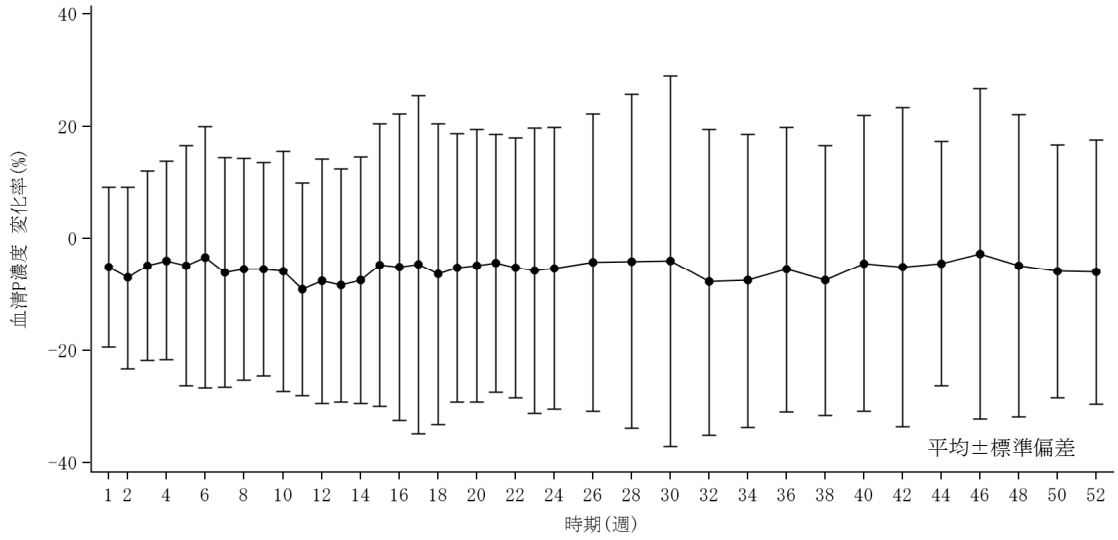
［資料 5.3.5.2-2 図 14.2.2-1 及び図 14.2.2-2 から改変引用］

血清イオン化 Ca 濃度（変化率）は血清補正 Ca 濃度と同様に，治療期 0 週，1 週，12 週，24 週，36 週及び 52 週でそれぞれ 2.619 ± 0.235 mg/dL，2.408 ± 0.239 mg/dL（-7.9 ± 7.1%），2.376 ± 0.199 g/dL（-8.6 ± 10.6%），2.423 ± 0.242 mg/dL（-6.7 ± 11.1%），2.399 ± 0.246 mg/dL（-7.9 ±

10.2%）及び 2.431 ± 0.184 mg/dL（-6.5 ± 9.2%）と投与開始 1 週後に低下した後，ほぼ一定の推移を示した。二元配置分散分析の結果，推移について統計学的に有意な差が認められた（p<0.001）。

血清 P 濃度測定値及び変化率の推移を図 2.7.3－12 に示した。血清 P 濃度（変化率）は治療期 0 週，1 週，12 週，24 週，36 週及び 52 週でそれぞれ 5.81 ± 1.26 mg/dL，5.45 ± 1.21 mg/dL（-5.1 ± 14.3%），5.25 ± 1.28 mg/dL（-7.6 ± 21.8%），5.36 ± 1.35 mg/dL（-5.4 ± 25.1%），5.32 ± 1.17 mg/dL（-5.6 ± 25.4%）及び 5.29 ± 1.08 mg/dL（-6.0 ± 23.6%）と投与開始 1 週後に低下した後，ほぼ一定の推移を示した。二元配置分散分析の結果，推移について統計学的に有意な差が認められた（p=0.0171）。





週	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52
症例数	157	157	156	153	154	152	155	155	155	155	154	151	153	152	152	152	152	152	150	150	150	150	146	147	146	144	144	143	143	143	141	141	140	139	138	138	140	140	139

図 2.7.3－12　血清 P 濃度の測定値及び変化率の推移

［資料 5.3.5.2-2 図 14.2.2-1 及び図 14.2.2-2 から改変引用］

血清補正 Ca×P 積（変化率）は，治療期 0 週，1 週，12 週，24 週，36 週及び 24 週でそれぞれ，55.634 ± 12.707，49.402 ± 12.010（-10.3 ± 14.1%），46.212 ± 12.202（-15.0 ± 20.9%），48.004 ± 12.714（-10.8 ± 26.2%），48.383 ± 11.004（-9.5 ± 28.4%）及び 48.176 ± 10.426（-10.2 ± 24.2%）と投与開始 1 週後に 10%ほど低下した後はほぼ一定に推移した。二元配置分散分析の結果，時点について統計学的に有意な差が認められた（p<0.001）。

iFGF23 は，治療期 0 週，12 週，24 週，36 週及び 52 週でそれぞれ，17054.83 ± 31866.97 pg/mL，8774.21 ± 17601.97 pg/mL，10470.76 ± 20989.52 pg/mL，9535.49 ± 15528.68 pg/mL 及び 10875.10 ± 15528.79 pg/mL であり，低下が認められた。二元配置分散分析の結果，推移について統計学的に有意な差が認められた（p=0.0129）。

BAP は，治療期 0 週，12 週，24 週，36 週及び 52 週でそれぞれ，16.08 ± 7.29 µg/L，16.47 ± 8.16 µg/L，11.75 ± 5.09 µg/L，10.86 ± 4.42 µg/L 及び 10.80 ± 3.85 µg/L であり，低下が認められた。二元配置分散分析の結果，推移について統計学的に有意な差が認められた（p<0.001）。

total P1NP は，治療期 0 週，12 週，24 週，36 週及び 52 週でそれぞれ，337.58 ± 241.16 ng/mL，303.20 ± 192.70 ng/mL，222.12 ± 146.29 ng/mL，187.21 ± 114.98 ng/mL 及び 179.20 ± 101.86 ng/mL であり，低下が認められた。二元配置分散分析の結果，推移について統計学的に有意な差が認められた（p<0.001）。

TRACP-5b は，治療期 0 週，12 週，24 週，36 週及び 52 週でそれぞれ，699.3 ± 337.5 mU/dL，435.1 ± 234.7 mU/dL L，356.6 ± 188.9 mU/dL L，309.9 ± 170.3 mU/dL L 及び 330.1 ± 172.3 mU/dL であり，低下が認められた。二元配置分散分析の結果，推移について統計学的に有意な差が認められた（p<0.001）。

副甲状腺体積は，スクリーニング時，治療期 24 週及び 52 週でそれぞれ，460.1 ± 1395.7 mm^3，251.6 ± 261.1 mm^3 及び 269.1 ± 304.2 mm^3 であり，減少が認められた。

2.7.3.2.3 AJ1004 試験（第 III 相比較試験）［資料 5.3.5.1-1］

2.7.3.2.3.1 被験者の内訳

被験者の内訳を図 2.7.3－11 に示した。

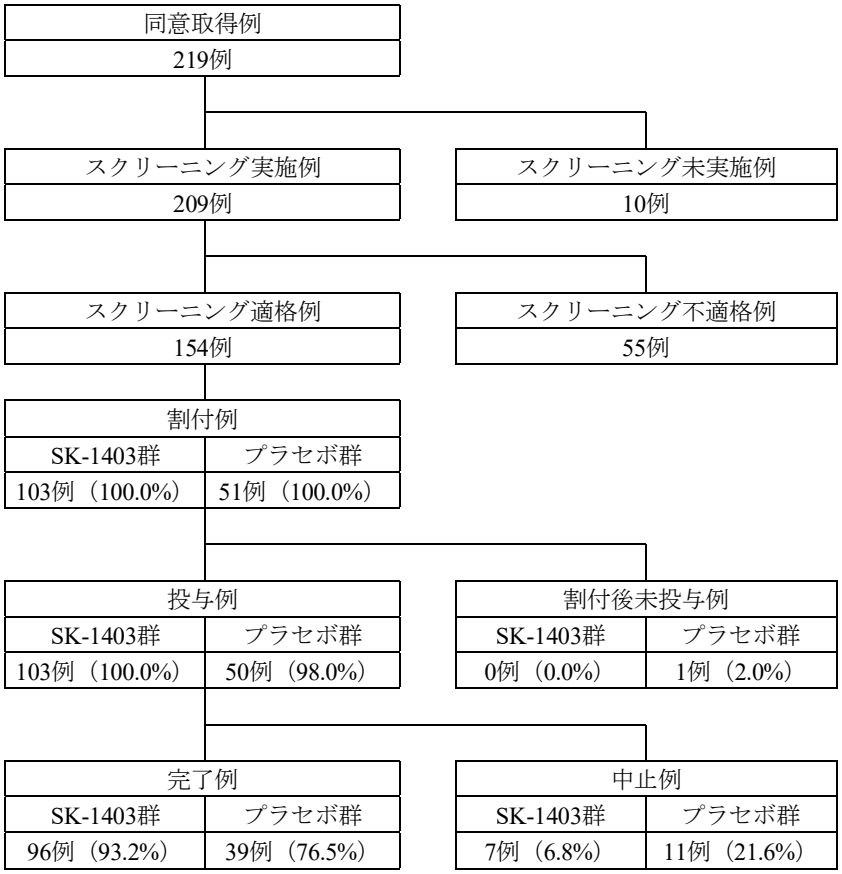


図 2.7.3－13 被験者の内訳

［資料 5.3.5.1-1 図 10-1 から改変引用］

219 例から同意を取得し，そのうち 209 例でスクリーニングを実施した。スクリーニングで 55 例が不適格となり，154 例が登録され，SK-1403 群又はプラセボ群に割り付けられた。割付後に治験薬の投与に至らなかった症例がプラセボ群で 1 例あり，投与症例は SK-1403 群 103 例，プラセボ群 50 例であった。中止症例は SK-1403 群で 7 例（6.8%），プラセボ群で 11 例（21.6%）あり，完了症例は SK-1403 群 96 例（93.2%），プラセボ群 39 例（76.5%）であった。中止症例の内訳は，SK-1403 群では，有害事象の発現により治験責任医師又は治験分担医師によって治験の継続が困難であると判断された症例が 2 例（1.9%），被験者から治験中止の申し出があった症例が 2 例（1.9%），治験責任医師又は治験分担医師の医学的判断により治験中止の必要性を認めた症例が 1 例（1.0%），その他の理由（継続した治験薬の休薬が 4 週間を超えることが確定）により中止した症例が 2 例（1.9%）であり，プラセボ群では継続した治験薬の休薬が 4 週間を超えた症例が 2 例（3.9%），有害事象の発現により治験責任医師又は治験分担医師によって治験の継続が困難であると判断された症例が 5 例（9.8%），治験責任医師又は治験分担医師の医学的判断により治験中止の必要性を認めた症例が 4 例

（7.8%）であった。

2.7.3.2.3.2 主要評価項目

治療期 22，23，24 週時の血清 iPTH 濃度平均値が 60 pg/mL 以上 240 pg/mL 以下を達成した被験者の割合（目標達成率）を表 2.7.3－10 に示した。目標達成率は SK-1403 群 67.0%（69 例/103 例）［95%信頼区間：57.0% - 75.9%］，プラセボ群 8.0%（4 例/50 例）［95%信頼区間：2.2% - 19.2%］であり，群間の差 59.0%［95%信頼区間：47.2% - 70.8%］は統計学的に有意であった（p<0.001）。

表 2.7.3－10 治療期 22，23，24 週時の血清 iPTH 濃度平均値 目標達成率

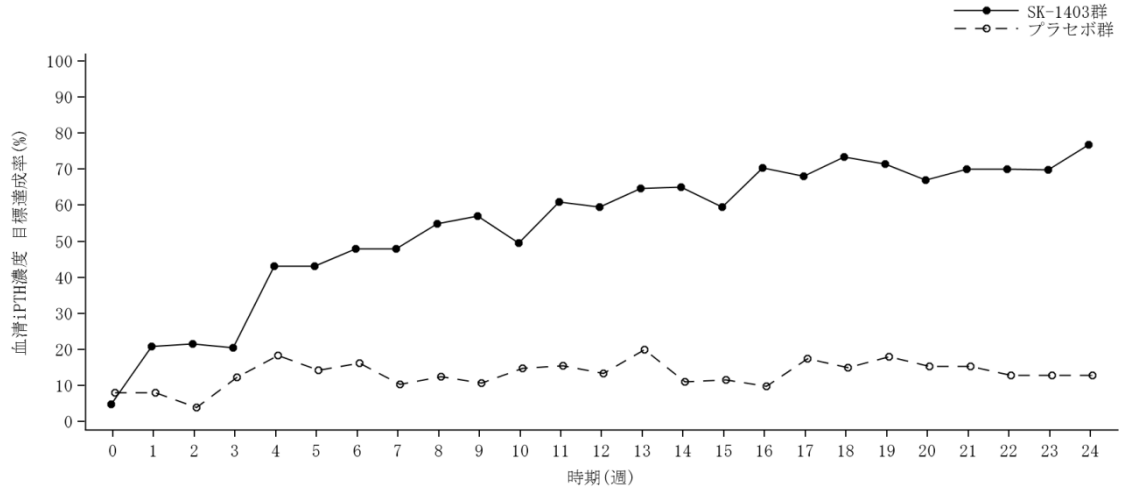
	SK-1403 群 （N=103）	プラセボ群 （N=50）
達成被験者数	69	4
目標達成率	67.0%	8.0%
95%信頼区間[1]	57.0% - 75.9%	2.2% - 19.2%
割合の差	59.0%	
割合の差の 95%信頼区間[2]	47.2% - 70.8%	
p 値[3]	<0.001	

[1] 正確な両側 95%信頼区間
[2] Wald 型の両側 95%信頼区間
[3] Fisher の直接確率検定
［資料 5.3.5.1-1 表 14.2.1-1 から改変引用］

目標達成率に対する影響因子を検討する目的で，目標達成率を目的変数とし，血清 iPTH 濃度ベースライン値，血清補正 Ca 濃度ベースライン値及び前治療薬の Wash out の有無を因子とした Logistc 回帰分析を実施したところ，影響因子として血清 iPTH 濃度ベースライン値が選択された。血清 iPTH 濃度ベースライン値を共変量とした Mantel-Haenszel 検定を行ったところ，群間の差 59.6%［95%信頼区間：48.1% - 71.2%］は統計学的に有意であった（p<0.001）。

2.7.3.2.3.3 副次評価項目

血清 iPTH 濃度が 60 pg/mL 以上 240 pg/mL 以下を達成した被験者の割合（目標達成率）の推移を図 2.7.3－12 に示した。SK-1403 群では投与期間を通して増加傾向が認められ，治療期 24 週では 76.8%（73 例/95 例）であった。プラセボ群では投与期間を通して 4.0%（2 例/50 例，2 週）から 20.0%（9 例/45 例，13 週）の範囲でほぼ一定に推移した。



週	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
SK-1403群	103	101	102	102	102	102	102	100	102	100	101	100	99	99	100	99	98	97	98	98	97	97	97	96	95
プラセボ群	50	50	50	49	49	49	49	48	48	47	47	45	45	45	45	43	41	40	40	39	39	39	39	39	39

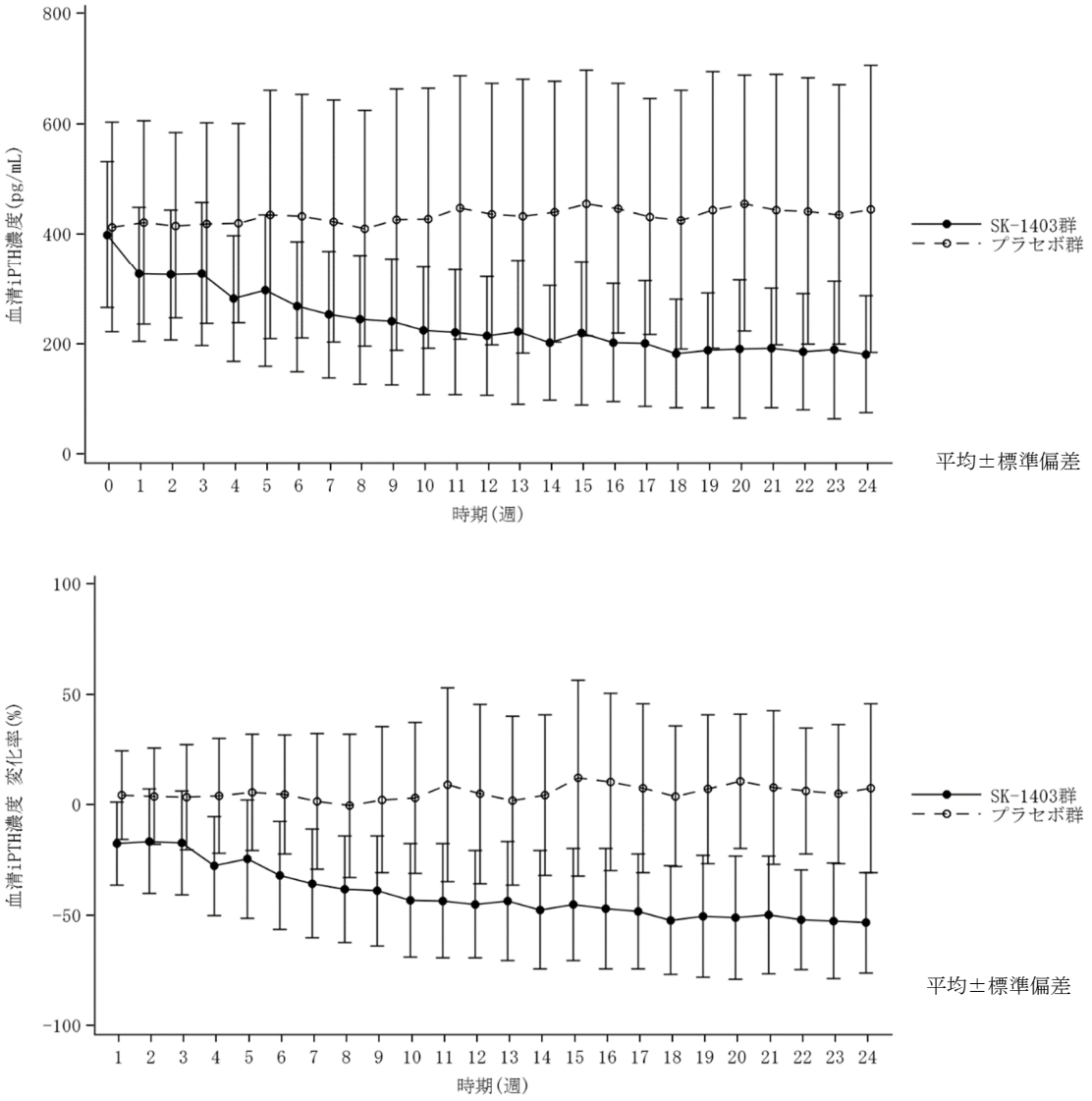
図 2.7.3－14　血清 iPTH 濃度　目標達成割合推移

［資料 5.3.5.1-1 図 14.2.1-1 から改変引用］

血清 iPTH 濃度（治療期 22，23，24 週時の平均値）のベースライン（治験薬投与開始 2 週間前，1 週間前及び治療期 0 週の平均値）からの変化率が-30%又は-50%以下を達成したそれぞれの被験者の割合について，-30%以下の達成割合は SK-1403 群及びプラセボ群でそれぞれ 80.6%（83 例/103 例）［95%信頼区間：71.6% - 87.7%］及び 8.0%（4 例/50 例）［95%信頼区間：2.2% - 19.2%］であり，群間の差 72.6%［95%信頼区間：61.9% - 83.3%］は統計学的に有意であった（p<0.001）。-50%以下の達成割合は SK-1403 群及びプラセボ群で 52.4%（54 例/103 例）［95%信頼区間：42.4% - 62.4%］及び 4.0%（2 例/50 例）［95%信頼区間：0.5% - 13.7%］であり，群間の差 48.4%［95%信頼区間：37.4% - 59.5%］は統計学的に有意であった（p<0.001）。

各時点における血清 iPTH 濃度のベースライン（治療期 0 週の検査値）からの変化率が-30%又は-50%以下を達成したそれぞれの被験者の割合について，-30%以下の達成割合は SK-1403 群で治療期 1 週の 20.8%（21 例/101 例）［95%信頼区間：13.4% - 30.0%］から徐々に上昇し，治療期 12 週及び 24 週でそれぞれ 76.8%（76 例/99 例）［95%信頼区間：67.2% - 84.7%］及び 85.3%（81 例/95 例）［95%信頼区間：76.5% - 91.7%］であった。プラセボ群では治療期 1 週，12 週及び 24 週でそれぞれ 2.0%（1 例/50 例）［95%信頼区間：0.1% - 10.6%］，22.2%（10 例/45 例）［95%信頼区間：11.2% - 37.1%］，15.4%（6 例/39 例）［95%信頼区間：5.9% - 30.5%］でほぼ一定に推移した。-50%以下の達成割合は SK-1403 群で治療期 1 週の 3.0%（3 例/101 例）［95%信頼区間：0.6% - 8.4%］から徐々に上昇し，治療期 12 週及び 24 週でそれぞれ 45.5%（45 例/99 例）［95%信頼区間：35.4% - 55.8%］及び 63.2%（60 例/95 例）［95%信頼区間：52.6% - 72.8%］であった。プラセボ群では治療期 1 週，12 週及び 24 週でそれぞれ 0.0%（0 例/50 例）［95%信頼区間：0.0% - 7.1%］，11.1%（5 例/45 例）［95%信頼区間：3.7% - 24.1%］，5.1%（2 例/39 例）［95%信頼区間：0.6% - 17.3%］でほぼ一定に推移した。

血清 iPTH 濃度及びベースライン（治療期 0 週の検査値）からの変化率の推移を図 2.7.3－13 に示した。血清 iPTH 濃度（変化率）は SK-1403 群では治療期 0 週，12 週及び 24 週でそれぞれ 398.6 ± 133.0 pg/mL, 214.5 ± 107.7 pg/mL（-45.0 ± 24.3%）及び 180.8 ± 105.9 pg/mL（-53.4 ± 22.7%）と徐々に低下したのに対し，プラセボ群では 412.5 ± 191.1 pg/mL, 436.1 ± 237.4 pg/mL（4.9 ± 40.5%）及び 445.4 ± 260.6 pg/mL（7.6 ± 38.3%）と若干の上昇傾向が認められた。この推移の差は二元配置分散分析の結果，統計学的に有意であった（p<0.001）。



週	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
SK-1403群	103	101	102	102	102	102	102	100	102	100	101	100	99	99	100	99	98	97	98	98	97	97	97	96	95
プラセボ群	50	50	50	49	49	49	49	48	48	47	47	45	45	45	45	43	41	40	40	39	39	39	39	39	39

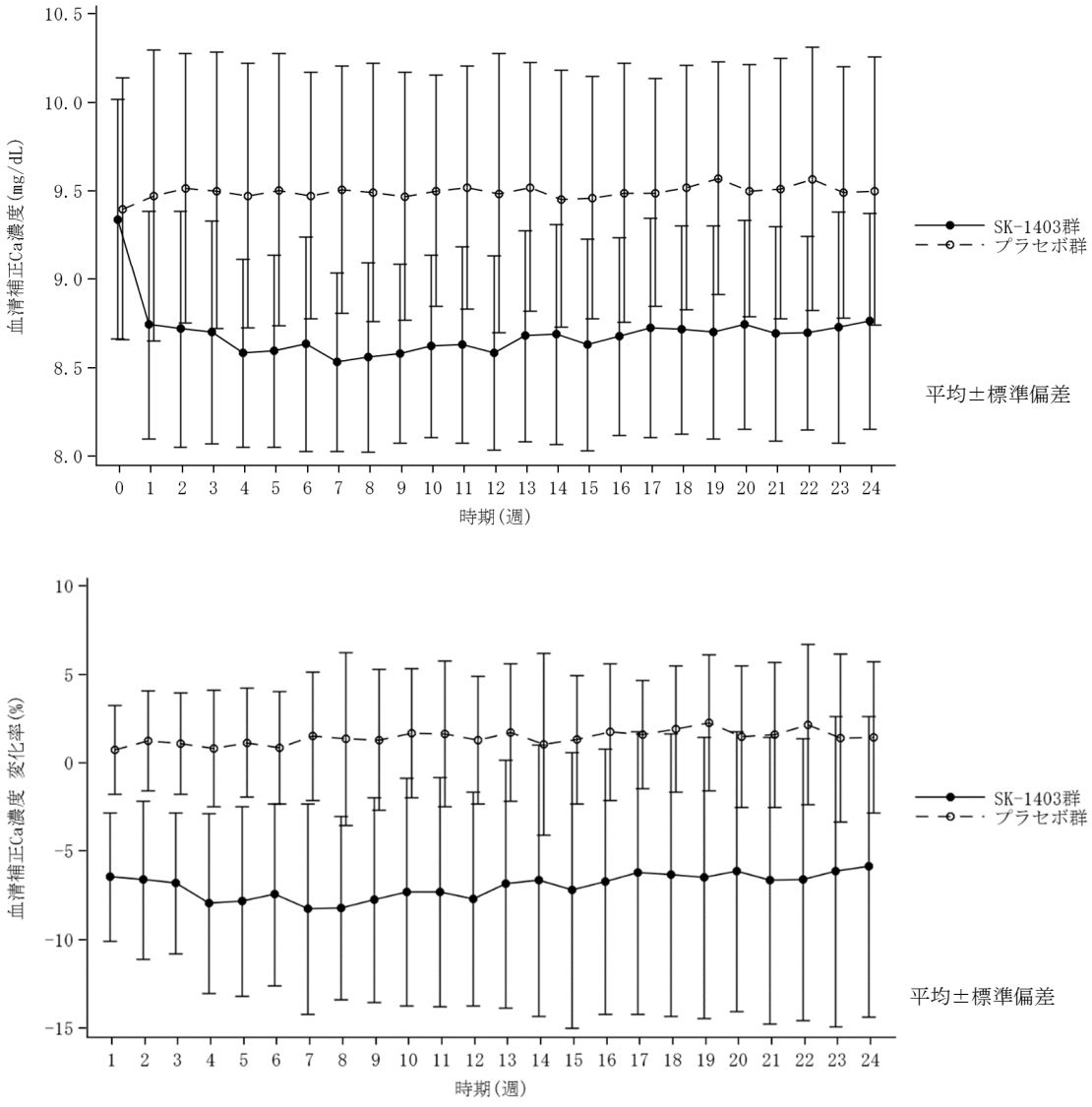
図 2.7.3－15　血清 iPTH 濃度の測定値及び変化率の推移

［資料 5.3.5.1-1 図 14.2.2-1 及び図 14.2.2-2 から改変引用］

血清 whole-PTH 濃度（変化率）は血清 iPTH 濃度と同様に，SK-1403 群では治療期 0 週，12 週及び 24 週でそれぞれ 227.59 ± 81.82 pg/mL，128.84 ± 68.58 pg/mL（-42.2 ± 27.2%），115.73 ± 77.48 pg/mL（-47.9 ± 26.6%）と低下し，プラセボ群では 241.28 ± 113.41 pg/mL, 261.76 ± 135.68

pg/mL（8.9 ± 43.0%），283.14 ± 148.29 pg/mL（20.1 ± 44.4%）と上昇した。この推移の差は二元配置分散分析の結果，統計学的に有意であった（p<0.001）。

血清補正 Ca 濃度及び変化率の推移を図 2.7.3－14 に示した。血清補正 Ca 濃度（変化率）は SK-1403 群で治療期 0 週に 9.34 ± 0.68 mg/dL であったのに対し，投与開始直後の治療期 1 週に 8.74 ± 0.64 mg/dL（-6.5 ± 3.6%）と低下した後，12 週及び 24 週でそれぞれ，8.59 ± 0.55 mg/dL（-7.7 ± 6.0%）及び 8.76 ± 0.61 mg/dL（-5.9 ± 8.5%）とほぼ一定の推移を示した。プラセボ群では治療期 0 週，1 週，12 週及び 24 週でそれぞれ，9.40 ± 0.74 mg/dL，9.47 ± 0.82mg/dL（0.8 ± 2.5%），9.49 ± 0.79 mg/dL（1.3 ± 3.6%），9.50 ± 0.76 mg/dL（1.5 ± 4.3%）とほぼ一定に推移した。この推移の差は二元配置分散分析の結果，統計学的に有意であった（p<0.001）。



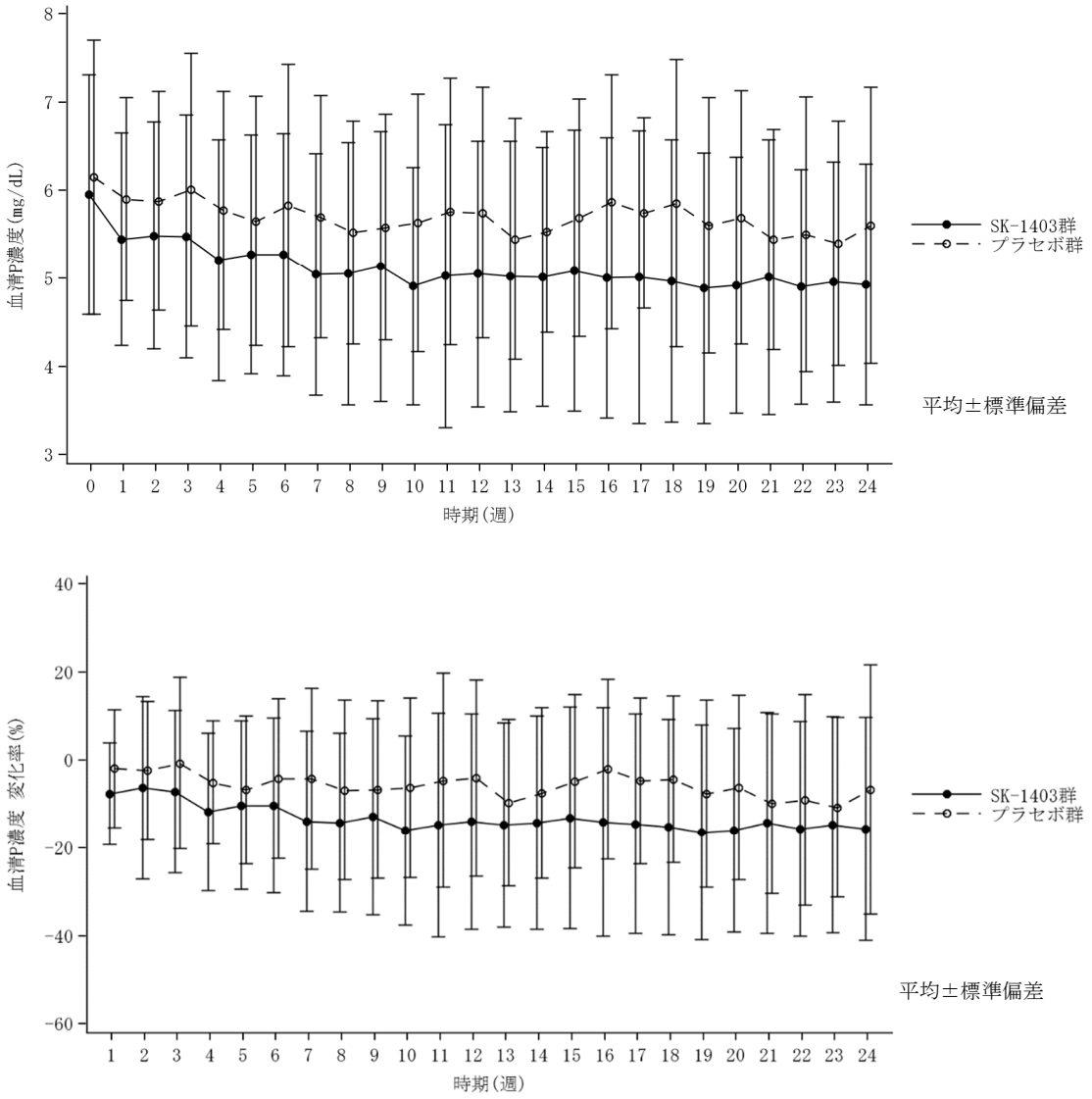
週	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
SK-1403群	103	101	102	102	102	102	102	100	102	100	101	100	99	99	100	99	98	97	98	98	97	97	97	96	95
プラセボ群	50	50	50	49	49	49	49	48	48	47	47	45	45	45	45	43	41	40	40	39	39	39	39	39	39

図 2.7.3－16　血清補正 Ca 濃度の変化率の推移

［資料 5.3.5.1-1 図 14.2.2-1 及び図 14.2.2-2 から改変引用］

イオン化 Ca 濃度（変化率）は血清補正 Ca 濃度と同様に，SK-1403 群では治療期 0 週は 2.490 ± 0.253 mEq/L であったのに対し，投与開始直後の治療期 1 週に 2.320 ± 0.245 mEq/L（-6.6 ± 7.4%）と低下した後は，治療期 12 週及び 24 週でそれぞれ，2.261 ± 0.208 mEq/L（-8.6 ± 10.2%）及び 2.319 ± 0.238 mEq/L（-6.2 ± 12.1%）とほぼ一定に推移した。プラセボ群では治療期 0 週，1 週，12 週及び 24 週でそれぞれ，2.489 ± 0.249 mEq/L，2.495 ± 0.284 mg/dL（0.4 ± 7.6%），2.519 ± 0.278 mEq/L（1.8 ± 8.5%），2.502 ± 0.217 mEq/L（0.3 ± 6.8%）とほぼ一定に推移した。この推移の差は二元配置分散分析の結果，統計学的に有意であった（p=0.0113）。

血清 P 濃度及び変化率の推移を図 2.7.3－15 に示した。血清 P 濃度（変化率）は SK-1403 群では治療期 0 週は 5.95 ± 1.36 mg/dL であったのに対し，治療期 1 週，12 週及び 24 週ではそれぞれ 5.44 ± 1.21 mg/dL（-7.6 ± 11.6%），5.05 ± 1.51 mg/dL（-13.9 ± 24.5%）及び 4.93 ± 1.37 pg/dL（-15.6 ± 25.4%）と投与開始後から徐々に低下した。プラセボ群では治療期 0 週，1 週，12 週及び 24 週で 6.15 ± 1.55 mg/dL，5.90 ± 1.15 mg/dL（-1.9 ± 13.5%），5.74 ± 1.42 mg/dL（-4.1 ± 22.3%）及び 5.60 ± 1.57 pg/dL（-6.7 ± 28.4%）と若干低下が認められた。二元配置分散分析の結果，両群の推移に統計学的に有意な差は認められなかった（p=0.9678）。



週	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
SK-1403群	103	101	102	102	102	102	102	100	102	100	101	100	99	99	100	99	98	97	98	98	97	97	97	96	95
プラセボ群	50	50	50	49	49	49	49	48	48	47	47	45	45	45	45	43	41	40	40	39	39	39	39	39	39

図 2.7.3－17　血清 P 濃度の変化率の推移

［資料 5.3.5.1-1 図 14.2.2-1 及び図 14.2.2-2 から改変引用］

血清補正 Ca×P 積（変化率）は，SK-1403 群では治療期 0 週，1 週，7 週，12 週及び 24 週でそれぞれ，55.648 ± 13.230，47.643 ± 11.135（-13.6 ± 11.4%），43.059 ± 12.173（-21.0 ± 19.9%），43.413 ± 13.572（-20.8 ± 22.6%）及び 43.393 ± 13.095（-20.6 ± 25.1%）と 1 週以降徐々に低下し 7 週で約 20%低下した後，ほぼ一定に推移した。プラセボ群では治療期 0 週，1 週，7 週，12 週及び 24 週でそれぞれ，57.851 ± 15.400，55.883 ± 11.642（-1.3 ± 12.8%），54.134 ±13.312（-3.2 ± 18.6%），54.486 ± 14.305（-3.2 ± 21.3%），53.181 ± 14.682（-5.7 ± 27.5%）と若干低下が認められるもののほぼ一定に推移した。二元配置分散分析の結果，両群の推移に統計学的に有意な差は認められなかった（p=0.2871）。

iFGF23 は，SK-1403 群では治療期 0 週，12 週及び 24 週でそれぞれ，14707.85 ± 20551.14 pg/mL，7989.34 ± 13187.87 pg/mL 及び 8862.31 ± 13630.33 pg/mL であったのに対し，プラセボ群ではそれぞれ，17795.25 ± 21255.92 pg/mL，20180.44 ± 25721.33 pg/mL 及び 21961.59 ± 25291.67 pg/mL であり，SK-1403 群で低下しプラセボ群で上昇が認められた。この推移の差は二元配置分散分析の結果，統計学的に有意であった（p<0.001）。

BAP は，SK-1403 群では治療期 0 週，12 週及び 24 週でそれぞれ，18.18 ± 9.33 µg/L，17.69 ± 10.27 µg/L 及び 14.77 ± 8.86 µg/L であったのに対し，プラセボ群ではそれぞれ，18.58 ± 11.98 µg/L，19.43 ± 12.83 µg/L 及び 21.05 ± 14.67 µg/L であり，SK-1403 群で低下しプラセボ群で上昇が認められた。この推移の差は二元配置分散分析の結果，統計学的に有意であった（p<0.001）。

total P1NP は，SK-1403 群では治療期 0 週，12 週及び 24 週でそれぞれ，390.34 ± 223.27 ng/mL，275.72 ± 156.47 ng/mL 及び 230.07 ± 120.49 ng/mL であったのに対し，プラセボ群ではそれぞれ，389.10 ± 276.76 ng/mL，441.02 ± 301.09 ng/mL 及び 428.51 ± 302.95 ng/mL であり，SK-1403 群で低下しプラセボ群では上昇が認められた。この推移の差は二元配置分散分析の結果，統計学的に有意であった（p<0.001）。

TRACP-5b は，SK-1403 群では治療期 0 週，12 週及び 24 週でそれぞれ，740.3 ± 340.4 mU/dL，443.5 ± 258.3 mU/dL L 及び 373.0 ± 216.8 mU/dL であったのに対し，プラセボ群ではそれぞれ，747.2 ± 380.6 mU/dL，733.3 ± 393.1 mU/dL 及び 737.3 ± 391.1 mU/dL であり，SK-1403 群で低下が認められ，プラセボ群では一定であった。この推移の差は二元配置分散分析の結果，統計学的に有意であった（p<0.001）。

2.7.3.3 全試験を通しての結果の比較と解析

2.7.3.3.1 試験対象集団

2.7.3.3.1.1 各試験における症例の内訳

各試験における症例の内訳を表 2.7.3－11 に示した。中止した症例の割合は AJ1004 試験のプラセボ群で高かった。

表 2.7.3－11 各試験における症例の内訳

試験番号	AJ1002	AJ1003	AJ1004	
			SK-1403 群	プラセボ群
登録症例数	58	157	103	51
投与症例数	58	157	103	50
完了症例数	52	138	96	39
中止症例数	6（10.3%）	19（12.1%）	7（6.8%）	11（21.6%）
中止理由	・休薬 6 週間超 1 例 ・有害事象 3 例 ・その他 2 例	・休薬の期間超 1 例 ・有害事象 4 例 ・中止の申し出 6 例 ・治験責任医師等判断 5 例 ・効果なし 2 例 ・その他 1 例	・有害事象 2 例 ・被験者申し出 2 例 ・治験責任医師等判断 1 例 ・その他（休薬 4 週間を超えることが確定）2 例	・休薬 4 週間超 2 例 ・有害事象 5 例 ・治験責任医師等判断 4 例

［資料 5.3.5.2-1 図 10-2 及び表 11-6，5.3.5.2-2 図 10-1 並びに 5.3.5.1-1 図 10-1 から改変引用］

2.7.3.3.1.2 各試験における被験者背景

各試験における被験者背景を表 2.7.3－12 に示した。被験者背景に試験間で大きな違いはなかった。

表 2.7.3－12 各試験における被験者背景

試験番号		AJ1002	AJ1003	AJ1004	
				SK-1403 群	プラセボ群
		(N=58)	(N=157)	(N=103)	(N=50)
性別	男	43（74.1%）	121（77.1%）	77（74.8%）	39（78.0%）
	女	15（25.9%）	36（22.9%）	26（25.2%）	11（22.0%）
年齢（歳）	Mean±SD	61.6 ± 9.1	60.3 ± 10.6	62.4 ± 12.6	65.8 ± 13.6
	<65	33（56.9%）	91（58.0%）	48（46.6%）	20（40.0%）
	≥65	25（43.1%）	66（42.0%）	55（53.4%）	30（60.0%）
身長（cm）	Mean±SD	162.72 ± 9.53	164.24 ± 8.54	163.40 ± 9.60	161.30 ± 8.43
透析後体重（kg）（0 週時）	Mean±SD	62.09 ± 14.03	64.82 ± 14.49	62.37 ± 13.92	59.84 ± 12.50
	<50.0	10（17.2%）	20（12.7%）	18（17.5%）	14（28.0%）
	≥50 <60.0	21（36.2%）	44（28.0%）	26（25.2%）	13（26.0%）
	≥60 <70.0	12（20.7%）	46（29.3%）	37（35.9%）	13（26.0%）
	≥70.0	15（25.9%）	47（29.9%）	22（21.4%）	10（20.0%）
BMI（kg/m^2）	Mean±SD	23.33 ± 4.29	23.87 ± 4.26	23.13 ± 3.64	22.89 ± 3.78
	<18.5	4（6.9%）	8（5.1%）	6（5.8%）	8（16.0%）
	≥18.5 <25.0	39（67.2%）	97（61.8%）	70（68.0%）	29（58.0%）
	≥25.0	15（25.9%）	52（33.1%）	27（26.2%）	13（26.0%）

試験番号		AJ1002	AJ1003	AJ1004	
				SK-1403 群	プラセボ群
		(N=58)	(N=157)	(N=103)	(N=50)
原疾患	慢性糸球体腎炎	20 (34.5%)	59 (37.6%)	36 (35.0%)	24 (48.0%)
	糖尿病性腎症	16 (27.6%)	31 (19.7%)	33 (32.0%)	10 (20.0%)
	腎硬化症	3 (5.2%)	22 (14.0%)	13 (12.6%)	5 (10.0%)
	多発性嚢胞腎	4 (6.9%)	13 (8.3%)	2 (1.9%)	1 (2.0%)
	その他	15 (25.9%)	32 (20.4%)	19 (18.4%)	10 (20.0%)
透析期間 (年)	Mean±SD	9.25 ± 6.47	10.04 ± 7.55	10.18 ± 8.48	8.00 ± 6.67
	<5	17 (29.3%)	45 (28.7%)	35 (34.0%)	25 (50.0%)
	≥5 <10	19 (32.8%)	49 (31.2%)	21 (20.4%)	6 (12.0%)
	≥10 <20	17 (29.3%)	48 (30.6%)	32 (31.1%)	16 (32.0%)
	≥20	5 (8.6%)	15 (9.6%)	15 (14.6%)	3 (6.0%)
透析方法	HD	29 (50.0%)	84 (53.5%)	43 (41.7%)	25 (50.0%)
	HDF	29 (50.0%)	73 (46.5%)	60 (58.3%)	25 (50.0%)
透析液 Ca 濃度	2.5	12 (20.7%)	78 (49.7%)	32 (31.1%)	14 (28.0%)
(mEq/L)	2.75	16 (27.6%)	46 (29.3%)	39 (37.9%)	21 (42.0%)
	3.0	30 (51.7%)	33 (21.0%)	32 (31.1%)	15 (30.0%)
	その他	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
排尿の有無	無	33 (56.9%)	82 (52.2%)	43 (41.7%)	14 (28.0%)
	有	25 (43.1%)	75 (47.8%)	60 (58.3%)	36 (72.0%)
リン吸着薬の有無	無	3 (5.2%)	11 (7.0%)	8 (7.8%)	4 (8.0%)
	有	55 (94.8%)	146 (93.0%)	95 (92.2%)	46 (92.0%)
リン吸着薬の内容	Ca 含有	8 (13.8%)	17 (10.8%)	7 (6.8%)	6 (12.0%)
	Ca 非含有	21 (36.2%)	83 (52.9%)	48 (46.6%)	25 (50.0%)
	併用	26 (44.8%)	46 (29.3%)	40 (38.8%)	15 (30.0%)
カルシウム製剤の	無	58 (100.0%)	142 (90.4%)	100 (97.1%)	48 (96.0%)
有無	有	0 (0.0%)	15 (9.6%)	3 (2.9%)	2 (4.0%)
活性型ビタミン D	無	12 (20.7%)	22 (14.0%)	27 (26.2%)	7 (14.0%)
製剤の有無	有	46 (79.3%)	135 (86.0%)	76 (73.8%)	43 (86.0%)
血清 iPTH 濃度*	Mean±SD	407.3 ± 233.7	404.1 ± 186.7	398.6 ± 133.0	412.5 ± 191.1
(pg/mL)	≤240	11 (19.0%)	19 (12.1%)	5 (4.9%)	4 (8.0%)
	>240 <500	32 (55.2%)	101 (64.3%)	79 (76.7%)	38 (76.0%)
	≥500	15 (25.9%)	37 (23.6%)	19 (18.4%)	8 (16.0%)
血清補正 Ca 濃度*	Mean±SD	9.56 ± 0.68	9.57 ± 0.60	9.34 ± 0.68	9.40 ± 0.74
(mg/dL)	<8.4	-	0 (0.0%)	2 (1.9%)	2 (4.0%)
	≥8.4 <9.0	14 (24.1%)	24 (15.3%)	37 (35.9%)	15 (30.0%)
	≥9.0 <10.0	28 (48.3%)	101 (64.3%)	49 (47.6%)	23 (46.0%)
	≥10.0	16 (27.6%)	32 (20.4%)	15 (14.6%)	10 (20.0%)
血清 P 濃度*	Mean±SD	5.33 ± 1.13	5.81 ± 1.26	5.95 ± 1.36	6.15 ± 1.55
(mg/dL)	<3.5	1 (1.7%)	2 (1.3%)	1 (1.0%)	1 (2.0%)
	≥3.5 ≤6.0	43 (74.1%)	94 (59.9%)	56 (54.4%)	26 (52.0%)
	>6.0	14 (24.1%)	61 (38.9%)	46 (44.7%)	23 (46.0%)
血清補正 Ca×P 積*	Mean±SD	51.095 ± 12.274	55.634 ± 12.707	55.648 ± 13.230	57.851 ± 15.400
血清 whole-PTH 濃度* (pg/mL)	Mean±SD	222.99 ± 110.58	251.90 ± 117.20	227.59 ± 81.82	241.28 ± 113.41

試験番号		AJ1002	AJ1003	AJ1004	
				SK-1403 群	プラセボ群
		(N=58)	(N=157)	(N=103)	(N=50)
iFGF23*（pg/mL）	Mean±SD	13509.7 ± 18201.7	17054.83 ± 31866.97	14707.85 ± 20551.14	17795.25 ± 21255.92
BAP*（μg/L）	Mean±SD	18.23 ± 13.22	16.08 ± 7.29	18.18±9.33	18.58±11.98
total P1NP*（ng/mL）	Mean±SD	402.32 ± 288.35	337.58 ± 241.16	390.34 ± 223.27	390.12 ± 276.13
TRACP-5b*（mU/dL）	Mean±SD	755.9 ± 413.3	699.3 ± 337.5	740.3 ± 340.4	747.2 ± 380.6

*：ベースライン値（0 週測定値。ただし，AJ1002 試験の血清 iPTH 濃度は投与前直近の観察期 2 回の測定値の平均値。）
発現例数（発現率），-：データなし。
［資料 5.3.5.2-1 表 14.1.1-1，5.3.5.2-2 表 14.1.1-1 及び 5.3.5.1-1 表 14.1.1-1 から改変引用］

2.7.3.3.2 全有効性試験の結果の比較検討

2.7.3.3.2.1 血清 iPTH 濃度目標達成率

各試験における血清 iPTH 濃度が 60 pg/mL 以上 240 pg/mL 以下を達成した被験者の割合（目標達成率）を表 2.7.3－13 に示した。SK-1403 投与による目標達成率は治療期 24 週で 70.4%～81.5%，52 週で 80.8%～94.2%であり，治療期 24 週では 7 割以上の症例で，52 週では 8 割以上の症例で血清 iPTH 濃度の目標が達成された。

表 2.7.3－13 各試験における血清 iPTH 濃度目標達成率

試験番号	AJ1002		AJ1003		AJ1004	
	24 週	52 週	24 週	52 週	24 週	
					SK-1403 群	プラセボ群
目標達成率	70.4% (38/54)	80.8% (42/52)	81.5% (119/146)	94.2% (131/139)	76.8% (73/95)	12.8% (5/39)
95%信頼区間	56.4% - 82.0%	67.5% - 90.4%	74.2% - 87.4%	89.0% - 97.5%	67.1% - 84.9%	4.3% - 27.4%

()：達成例数/症例数
［資料 5.3.5.2-1 表 14.2.11-1，5.3.5.2-2 表 14.2.1-1 及び 5.3.5.1-1 表 14.2.3-1 から改変引用］

2.7.3.3.2.2 血清 iPTH 濃度変化率が-30%又は-50%以下の達成率

各試験における血清 iPTH 濃度変化率が-30%又は-50%以下を達成した被験者の割合（達成率）を表 2.7.3－14 に示した。各達成率はそれぞれ 68.4%～89.9%及び 47.4%～73.4%であり，-30%以下の達成は治療期 18 週で 6 割以上，24 週以降で 8 割以上の症例で，-50%以下の達成は治療期 18 週でほぼ半数，24 週で 6 割以上，52 週で 7 以上の症例で達成された。

表 2.7.3－14 各試験における血清 iPTH 濃度変化率-30%以下又は-50%以下の達成率

試験番号	AJ1002	AJ1003		AJ1004	
	18 週*	24 週	52 週	24 週	
				SK-1403 群	プラセボ群
-30%以下達成率	68.4% (39/57)	82.9% (121/146)	89.9% (125/139)	85.3% (81/95)	15.4% (6/39)
95%信頼区間	54.8% - 80.1%	75.8% - 88.6%	83.7% - 94.4%	76.5% - 91.7%	5.9% - 30.5%
-50%以下達成率	47.4% (27/57)	61.6% (90/146)	73.4% (102/139)	63.2% (60/95)	5.1% (2/39)
95%信頼区間	34.0% - 61.0%	53.2% - 69.6%	65.2% - 80.5%	52.6% - 72.8%	0.6% - 17.3%

()：達成例数/症例数，*：AJ1002 試験では本評価項目について 18 週時以外の解析を実施していない。
［資料 5.3.5.2-1 表 14.2.2-1，5.3.5.2-2 表 14.2.2-1 及び 5.3.5.1-1 表 14.2.5-1 から改変引用］

2.7.3.3.2.3 各検査の測定値及び変化率

各試験における血清中各検査測定値及び変化率を表 2.7.3－15 に示した。血清 iPTH 濃度はいずれの試験においても SK-1403 投与により管理目標内（60 pg/mL 以上 240 pg/mL 以下）となり，治療期 24 週以降の変化率では-46.2%～-60.1%の低下が認められた。一方，血清補正 Ca 濃度は SK-1403 投与開始 1 週後に 5%～10%程度低下した後はほぼ一定であった。

表 2.7.3－15 各試験における血清中各検査測定値及び変化率

試験番号		AJ1002	AJ1003	AJ1004	
				SK-1403 群	プラセボ群
iPTH 濃度（pg/mL）	0 週	407.3 ± 233.7	404.1 ± 186.7	398.6 ± 133.0	412.5 ± 191.1
	24 週	193.5 ± 100.4	160.2 ± 95.1	180.8 ± 105.9	445.4 ± 260.6
	52 週	144.6 ± 68.3	137.1 ± 54.6	-	-
iPTH 濃度変化率（%）	24 週	-46.2 ± 29.7	-54.3 ± 27.5	-53.4 ± 22.7	7.6 ± 38.3
	52 週	-56.9 ± 33.6	-60.1 ± 20.4	-	-
補正 Ca 濃度（mg/dL）	0 週	9.56 ± 0.68	9.57 ± 0.60	9.34 ± 0.68	9.40 ± 0.74
	1 週	8.58 ± 0.77	9.04 ± 0.62	8.74 ± 0.64	9.47 ± 0.82
	24 週	8.87 ± 0.80	8.97 ± 0.60	8.76 ± 0.61	9.50 ± 0.76
	52 週	9.13 ± 0.81	9.10 ± 0.49	-	-
補正 Ca 濃度変化率	1 週	-10.3 ± 4.0	-5.5 ± 3.9	-6.5 ± 3.6	0.8 ± 2.5
（%）	24 週	-7.4 ± 7.6	-5.9 ± 7.1	-5.9 ± 8.5	1.5 ± 4.3
	52 週	-4.6 ± 7.5	-4.7 ± 6.6	-	-
P 濃度（mg/dL）	0 週	5.33 ± 1.13	5.81 ± 1.26	5.95 ± 1.36	6.15 ± 1.55
	24 週	5.14 ± 1.31	5.36 ± 1.35	4.93 ± 1.37	5.60 ± 1.57
	52 週	4.93 ± 1.35	5.29 ± 1.08	-	-
P 濃度変化率（%）	24 週	-0.8 ± 24.1	-5.4 ± 25.1	-15.6 ± 25.4	-6.7 ± 28.4
	52 週	-3.5 ± 25.8	-6.0 ± 23.6	-	-
補正 Ca×P 積	0 週	51.095 ± 12.274	55.634 ± 12.707	55.648 ± 13.230	57.851 ± 15.400
	24 週	45.673 ± 12.390	48.004 ± 12.714	43.393 ± 13.095	53.181 ± 14.682
	52 週	44.968 ± 12.576	48.176 ± 10.426	-	-
補正 Ca×P 積変化率	24 週	-8.2 ± 23.6	-10.8 ± 26.2	-20.6 ± 25.1	-5.7 ± 27.5
（%）	52 週	-7.7 ± 26.8	-10.2 ± 24.2	-	-
whole-PTH 濃度	0 週	222.99 ±110.58	251.90 ± 117.20	227.59 ± 81.82	241.28 ± 113.41
（pg/mL）	24 週*	118.99 ±69.49	91.32 ± 62.59	115.73 ± 77.48	283.14 ± 148.29
	52 週	80.04 ±49.49	88.78 ± 37.92	-	-
whole-PTH 濃度変化率	24 週*	-40.1 ±35.6	-59.0 ± 23.8	-47.9 ± 26.6	20.1 ± 44.4
（%）	52 週	-58.4 ±33.4	-58.7 ± 21.4	-	-
iFGF23（pg/mL）	0 週	13509.7 ± 18201.7	17054.83 ± 31866.97	14707.85 ± 20551.14	17795.25 ± 21255.92
	24 週*	9505.2 ± 17094.8	10470.76 ± 20989.52	8862.31 ± 13630.33	21961.59 ± 25291.67
	52 週	8885.4 ± 11806.7	10875.10 ± 15528.79	-	-
iFGF23 変化率（%）	24 週*	-34.1 ± 52.6	-21.0 ± 103.4	-30.1 ± 105.6	60.6 ± 282.7
	52 週	4.9 ± 160.0	17.7 ± 289.1	-	-

試験番号		AJ1002	AJ1003	AJ1004	
				SK-1403 群	プラセボ群
BAP（μg/L）	0 週	18.23 ± 13.22	16.08 ± 7.29	18.18 ± 9.33	18.58 ± 11.98
	24 週*	14.23 ± 9.37	11.75 ± 5.09	14.77 ± 8.86	21.05 ± 14.67
	52 週	11.23 ± 5.60	10.80 ± 3.85	-	-
BAP 変化率（μg/L）	24 週*	-12.6 ± 28.6	-21.8 ± 26.0	-13.4 ± 27.8	12.0 ± 32.7
	52 週	-25.9 ± 47.8	-25.7 ± 25.5	-	-
total P1NP（ng/mL）	0 週	402.32 ± 288.35	337.58 ± 241.16	390.34 ± 223.27	389.10 ± 276.76
	24 週*	256.48 ± 214.93	222.12 ± 146.29	230.07 ± 120.49	428.51 ± 302.95
	52 週	236.53 ± 191.65	179.20 ± 101.86	-	-
total P1NP 変化率（%）	24 週*	-27.4 ± 35.4	-18.3 ± 56.2	-30.1 ± 34.7	8.8 ± 36.2
	52 週	-26.2 ± 73.6	-29.1 ± 53.2	-	-
TRACP-5b（mU/dL）	0 週	755.9 ± 413.3	699.3 ± 337.5	740.3 ± 340.4	747.2 ± 380.6
	24 週*	456.8 ± 255.3	356.6 ± 188.9	373.0 ± 216.8	737.3 ± 391.1
	52 週	405.3 ± 205.1	330.1 ± 172.3	-	-
TRACP-5b 変化率	24 週*	-32.4 ± 37.4	-43.8 ± 28.0	-46.7 ± 22.4	-0.7 ± 24.9
（%）	52 週	-40.9 ± 38.2	-47.2 ± 24.4	-	-

Mean ± SD，*：AJ1002 試験は 22 週
-：データなし。
［資料 5.3.5.2-1 表 14.2.12-1 及び表 14.2.13-1, 5.3.5.2-2 表 14.2.3-1 及び表 14.2.3-2 並びに 5.3.5.1-1 表 14.2.6.1 及び表 14.2.6.2 から改変引用］

2.7.3.3.3 部分集団における結果の比較

各試験における血清 iPTH 濃度目標達成率の部分集団解析結果を表 2.7.3－16 に示した。AJ1004 試験における Logistic 回帰分析の結果により影響因子として選択された血清 iPTH 濃度ベースライン値による部分集団解析では，ベースライン値が 500 pg/dL 以上の部分集団で目標達成率が低い傾向が認められたが，AJ1002 試験及び AJ1003 試験の治療期 52 週の結果では大きな影響は認められなかった。その他の因子による解析では各部分集団で違いが認められるものはなかった。

表 2.7.3－16　各試験における血清 iPTH 濃度目標達成率（%）の部分集団解析

試験番号			AJ1002		AJ1003	AJ1004	
						SK-1403 群	プラセボ群
			18 週	52 週	52 週	24 週	24 週
性別	男	N	42	37	121	77	39
		達成率	57.1%	81.1%	82.6%	64.9%	10.3%
	女	N	15	15	36	26	11
		達成率	60.0%	80.0%	86.1%	73.1%	0.0%
年齢（歳）	<65	N	33	30	91	48	20
		達成率	66.7%	86.7%	83.5%	66.7%	10.0%
	≥65	N	24	22	66	55	30
		達成率	45.8%	72.7%	83.3%	67.3%	6.7%
透析後体重（kg）	<50.0	N	10	10	20	18	14
		達成率	50.0%	60.0%	90.0%	72.2%	7.1%
	≥50 <60.0	N	21	18	44	26	13
		達成率	76.2%	88.9%	84.1%	53.8%	7.7%
	≥60 <70.0	N	12	12	46	37	13
		達成率	33.3%	83.3%	82.6%	78.4%	0.0%
	≥70.0	N	14	12	47	22	10
		達成率	57.1%	83.3%	80.9%	59.1%	20.0%
原疾患	慢性糸球体腎炎	N	19	15	59	36	24
		達成率	84.2%	86.7%	81.4%	72.2%	4.2%
	糖尿病性腎症	N	16	15	31	33	10
		達成率	43.8%	80.0%	87.1%	66.7%	20.0%
	腎硬化症	N	3	3	22	13	5
		達成率	100.0%	33.3%	77.3%	61.5%	0.0%
	多発性嚢胞腎	N	4	4	13	2	1
		達成率	50.0%	75.0%	84.6%	100.0%	0.0%
	その他	N	15	15	32	19	10
		達成率	33.3%	86.7%	87.5%	57.9%	10.0%
透析期間（年）	<5	N	16	16	45	35	25
		達成率	56.3%	75.0%	88.9%	68.6%	8.0%
	≥5 <10	N	19	14	49	21	6
		達成率	63.2%	71.4%	81.6%	61.9%	0.0%
	≥10 <20	N	17	17	48	32	16
		達成率	52.9%	88.2%	81.3%	71.9%	12.5%
	≥20	N	5	5	15	15	3
		達成率	60.0%	100.0%	80.0%	60.0%	0.0%
透析方法	HD	N	28	27	84	43	25
		達成率	53.6%	74.1%	88.1%	60.5%	8.0%
	HDF	N	29	25	73	60	25
		達成率	62.1%	88.0%	78.1%	71.7%	8.0%
透析液 Ca 濃度（mEq/L）	2.5	N	11	11	78	32	14
		達成率	36.4%	72.7%	82.1%	68.8%	21.4%
	2.75	N	16	15	46	39	21
		達成率	56.3%	73.3%	89.1%	61.5%	4.8%
	3.0	N	30	26	33	32	15
		達成率	66.7%	88.5%	78.8%	71.9%	0.0%
排尿の有無	無	N	33	30	82	43	14
		達成率	66.7%	76.7%	82.9%	72.1%	7.1%
	有	N	24	22	75	60	36
		達成率	45.8%	86.4%	84.0%	63.3%	8.3%
リン吸着薬の有無	無	N	3	3	11	8	4
		達成率	0.0%	100.0%	81.8%	62.5%	0.0%
	有	N	54	49	146	95	46
		達成率	61.1%	79.6%	83.6%	67.4%	8.7%

試験番号			AJ1002		AJ1003	AJ1004	
						SK-1403 群	プラセボ群
			18 週	52 週	52 週	24 週	24 週
リン吸着薬の内容	Ca 含有	N	8	7	17	7	6
		達成率	50.0%	71.4%	82.4%	71.4%	0.0%
	Ca 非含有	N	21	19	83	48	25
		達成率	61.9%	84.2%	88.0%	70.8%	4.0%
	併用	N	25	23	46	40	15
		達成率	64.0%	78.3%	76.1%	62.5%	20.0%
カルシウム製剤の有無	無	N	57	52	142	100	48
		達成率	57.9%	80.8%	83.8%	66.0%	8.3%
	有	N	0	0	15	3	2
		達成率	-	-	80.0%	100.0%	0.0%
活性型ビタミン D 製剤の有無	無	N	11	11	22	27	7
		達成率	54.5%	81.8%	81.8%	44.4%	0.0%
	有	N	46	41	135	76	43
		達成率	58.7%	80.5%	83.7%	75.0%	9.3%
血清 iPTH 濃度ベースライン値*（pg/mL）	≤240	N	11	9	19	5	4
		達成率	72.7%	55.6%	84.2%	80.0%	0.0%
	>240 <500	N	31	29	101	79	38
		達成率	64.5%	89.7%	89.1%	73.4%	10.5%
	≥500	N	15	14	37	19	8
		達成率	33.3%	78.6%	67.6%	36.8%	0.0%
血清補正 Ca 濃度ベースライン値*（mg/dL）	<8.4	N	-	-	0	2	2
		達成率	-	-	-	0.0%	0.0%
	≥8.4 <9.0	N	13	11	24	37	15
		達成率	53.8%	72.7%	91.7%	67.6%	13.3%
	≥9.0 <10.0	N	28	27	101	49	23
		達成率	67.9%	74.1%	83.2%	71.4%	8.7%
	≥10.0	N	16	14	32	15	10
		達成率	43.8%	100.0%	78.1%	60.0%	0.0%
血清 P 濃度ベースライン値*（mg/dL）	<3.5	N	1	1	2	1	1
		達成率	100.0%	0.0%	100.0%	100.0%	0.0%
	≥3.5 ≤6.0	N	42	41	94	56	26
		達成率	57.1%	85.4%	87.2%	60.7%	3.8%
	>6.0	N	14	10	61	46	23
		達成率	57.1%	70.0%	77.0%	73.9%	13.0%
被験者ごとの SK-1403 最終投与量	0 μg	N	4	0	-	-	-
		達成率	50.0%	-	-	-	-
	25 μg	N	9	12	31	28	1
		達成率	77.8%	66.7%	83.9%	64.3%	0.0%
	50 μg	N	16	12	36	17	3
		達成率	81.3%	83.3%	91.7%	70.6%	33.3%
	100 μg	N	5	6	26	17	2
		達成率	20.0%	66.7%	96.2%	76.5%	50.0%
	150 μg	N	8	5	17	15	2
		達成率	87.5%	80.0%	70.6%	66.7%	0.0%
	200 μg	N	3	4	13	9	4
		達成率	33.3%	100.0%	76.9%	77.8%	0.0%
	250 μg	N	3	4	6	7	8
		達成率	0.0%	100.0%	83.3%	57.1%	25.0%
	300 μg	N	9	9	28	10	30
		達成率	22.2%	88.9%	71.4%	50.0%	0.0%

試験番号			AJ1002		AJ1003	AJ1004	
						SK-1403 群	プラセボ群
			18 週	52 週	52 週	24 週	24 週
被験者ごとの	25 μg	N	0	0	8	16	1
SK-1403		達成率	-	-	87.5%	56.3%	0.0%
最大投与量	50 μg	N	28	20	33	25	2
		達成率	78.6%	70.0%	84.8%	72.0%	50.0%
	100 μg	N	6	8	39	20	3
		達成率	16.7%	87.5%	92.3%	80.0%	33.3%
	150 μg	N	8	6	25	15	2
		達成率	87.5%	66.7%	80.0%	66.7%	0.0%
	200 μg	N	3	5	14	10	4
		達成率	33.3%	100.0%	85.7%	70.0%	0.0%
	250 μg	N	3	2	9	7	8
		達成率	0.0%	100.0%	77.8%	57.1%	25.0%
	300 μg	N	9	11	29	10	30
		達成率	22.2%	90.9%	72.4%	50.0%	0.0%

目標達成率は，AJ1002 試験は 18 週時，AJ1003 試験は 24 週時，AJ1004 試験は 22，23，24 週時平均値の血清 iPTH 濃度から算出した。

- : データなし又は算出なし。

* : 0 週測定値。ただし，AJ1002 試験の血清 iPTH 濃度は投与前直近の観察期 2 回の測定値の平均値。

［資料 5.3.5.2-1 表 14.2.7-1～表 14.2.7-21 及び表 14.2.14-1～表 14.2.14-21, 5.3.5.2-2 表 14.2.6.-1～表 14.2.6-21 並びに 5.3.5.1-1 表 14.2.9.1～表 14.2.9-23 から改変引用］

2.7.3.4　推奨用法・用量（案）に関する臨床情報の解析

SK-1403 の用法及び用量（案）並びに用法及び用量に関連する注意（案）（開始用量及び用量調整に関する部分）を以下に設定した。

【用法及び用量】（案）
通常，成人には，ウパシカルセトナトリウムとして 1 回 25 μg を開始用量とし，週 3 回，透析終了時の返血時に透析回路静脈側に注入する。血清カルシウム濃度に応じて開始用量を 1 回 50 μg とすることができる。以後は，患者の副甲状腺ホルモン（PTH）及び血清カルシウム濃度の十分な観察のもと，1 回 25～300 μg の範囲内で適宜用量を調整する。

【用法及び用量に関連する注意】（案）（開始用量及び用量調整に関する部分）
1) 本剤は血中カルシウムの低下作用を有するので, 血清カルシウム濃度が低値でないこと（目安として 8.4 mg/dL 以上）を確認して投与を開始すること。
2) 血清カルシウム濃度が 9.0 mg/dL 以上の場合は，開始用量として 1 回 50 μg を考慮すること。
3) 増量する場合には増量幅を 50 μg（ただし，25 μg から増量する場合は 50 μg へ増量）とし，2 週間以上の間隔をあけて行うこと。

2.7.3.4.1　開始用量及び投与開始時の血清 Ca 濃度の確認

SK-1403 は CaSR 作動薬であり，Ca 濃度を低下させる作用を有する。このため，SK-1403 の開始用量は以下の理由から，血清補正 Ca 濃度が 9.0 mg/dL 未満の場合 25 μg，9.0 mg/dL 以上の場合 50 μg とした。また, AJ1001 試験以降では安全性を考慮して血清 Ca 濃度が 8.4 mg/dL 以上の患者を対象としたことから, SK-1403 の投与開始前に血清 Ca 濃度を測定して低値でないことを確認し，試験を実施した。

AJ1001 試験において血液透析下の SHPT 患者を対象にプラセボ，SK-1403 の 50，100 及び 200 μg を 3 週間投与したところ, 以下に示した結果が得られたことから（2.7.2.2.3.2, 2.7.6.2），血清 iPTH 濃度の低下が認められ，血清補正 Ca 濃度が過度に低下する可能性が低い 50 μg を AJ1002 試験の開始用量として設定した。

・SK-1403 の血漿中未変化体のトラフ濃度は上昇せず，蓄積性はなかった。
・いずれの投与量の群においても安全性に特段の問題はなかった。
・投与終了時における血清 iPTH 濃度の変化率は，プラセボ群，50 μg 群，100 μg 群及び 200 μg 群でそれぞれ 17.24%，-7.64%，-24.78%，及び-36.23%であり，用量依存的に血清 iPTH 濃度が低下する傾向が認められた。
・投与終了時における血清補正 Ca 濃度の変化率は，プラセボ群，50 μg 群，100 μg 群及び 200 μg 群でそれぞれ-1.20%，-9.51%，-11.87%，-17.14%であり用量依存的に低下する傾向が認められた。
・投与期間中に血清補正 Ca 濃度が 7.5 mg/dL 未満に低下した症例数は，50，100 及び 200 μg 投与群でそれぞれ 8 例中 0 例（0%），8 例中 2 例（25.0%）及び 10 例中 3 例（30.0%）であった（過量投与症例を除く）。

AJ1002 試験の結果，開始用量 50 μg における有効性が確認でき，かつ安全性に大きな問題

はなかったが，投与初期において過度の血清補正 Ca 濃度の低下（<7.5 mg/dL）による休薬が 58 例中 9 例（15.5%）に 10 件発生した（表 2.7.4.7―34）。初期値 9.0 mg/dL 未満の患者に開始用量 50 μg を投与した際に高頻度に発現する傾向が認められたことから（表 2.7.4.7―35），これらの患者においては 50 μg でも薬剤の効果が過剰に発現していると考え，AJ1004 試験及び AJ1003 試験における SK-1403 の開始用量は，治験薬投与開始 1 週前の血清補正 Ca 濃度が 9.0 mg/dL 以上の場合は 50 μg とするが，9.0 mg/dL 未満の場合は 25 μg とすることで，投与初期の血清補正 Ca 濃度低下の発現を減じることができると考えた。

AJ1004 試験の結果，過度の血清補正 Ca 濃度低下に伴う休薬は 103 例中 2 例（1.9%）に 2 件発生したが（表 2.7.4.7―34），2 例とも休薬後 1 週間で回復し，再投与後に血清補正 Ca 濃度低下により再度休薬した患者はいなかった。AJ1003 試験においては，過度の血清補正 Ca 濃度低下に伴う休薬は発生しなかった。

また，有効性については，血清 iPTH 濃度目標達成率において試験間で大きな違いはなかった（2.7.3.3.2.1）。さらに AJ1002 試験における主要評価項目の評価時期である治療期 18 週時の目標達成率においては，AJ1002 試験で 57.9%（33 例/57 例）であったのに対し，AJ1004 試験及び AJ1003 試験ではそれぞれ 73.5%（72 例/98 例），68.0%（102 例/150 例）であり，AJ1002 試験の目標達成率より高かったことから，開始用量を変更したことによる有効性の減弱はないと判断した。

以上より，SK-1403 の開始用量は一律で 50 μg とするよりも投与前の血清補正 Ca 濃度によって 25 μg 又は 50 μg を選択する方が，有効性を保ちつつ，より安全に投与できると考えた。また，AJ1001 試験以降において血清 Ca 濃度が 8.4 mg/dL 以上であることを確認した上で SK-1403 を投与した結果，以上に示したとおり大きな安全性の問題はなかったことから，血清 Ca 濃度が低値でないこと（目安として 8.4 mg/dL 以上）を確認して投与を開始することは適切であると考えた。

2.7.3.4.2　最大用量

SK-1403 を 300 μg まで増量が必要であった被験者の割合は，個体内用量調整で行った AJ1002 試験で 20.7%（12 例/58 例），AJ1003 試験で 18.5%（29 例/157 例），AJ1004 試験で 9.7%（10 例/103 例）であったが（表 2.7.4.7―2），これらの試験において安全性に大きな問題は認められなかった。

また有効性においても，最大投与量として 300 μg を投与された被験者における血清 iPTH 濃度の目標達成率は，AJ1002 試験で 90.9%（52 週，10 例/11 例），AJ1003 試験で 72.4%（52 週，21 例/29 例），AJ1004 試験で 50.0%（24 週，5 例/10 例）であり（表 2.7.3－16），有効性が確認されている。以上の結果から，有効性及び安全性が確認された用量 300 μg を「本剤の投与可能な最大用量」に設定した。

2.7.3.4.3　用量調整幅及び間隔

SK-1403 は CaSR 作動薬であり，血清補正 Ca 濃度を低下させる作用を有するため，血清補正 Ca 濃度の過度な低下を避けながら用量調整を行う必要がある。

用量調整幅については，急激な増量は避けるべきと考え，AJ1002 試験において増減量を 50 μg 幅（50 μg と 25 μg の間の増減量を除く）で用量調整することとした。その結果，増量・

減量に基づく大きな問題は認められず，50 μg 幅（50 μg と 25 μg の間の増減量を除く）で用量調整することが適切であると考えた。

増量間隔については，AJ1001 試験の結果，血清補正 Ca 濃度は SK-1403 の投与開始後速やかに低下し 1～2 週間で安定することが確認された。また，AJ1004 試験及び AJ1003 試験における増量間隔について，同一用量で 3 週間以上維持し，増量する直前（すなわち同一用量を 2 週間以上投与した時点）の血清補正 Ca 濃度が 8.4 mg/dL 以上である場合に増量すること，とした。その結果，前項（2.7.3.4.1）に示したとおり過度の血清補正 Ca 濃度低下の発現は少なく，2 試験の合計で 260 例中 2 例（0.8%）であったことが確認された。

以上より，同一用量で 2 週間以上投与した場合の血清補正 Ca 濃度が 8.4 mg/dL 以上である場合に増量することで，血清補正 Ca 濃度の過度な低下リスクを抑えながら安全に増量できると考えた。また，臨床試験においては臨床検査値測定機関による中央判定値を用いて増量判定を行ったが，実診療時には血清 Ca 濃度の検査実施後，即日のうちに結果が判明する施設も存在することから，増量間隔は「2 週間以上の間隔をあけて行うこと。」とした。

2.7.3.5　効果の持続，耐薬性

AJ1002 試験及び AJ1003 試験において維持血液透析実施中の患者に SK-1403 を 25 μg から 300 μg の用量で 52 週間投与した結果，血清 iPTH 濃度の目標達成率は経時的に増加し，血清 iPTH 濃度は経時的に低下したことから，長期投与による効果の減弱は認められず耐薬性はないものと考える。

2.7.3.6　付録

該当なし。

ウパシタ静注透析用25μgシリンジ
ウパシタ静注透析用50μgシリンジ
ウパシタ静注透析用100μgシリンジ
ウパシタ静注透析用150μgシリンジ
ウパシタ静注透析用200μgシリンジ
ウパシタ静注透析用250μgシリンジ
ウパシタ静注透析用300μgシリンジ

第2部（モジュール2）

2.7.4 臨床的安全性

株式会社三和化学研究所

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略号一覧表

略号	略号内容
BAP	Bone specific alkaline phosphatase　骨型アルカリフォスファターゼ
BMI	Body Mass Index　肥満指数
CaSR	Calcium-sensing receptor　カルシウム感知受容体
CYP	Cytochrome P450　シトクロム P450
HLGT	High Level Group Terms　高位グループ語
iFGF23	intact fibroblast growth factor 23　インタクト線維芽細胞増殖因子 23
iPTH	intact parathyroid hormone　インタクト副甲状腺ホルモン
MedDRA/J	Medical dictionary for regulatory activities/Japanese version　ICH 国際医薬用語集日本語版
P1NP	type I procollagen N-terminal propeptide　I 型プロコラーゲン架橋 N-プロペプチド
PT	Preferred Term　基本語
PTH	Parathyroid hormone　副甲状腺ホルモン
QTc	Corrected QT interval　補正 QT
QTcF	Corrected QT interval with Fridericia method　Fridericia による補正 QT
SHPT	Secondary hyperparathyroidism　二次性副甲状腺機能亢進症
SMQ	Standardised MedDRA Queries　MedDRA 標準検索式
SOC	System Organ Class　器官別大分類
whole-PTH	whole parathyroid hormone　ホール副甲状腺ホルモン
TRACP-5b	Tartrate-resistant acid phosphatase-5b　酒石酸抵抗性酸性フォスファターゼ

2.7.4　臨床的安全性

2.7.4.1　医薬品への曝露

2.7.4.1.1　総括的安全性評価計画及び安全性試験の記述

2.7.4.1.1.1　臨床的安全性に関する臨床試験の概観

SK-1403 はカルシウム感知受容体（以下，CaSR）作動薬であり，血液透析療法を実施中の患者を対象にした二次性副甲状腺機能亢進症（以下，SHPT）治療薬として開発した。

SK-1403 の臨床的安全性については，第 I 相試験である健康成人男子を対象とした単回投与試験（AJ0001 試験），第 I/II 相試験である維持血液透析下の SHPT 患者を対象とした単回及び反復静脈内投与試験（AJ1001 試験），第 II 相試験である維持血液透析下の SHPT 患者を対象とした SK-1403 の用量調整試験（AJ1002 試験）並びに第 III 相試験である維持血液透析下の SHPT 患者を対象とした長期投与試験（AJ1003 試験）及び二重盲検並行群間比較試験（AJ1004 試験）の 5 試験の結果に基づき評価した（表 2.7.4－1）。個々の試験成績の詳細については 2.7.6 に示した。

表 2.7.4－1　臨床的安全性評価に係る試験の概略

試験番号	目的	デザイン	投与量	投与例数	投与期間（投与回数）	添付資料番号
AJ0001（第 I 相試験）	健康成人男子を対象とした単回投与時の安全性，薬物動態，薬力学的評価の検討	単施設 ランダム化 プラセボ対照 二重盲検 逐次増量	プラセボ 0.01 mg 0.1 mg 1.0 mg 2.5 mg	8 例 6 例 6 例 6 例 6 例	単回 （1 回）	5.3.3.1-1
AJ1001（第 I/II 相試験）	維持血液透析下の SHPT 患者を対象とした単回投与時の安全性，薬物動態，薬力学的評価の検討	多施設共同 ランダム化 プラセボ対照 二重盲検 逐次増量	プラセボ 0.025 mg 0.05 mg 0.1 mg 0.2 mg 0.4 mg 0.6 mg 0.8 mg	15 例 4 例 4 例 4 例 4 例 4 例 4 例 5 例	単回 （1 回）	5.3.3.2-1
	維持血液透析下の SHPT 患者を対象とした反復投与時の安全性，薬物動態，薬力学的評価の検討	多施設共同 ランダム化 プラセボ対照 二重盲検 逐次増量	プラセボ 0.05 mg 0.1 mg 0.2 mg	11 例 9 例 9 例 10 例	週 3 回 22 日間 （9 回）	
AJ1002（第 II 相用量調整試験）	治療第 I 期 維持血液透析下の SHPT 患者を対象とした有効性及び安全性の検討 治療第 II 期 長期投与の安全性及び有効性の検討	多施設共同 非盲検 非対照 個体内用量調整	SK-1403 25～300 μg	58 例	週 3 回 52 週 第 I 期：18 週 （54 回） 第 II 期：34 週 （102 回）	5.3.5.2-1
AJ1003（第 III 相長期投与試験）	維持血液透析下の SHPT 患者を対象とした長期投与の安全性及び有効性の検討	多施設共同 非盲検 非対照 個体内用量調整	SK-1403 25～300 μg	157 例	週 3 回 52 週 （156 回）	5.3.5.2-2
AJ1004（第 III 相比較試験）	維持血液透析下の SHPT 患者を対象としたプラセボに対する優越性の検証及び安全性の検討	多施設共同 ランダム化 プラセボ対照 二重盲検 並行群間比較 個体内用量調整	プラセボ SK-1403 25～300 μg	50 例 103 例	週 3 回 24 週 （72 回）	5.3.5.1-1

本項における臨床的安全性の評価については以下の方針で記載した。AJ1002 試験，AJ1003 試験及び AJ1004 試験は，維持血液透析下の SHPT 患者を対象とし，投与期間 24 週以上の試験であることから，安全性について評価する主要な試験と位置付けた。プラセボとの比較を行った唯一の試験である AJ1004 試験については個別の試験結果を記載した。また，AJ1002 試験，AJ1003 試験及び AJ1004 試験の 3 試験については，臨床的安全性の評価方法が同じでかつ類似したデザインで実施された試験であることから，併合解析を行った。AJ0001 試験及び AJ1001 試験についてはその他の試験として，個々の試験結果を基に主に有害事象について記載した。

全ての臨床試験で，自覚症状及び他覚所見の収集，臨床検査［血液学的検査，血液生化学検査，骨代謝マーカー測定（AJ0001 試験を除く），血清 P 及び Ca 濃度調節関連因子測定］，安静時 12 誘導心電図検査，バイタルサイン（血圧，脈拍数）測定並びに体重測定を実施し，SK-1403 の臨床的安全性を評価した。AJ1001 試験の反復投与パート，AJ1002 試験，AJ1003 試験及び AJ1004 試験においては眼科学的検査を実施し，SK-1403 の水晶体混濁に対する影響について評価した。

臨床検査は中央測定で行い，臨床検査値の異常の判定は，測定委託先の基準値に基づき判定した。臨床検査値の異常が認められた場合，治験責任医師又は治験分担医師が 2.7.4.1.1.2（2）の定義に基づき有害事象であるか否かを判定した。

安静時 12 誘導心電図検査については，各測定時点で 3 回測定し，測定結果を第三者である心電図解析委託機関に送付し，統一的に個々の心電図の所見，QT 間隔，QTcF，QRS 間隔，RR 間隔，PR 間隔について評価を行った（AJ0001 試験を除く）。治験責任医師又は治験分担医師は，心電図波形及び自動解析結果と心電図解析委託機関における評価結果を基に，異常所見の有無を 3 段階（1. 正常，2. 臨床的に問題とならない異常，3. 臨床的に問題となる異常）で判定した。

眼科学的検査については，治験薬投与前後でスリットランプを用いた検査（細隙灯顕微鏡検査）を実施し，スクリーニング検査時に水晶体の状態（無水晶体，人工水晶体，有水晶体，不明）及び有水晶体の場合には，水晶体の混濁の有無を確認した。治験薬投与後には，スクリーニング検査時と比較して臨床上問題となる悪化の有無を確認した。

2.7.4.1.1.2　臨床的安全性の評価

（1）臨床的安全性の解析対象集団

治験薬が 1 回以上投与された被験者を臨床的安全性の解析対象（安全性解析対象集団）とした。

（2）有害事象の定義

治験薬との因果関係の有無を問わず，治験薬を投与された被験者に生じた全ての好ましくない又は意図しない疾病又はその徴候（臨床検査値の異常を含む）を有害事象と定義した。

(3) 有害事象名のコーディング

各試験において症例報告書で収集した有害事象名は，ICH 国際医薬用語集日本語版（以下，MedDRA/J）に基づき，器官別大分類（以下，SOC）及び基本語（以下，PT）でコーディングした。この際，AJ0001 試験では MedDRA/J バージョン 17.1 を，AJ1001 試験では MedDRA/J バージョン 18.1 を，AJ1002 試験では MedDRA/J バージョン 20.0 を，AJ1003 試験及び AJ1004 試験では MedDRA/J バージョン 21.1 をそれぞれ使用した。一方，併合解析の実施にあたり，主要な 3 試験（AJ1002 試験，AJ1003 試験，AJ1004 試験）における有害事象名を MedDRA/J バージョン 22.1 に基づいて再コーディングした。

(4) 重篤性及び重症度の定義

以下のいずれかに該当する有害事象を重篤とし，その他を非重篤とした。

1. 死亡
2. 死亡につながるおそれのある症例
3. 治療のために病院又は診療所への入院又は入院期間の延長が必要とされる症例
4. 障害
5. 1～4 に準じて重篤である症例
6. 後世代における先天性の疾病又は異常

有害事象の重症度は以下の 3 段階で判定した。

1. 軽度：日常の生活に特に支障を来さない
2. 中等度：日常の生活に支障を来す
3. 高度：日常の生活がほとんどおくれない

(5) 治験薬との因果関係

有害事象と治験薬との因果関係は「有」，「無」の 2 段階で判定し，「有」と判定された事象を「副作用」と定義した。

(6) 特に留意した有害事象

併合解析において，以下に示す有害事象について特に留意した有害事象として発現状況を検討した。表 2.7.4－2 にそれぞれの有害事象の集計対象についての定義を示した。

1) 「低カルシウム血症」に関連する有害事象

SK-1403 の薬理作用である血清副甲状腺ホルモン（以下，PTH）濃度低下の結果として，血清 Ca 濃度が低下し，「低カルシウム血症」が発現するおそれがある。

2) 「骨代謝障害」に関連する有害事象

SK-1403 の薬理作用である血清 PTH 濃度低下の結果として，無形成骨等の「骨代謝障害」に関連する有害事象が発現するおそれがある。

3）「胃腸障害」に関連する有害事象

既存の CaSR 作動薬における主な副作用として，悪心，嘔吐，腹部不快感，下痢，食欲減退等の「胃腸障害」が認められている。

4）「QT 延長」に関連する有害事象

SK-1403 の薬理作用である血清 PTH 濃度低下の結果として，血清 Ca 濃度が低下し，「QT 延長」に関連する有害事象の発現リスクが増大するおそれがある。

5）「水晶体混濁」に関連する有害事象

SK-1403 の非臨床反復投与毒性試験において水晶体の混濁が認められている。

表 2.7.4－2　特に留意した有害事象の定義

特に留意した有害事象	集計対象とした有害事象
「低カルシウム血症」に関連する有害事象	PT「低カルシウム血症」，PT「血中カルシウム減少」，PT「補正カルシウム減少」
「骨代謝障害」に関連する有害事象	PT「飢餓骨症候群」，PT「骨代謝障害」，PT「低回転型骨症」，HLGT「骨折」
「胃腸障害」に関連する有害事象	SOC「胃腸障害」
「QT 延長」に関連する有害事象	SMQ「トルサード　ド　ポアント／QT 延長」（狭域）
「水晶体混濁」に関連する有害事象	SMQ「水晶体障害」（狭域）

PT：基本語，HLGT：高位グループ語，SOC：器官別大分類，SMQ：MedDRA 標準検索式

2.7.4.1.1.3　統計解析の概観

（1）有害事象の集計における定義

重篤な有害事象のうち，転帰が死亡以外である事象を「その他の重篤な有害事象」と定義した。また，治験薬の中止，休薬又は減量の理由となった有害事象のうち，重篤な有害事象を除いた事象を「他の重要な有害事象」と定義した。併合解析においては，SK-1403 併合群で発現率が 2%以上であった有害事象を「比較的よく見られる有害事象」と定義して解析した。一方，本項では発現率 5%以上の有害事象について「2.7.4.2.1.2 比較的よく見られる有害事象」に記載した。

（2）併合解析における集計方法

全ての有害事象，死亡に至った有害事象，その他の重篤な有害事象，他の重要な有害事象及び特に留意した有害事象について，全体，重症度別及び時期別の発現状況を集計した。また，これらの事象の発現状況について，内因性要因及び外因性要因による部分集団解析を行った。比較的よく見られる有害事象については，各事象の発現状況を集計した。

特に留意した有害事象の発現状況については，表 2.7.4－2 に示した該当する事象を集計した。

臨床検査値，バイタルサイン，体重については，各時点の測定値を集計した。安静時 12 誘導心電図検査については，正常，異常の変動の度数を集計した。

2.7.4.1.2　全般的な曝露状況

(1) AJ1004 試験

維持血液透析下の SHPT 患者を対象として，SK-1403 又はプラセボを週 3 回，24 週間投与した。治験薬の投与量は，血清インタクト副甲状腺ホルモン（以下，iPTH）濃度を 60～240 pg/mL の範囲に維持することを目標に，被験者ごとに 25～300 μg の範囲で調整した。

SK-1403 群における治験薬の総投与量の平均値は 6586.7 μg，中央値は 6550.0 μg，投与期間の平均値は 160.3 日，中央値は 166.0 日，投与率及び投与遵守率*の平均値はそれぞれ97.19%及び98.34%であった。最大投与量は50 μgの被験者が最も多く(24.3%)，最終投与量は 25 μg の被験者が最も多かった（27.2%)。

プラセボ群における治験薬の総投与量の平均値は 10771.0 μg，中央値は 13175.0 μg，投与期間の平均値は 146.0 日，中央値は 166.0 日，投与率及び投与遵守率*の平均値はそれぞれ 98.07%及び 99.02%であった。最大投与量は 300 μg の被験者が最も多く（60.0%)，最終投与量は 300 μg の被験者が最も多かった（60.0%)。

*：投与率＝（投与可能回数 ― 未投与回数）÷投与可能回数×100
　投与遵守率＝（投与可能回数 ― 投与の不遵守回数）÷投与可能回数×100

(2) AJ1002 試験，AJ1003 試験，AJ1004 試験の併合解析

維持血液透析下の SHPT 患者を対象として，SK-1403 又はプラセボを週 3 回，24 又は 52 週間投与した。治験薬の投与量は，血清 iPTH 濃度を 60～240 pg/mL の範囲に維持することを目標に，被験者ごとに 25～300 μg の範囲で調整した。治験薬の総投与量と投与期間の集計結果を表 2.7.4.7－1 に，最大投与量別の被験者割合を表 2.7.4.7－2 に，最終投与量別の被験者割合を表 2.7.4.7－3 に，減量状況を表 2.7.4.7－4 に，減量幅のシフトテーブルを表 2.7.4.7－5 に，休薬状況を表 2.7.4.7－6 に示した。

SK-1403 併合群における治験薬の総投与量の平均値は 13542.1 μg, 中央値は 9300.0 μg, 投与期間の平均値は 280.5 日，中央値は 362.0 日であった。投与期間別の集計では 38 週超 52 週以下の症例の割合が最も高く，61.0%であった。最大投与量は 50 μg の被験者が最も多く（25.8%)，最終投与量は 25 μg の被験者が最も多かった（23.0%)。治験薬の減量は 198 件あり，50 μg から 25 μg への減量が 53 件と最も多かった。

プラセボ群の総投与量，投与期間，最大投与量及び最終投与量は（1）AJ1004 試験に記載したとおりである。併合解析で実施した，投与期間別の集計では 21 週超 24 週以下の症例の割合が最も高く，78.0%であった。治験薬の減量は 4 件あり，25 μg から

休薬への減量が 2 件であった。

(3) その他の試験

1) AJ0001 試験

健康成人男子を対象として，SK-1403 を 0.01～2.5 mg の用量で 1 回投与した。

2) AJ1001 試験

a) 単回投与

維持血液透析下の SHPT 患者を対象として，SK-1403 を 0.025～0.8 mg の用量で 1 回投与した。

b) 反復投与

維持血液透析下の SHPT 患者を対象として，SK-1403 を 0.05～0.2 mg の用量で週 3 回，22 日間投与した。

0.05 mg 群 1 例において 2 回，0.1 mg 群 1 例において 1 回の過量投与が発生し，いずれも SK-1403 1 mg が投与された。これらの症例における有害事象，検査結果等については割付けられた群で集計した。

2.7.4.1.3 治験対象集団の人口統計学的特性及びその他の特性

(1) AJ1004 試験

被験者の人口統計学的特性及びその他の特性を表 2.7.4－3 に示した。

SK-1403 群における性別の割合は男性 74.8%，女性 25.2%，年齢は 62.4 歳（平均，以下同じ），BMI は 23.13 kg/m^2，透析期間は 10.18 年，血清 iPTH 濃度は 398.6 pg/mL，血清補正 Ca 濃度は 9.34 mg/dL，血清 P 濃度は 5.95 mg/dL，血清補正 Ca×P 積は 55.648，血清ホール副甲状腺ホルモン（以下，whole-PTH）は 227.59 pg/mL であった。リン吸着薬を使用している被験者の割合は 92.2%，カルシウム製剤を使用している被験者の割合は 2.9%，活性型ビタミン D 製剤を使用している被験者の割合は 73.8%であった。

プラセボ群における性別の割合は男性 78.0%，女性 22.0%，年齢は 65.8 歳，BMI は 22.89 kg/m^2，透析期間は 8.00 年，血清 iPTH 濃度は 412.5 pg/mL，血清補正 Ca 濃度は 9.40 mg/dL，血清 P 濃度は 6.15 mg/dL，血清補正 Ca×P 積は 57.851，血清 whole-PTH は 241.28 pg/mL であった。リン吸着薬を使用している被験者の割合は 92.0%，カルシウム製剤を使用している被験者の割合は 4.0%，活性型ビタミン D 製剤を使用している被験者の割合は 86.0%であった。

表 2.7.4－3　被験者背景（AJ1004 試験）

部分集団		SK-1403 群 (N=103)	プラセボ群 (N=50)	p 値	
性別	男	77(74.8%)	39(78.0%)	0.6933	[1]
	女	26(25.2%)	11(22.0%)		
年齢(歳)	n	103	50	0.1314	[2]
	Mean ± SD	62.4 ± 12.6	65.8 ± 13.6		
年齢　カテゴリ	<65 歳	48(46.6%)	20(40.0%)	0.4902	[1]
	≥65 歳	55(53.4%)	30(60.0%)		
BMI(kg/m^2)	n	103	50	0.7062	[2]
	Mean ± SD	23.13 ± 3.64	22.89 ± 3.78		
原疾患	慢性糸球体腎炎	36(35.0%)	24(48.0%)	0.4524	[1]
	糖尿病性腎症	33(32.0%)	10(20.0%)		
	腎硬化症	13(12.6%)	5(10.0%)		
	多発性嚢胞腎	2(1.9%)	1(2.0%)		
	その他	19(18.4%)	10(20.0%)		
透析期間(年)	n	103	50	0.1131	[2]
	Mean ± SD	10.18 ± 8.48	8.00 ± 6.67		
透析期間　カテゴリ	<5 年	35(34.0%)	25(50.0%)	0.0809	[3]
	5 年 - <10 年	21(20.4%)	6(12.0%)		
	10 年 - <20 年	32(31.1%)	16(32.0%)		
	≥20 年	15(14.6%)	3(6.0%)		
透析方法	HD:血液透析	43(41.7%)	25(50.0%)	0.3871	[1]
	HDF:血液透析濾過	60(58.3%)	25(50.0%)		
透析液 Ca 濃度	2.5 mEq/L	32(31.1%)	14(28.0%)	0.9066	[1]
	2.75 mEq/L	39(37.9%)	21(42.0%)		
	3.0 mEq/L	32(31.1%)	15(30.0%)		
	その他	0(0.0%)	0(0.0%)		
リン吸着薬の有無	無	8(7.8%)	4(8.0%)	1.0000	[1]
	有	95(92.2%)	46(92.0%)		
Ca 製剤の有無	無	100(97.1%)	48(96.0%)	0.6620	[1]
	有	3(2.9%)	2(4.0%)		
活性型ビタミン D 製剤の有無	無	27(26.2%)	7(14.0%)	0.1005	[1]
	有	76(73.8%)	43(86.0%)		
血清 iPTH 濃度ベースライン値 (pg/mL)	n	103	50	0.6446	[2]
	Mean ± SD	398.6 ± 133.0	412.5 ± 191.1		
血清 iPTH 濃度ベースライン値 カテゴリ	≤240 pg/mL	5(4.9%)	4(8.0%)	0.5075	[3]
	>240 pg/mL - <500 pg/mL	79(76.7%)	38(76.0%)		
	≥500 pg/mL	19(18.4%)	8(16.0%)		
血清補正 Ca 濃度ベースライン値 (mg/dL)	n	103	50	0.6240	[2]
	Mean ± SD	9.34 ± 0.68	9.40 ± 0.74		
血清補正 Ca 濃度ベースライン値 カテゴリ	<8.4 mg/dL	2(1.9%)	2(4.0%)	0.5273	[3]
	8.4 mg/dL - <9.0 mg/dL	37(35.9%)	15(30.0%)		
	9.0 mg/dL - ≤10.0 mg/dL	49(47.6%)	23(46.0%)		
	>10.0 mg/dL	15(14.6%)	10(20.0%)		
血清 P 濃度ベースライン値(mg/dL)	n	103	50	0.4244	[2]
	Mean ± SD	5.95 ± 1.36	6.15 ± 1.55		
血清 P 濃度ベースライン値 カテゴリ	<3.5 mg/dL	1(1.0%)	1(2.0%)	0.9304	[3]
	3.5 mg/dL - ≤6.0 mg/dL	56(54.4%)	26(52.0%)		
	>6.0mg/dL	46(44.7%)	23(46.0%)		
被験者ごとの開始時投与量	25 μg	27(26.2%)	13(26.0%)	1.0000	[1]
	50 μg	76(73.8%)	37(74.0%)		

[1] Fisher の直接確率検定
[2] 2 標本 t 検定
[3] Wilcoxon の順位和検定
［資料 5.3.5.1-1　表 14.1.1-1 から改変引用］

(2) AJ1002 試験，AJ1003 試験，AJ1004 試験の併合解析

被験者の人口統計学的特性及びその他の特性を表 2.7.4.7－7 に示した。

SK-1403 併合群における性別の割合は男性 75.8%，女性 24.2%，年齢は 61.2 歳，BMI は 23.53 kg/m^2，透析期間は 9.94 年，血清 iPTH 濃度は 402.9 pg/mL，血清補正 Ca 濃度は 9.50 mg/dL，血清 P 濃度は 5.77 mg/dL，血清補正 Ca×P 積は 54.811，血清 whole-PTH は 238.75 pg/mL であった。リン吸着薬を使用している被験者の割合は 93.1%，カルシウム製剤を使用している被験者の割合は 5.7%，活性型ビタミン D 製剤を使用している被験者の割合は 80.8%であった。

プラセボ群の人口統計学的特性及びその他の特性は（1）AJ1004 試験に記載したとおりである。

(3) その他の試験

1) AJ0001 試験

被験者は健康成人男子であり，各群の年齢は21.7～25.6 歳，BMI は20.12～21.35 kg/m^2 であった（2.7.6.1.2 (2)）。

2) AJ1001 試験

a) 単回投与

被験者は維持透析下の SHPT 患者であり，各群の年齢は 57.8～67.5 歳，BMI は 20.71～26.28 kg/m^2，透析期間は 2.44～16.26 年，血清 iPTH 濃度は 267.3～538.7 pg/mL，血清補正 Ca 濃度は 9.30～10.20 mg/dL，血清 P 濃度は 2.98～4.08 mg/dL であった（2.7.6.2.2 (2)）。

b) 反復投与

被験者は維持透析下の SHPT 患者であり，各群の年齢は 53.7～65.2 歳，BMI は 22.58～23.91 kg/m^2，透析期間は 6.69～12.09 年，血清 iPTH 濃度は 368.8～507.5 pg/mL，血清補正 Ca 濃度は 9.43～9.92 mg/dL，血清 P 濃度は 5.26～6.33 mg/dL であった（2.7.6.2.2 (2)）。

2.7.4.2 有害事象

2.7.4.2.1 有害事象の解析

2.7.4.2.1.1 有害事象全体

(1) AJ1004 試験

有害事象及び副作用発現割合を表 2.7.4－4 に，症状別の有害事象一覧を表 2.7.4－5 に示した。

有害事象の発現率は，SK-1403 群で 85.4%（88/103 例），プラセボ群で 72.0%（36/50 例）であり，投与群間に統計学的な有意差は認められなかった（p=0.0768）。また，副作用の発現率は SK-1403 群で 11.7%（12/103 例），プラセボ群で 8.0%（4/50 例）であり，投与群間に統計学的な有意差は認められなかった（p=0.5831）。

SK-1403 群で認められた副作用の症状別の内訳は，「補正カルシウム減少」が 8.7%（9/103 例）で，「悪心」，「シャント血栓症」，「食欲減退」及び「筋痙縮」がいずれも 1.0%（1/103 例）発現した。一方，プラセボ群において認められた副作用の症状別の内訳は，「心房細動」，「慢性心不全」，「腹部不快感」，「嘔吐」及び「心窩部不快感」がいずれも 2.0%（1/50 例）発現した。

表 2.7.4－4　有害事象及び副作用発現割合（AJ1004 試験）

	発現例数（割合）		
	SK-1403 群 (N=103)	プラセボ群 (N=50)	p 値[1]
有害事象	88(85.4%)	36(72.0%)	0.0768
副作用	12(11.7%)	4(8.0%)	0.5831

[1] Fisher の直接確率検定
資料 5.3.5.1-1　表 14.3.1-1 から引用

表 2.7.4－5　症状別の有害事象及び副作用の一覧（AJ1004 試験）

	有害事象		副作用	
	SK-1403 群 (N=103)	プラセボ群 (N=50)	SK-1403 群 (N=103)	プラセボ群 (N=50)
有害事象名(SOC/PT)	合計	合計	合計	合計
血液およびリンパ系障害	3(2.9%)	0(0.0%)		
播種性血管内凝固	1(1.0%)	0(0.0%)		
鉄欠乏性貧血	2(1.9%)	0(0.0%)		
腎性貧血	1(1.0%)	0(0.0%)		
心臓障害	2(1.9%)	2(4.0%)	0(0.0%)	1(2.0%)
狭心症	1(1.0%)	1(2.0%)		
心房細動	0(0.0%)	1(2.0%)	0(0.0%)	1(2.0%)
慢性心不全	0(0.0%)	1(2.0%)	0(0.0%)	1(2.0%)
心室性頻脈	1(1.0%)	0(0.0%)		
耳および迷路障害	2(1.9%)	1(2.0%)		
難聴	1(1.0%)	0(0.0%)		
迷路性回転性めまい	1(1.0%)	0(0.0%)		
頭位性回転性めまい	0(0.0%)	1(2.0%)		
内分泌障害	0(0.0%)	1(2.0%)		
甲状腺機能低下症	0(0.0%)	1(2.0%)		
眼障害	9(8.7%)	2(4.0%)		
白内障	2(1.9%)	0(0.0%)		
霰粒腫	1(1.0%)	0(0.0%)		
糖尿病網膜症	1(1.0%)	0(0.0%)		
ドライアイ	1(1.0%)	0(0.0%)		
網膜出血	0(0.0%)	1(2.0%)		
強膜炎	1(1.0%)	0(0.0%)		
硝子体浮遊物	1(1.0%)	1(2.0%)		
硝子体出血	2(1.9%)	0(0.0%)		
黄斑線維症	1(1.0%)	0(0.0%)		
胃腸障害	32(31.1%)	13(26.0%)	1(1.0%)	3(6.0%)
腹部不快感	2(1.9%)	3(6.0%)	0(0.0%)	1(2.0%)
腹部膨満	1(1.0%)	0(0.0%)		
腹痛	1(1.0%)	0(0.0%)		
上腹部痛	2(1.9%)	1(2.0%)		
アフタ性潰瘍	1(1.0%)	0(0.0%)		
慢性胃炎	2(1.9%)	0(0.0%)		
大腸炎	1(1.0%)	0(0.0%)		
便秘	1(1.0%)	0(0.0%)		
齲歯	2(1.9%)	1(2.0%)		

	有害事象		副作用	
	SK-1403 群 (N=103)	プラセボ群 (N=50)	SK-1403 群 (N=103)	プラセボ群 (N=50)
有害事象名(SOC/PT)	合計	合計	合計	合計
下痢	11(10.7%)	2(4.0%)		
十二指腸炎	1(1.0%)	0(0.0%)		
嚥下障害	1(1.0%)	0(0.0%)		
腸炎	1(1.0%)	1(2.0%)		
胃炎	1(1.0%)	0(0.0%)		
歯肉痛	1(1.0%)	0(0.0%)		
悪心	3(2.9%)	1(2.0%)	1(1.0%)	0(0.0%)
耳下腺腫大	1(1.0%)	0(0.0%)		
直腸出血	0(0.0%)	1(2.0%)		
歯痛	2(1.9%)	0(0.0%)		
嘔吐	5(4.9%)	4(8.0%)	0(0.0%)	1(2.0%)
心窩部不快感	0(0.0%)	1(2.0%)	0(0.0%)	1(2.0%)
軟便	1(1.0%)	0(0.0%)		
一般・全身障害および投与部位の状態	8(7.8%)	1(2.0%)		
無力症	1(1.0%)	0(0.0%)		
胸痛	1(1.0%)	0(0.0%)		
異常感	2(1.9%)	0(0.0%)		
末梢性浮腫	1(1.0%)	0(0.0%)		
疼痛	1(1.0%)	0(0.0%)		
発熱	0(0.0%)	1(2.0%)		
末梢腫脹	1(1.0%)	0(0.0%)		
血管穿刺部位発疹	1(1.0%)	0(0.0%)		
肝胆道系障害	2(1.9%)	0(0.0%)		
胆管炎	1(1.0%)	0(0.0%)		
急性胆嚢炎	1(1.0%)	0(0.0%)		
感染症および寄生虫症	51(49.5%)	16(32.0%)		
口角口唇炎	1(1.0%)	0(0.0%)		
膀胱炎	3(2.9%)	0(0.0%)		
胃腸炎	2(1.9%)	1(2.0%)		
歯肉炎	5(4.9%)	0(0.0%)		
帯状疱疹	0(0.0%)	1(2.0%)		
麦粒腫	2(1.9%)	1(2.0%)		
膿痂疹	1(1.0%)	0(0.0%)		
インフルエンザ	2(1.9%)	0(0.0%)		
肝膿瘍	1(1.0%)	0(0.0%)		
細菌性髄膜炎	1(1.0%)	0(0.0%)		
上咽頭炎	25(24.3%)	12(24.0%)		
外耳炎	0(0.0%)	1(2.0%)		
中耳炎	1(1.0%)	0(0.0%)		
歯周炎	1(1.0%)	0(0.0%)		
咽頭炎	9(8.7%)	1(2.0%)		
肺炎	1(1.0%)	2(4.0%)		
敗血症	1(1.0%)	0(0.0%)		
副鼻腔炎	1(1.0%)	0(0.0%)		
皮膚感染	1(1.0%)	0(0.0%)		
皮下組織膿瘍	1(1.0%)	0(0.0%)		
足部白癬	2(1.9%)	1(2.0%)		
ヘリコバクター感染	1(1.0%)	0(0.0%)		
シャント感染	1(1.0%)	0(0.0%)		
細菌性扁桃炎	1(1.0%)	0(0.0%)		
傷害、中毒および処置合併症	25(24.3%)	9(18.0%)	1(1.0%)	0(0.0%)
動物咬傷	0(0.0%)	1(2.0%)		
節足動物刺傷	1(1.0%)	0(0.0%)		
上顆炎	0(0.0%)	1(2.0%)		
大腿骨頚部骨折	0(0.0%)	1(2.0%)		
大腿骨骨折	1(1.0%)	0(0.0%)		

	有害事象		副作用	
	SK-1403 群 (N=103)	プラセボ群 (N=50)	SK-1403 群 (N=103)	プラセボ群 (N=50)
有害事象名(SOC/PT)	合計	合計	合計	合計
足骨折	0(0.0%)	1(2.0%)		
眼内異物	1(1.0%)	0(0.0%)		
熱疲労	1(1.0%)	0(0.0%)		
靭帯捻挫	2(1.9%)	0(0.0%)		
爪裂離	1(1.0%)	0(0.0%)		
引っかき傷	0(0.0%)	1(2.0%)		
挫傷	9(8.7%)	3(6.0%)		
熱傷	1(1.0%)	0(0.0%)		
シャント血栓症	1(1.0%)	0(0.0%)	1(1.0%)	0(0.0%)
四肢損傷	2(1.9%)	1(2.0%)		
処置による疼痛	1(1.0%)	0(0.0%)		
皮膚擦過傷	5(4.9%)	0(0.0%)		
熱中症	1(1.0%)	0(0.0%)		
皮膚創傷	0(0.0%)	1(2.0%)		
臨床検査	11(10.7%)	4(8.0%)	9(8.7%)	0(0.0%)
血中ビリルビン増加	1(1.0%)	0(0.0%)		
血中副甲状腺ホルモン増加	0(0.0%)	1(2.0%)		
脳性ナトリウム利尿ペプチド増加	0(0.0%)	1(2.0%)		
血中アルカリホスファターゼ増加	1(1.0%)	0(0.0%)		
便潜血陽性	0(0.0%)	2(4.0%)		
補正カルシウム減少	9(8.7%)	0(0.0%)	9(8.7%)	0(0.0%)
補正カルシウム増加	0(0.0%)	1(2.0%)		
代謝および栄養障害	5(4.9%)	1(2.0%)	1(1.0%)	0(0.0%)
葉酸欠乏	1(1.0%)	0(0.0%)		
高カリウム血症	1(1.0%)	0(0.0%)		
食欲減退	3(2.9%)	1(2.0%)	1(1.0%)	0(0.0%)
筋骨格系および結合組織障害	24(23.3%)	2(4.0%)	1(1.0%)	0(0.0%)
関節痛	3(2.9%)	0(0.0%)		
関節炎	1(1.0%)	0(0.0%)		
背部痛	5(4.9%)	1(2.0%)		
関節滲出液	1(1.0%)	0(0.0%)		
腰部脊柱管狭窄症	1(1.0%)	0(0.0%)		
筋痙縮	1(1.0%)	0(0.0%)	1(1.0%)	0(0.0%)
筋肉痛	4(3.9%)	0(0.0%)		
頚部痛	2(1.9%)	0(0.0%)		
骨粗鬆症	1(1.0%)	0(0.0%)		
四肢痛	1(1.0%)	0(0.0%)		
関節周囲炎	2(1.9%)	0(0.0%)		
脊柱管狭窄症	1(1.0%)	0(0.0%)		
滑液嚢腫	1(1.0%)	0(0.0%)		
腱鞘炎	5(4.9%)	0(0.0%)		
弾発指	2(1.9%)	0(0.0%)		
椎間板突出	0(0.0%)	1(2.0%)		
筋骨格系胸痛	1(1.0%)	0(0.0%)		
神経系障害	8(7.8%)	2(4.0%)		
脳梗塞	2(1.9%)	1(2.0%)		
浮動性めまい	2(1.9%)	1(2.0%)		
頭痛	1(1.0%)	0(0.0%)		
頚髄神経根障害	1(1.0%)	0(0.0%)		
ラクナ梗塞	1(1.0%)	0(0.0%)		
視床出血	1(1.0%)	0(0.0%)		
血栓性脳梗塞	1(1.0%)	0(0.0%)		
精神障害	2(1.9%)	0(0.0%)		
不眠症	1(1.0%)	0(0.0%)		
夢遊症	1(1.0%)	0(0.0%)		
腎および尿路障害	1(1.0%)	0(0.0%)		

	有害事象		副作用	
	SK-1403 群 (N=103)	プラセボ群 (N=50)	SK-1403 群 (N=103)	プラセボ群 (N=50)
有害事象名(SOC/PT)	合計	合計	合計	合計
血尿	1(1.0%)	0(0.0%)		
生殖系および乳房障害	1(1.0%)	0(0.0%)		
不正子宮出血	1(1.0%)	0(0.0%)		
呼吸器、胸郭および縦隔障害	11(10.7%)	5(10.0%)		
咳嗽	1(1.0%)	0(0.0%)		
鼻出血	0(0.0%)	1(2.0%)		
過換気	0(0.0%)	1(2.0%)		
アレルギー性鼻炎	2(1.9%)	0(0.0%)		
喀痰増加	1(1.0%)	0(0.0%)		
上気道の炎症	3(2.9%)	3(6.0%)		
アレルギー性気管支炎	1(1.0%)	0(0.0%)		
口腔咽頭不快感	1(1.0%)	0(0.0%)		
口腔咽頭痛	2(1.9%)	0(0.0%)		
皮膚および皮下組織障害	21(20.4%)	5(10.0%)		
水疱	1(1.0%)	1(2.0%)		
皮膚嚢腫	1(1.0%)	0(0.0%)		
接触皮膚炎	2(1.9%)	0(0.0%)		
湿疹	7(6.8%)	2(4.0%)		
皮脂欠乏性湿疹	1(1.0%)	0(0.0%)		
皮下出血	2(1.9%)	0(0.0%)		
爪甲剥離症	1(1.0%)	0(0.0%)		
点状出血	0(0.0%)	1(2.0%)		
そう痒症	1(1.0%)	0(0.0%)		
皮膚びらん	3(2.9%)	0(0.0%)		
皮膚剥脱	3(2.9%)	1(2.0%)		
皮膚潰瘍	2(1.9%)	0(0.0%)		
皮脂欠乏症	1(1.0%)	0(0.0%)		
偽毛包炎	1(1.0%)	0(0.0%)		
外科および内科処置	2(1.9%)	0(0.0%)		
白内障手術	1(1.0%)	0(0.0%)		
歯科インプラント埋込み	1(1.0%)	0(0.0%)		
血管障害	5(4.9%)	2(4.0%)		
高血圧	2(1.9%)	0(0.0%)		
末梢性虚血	1(1.0%)	0(0.0%)		
血栓性静脈炎	0(0.0%)	1(2.0%)		
末梢動脈閉塞性疾患	1(1.0%)	1(2.0%)		
内出血	1(1.0%)	0(0.0%)		
合計	88(85.4%)	36(72.0%)	12(11.7%)	4(8.0%)

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［資料 5.3.5.1-1　表 14.3.1-2 及び表 14.3.1-3 から改変引用］

（2）AJ1002 試験，AJ1003 試験，AJ1004 試験の併合解析

全ての有害事象の発現状況を表 2.7.4.7－8 に，重症度別発現状況を表 2.7.4.7－9 に，時期別発現状況を表 2.7.4.7－10 に示した。

SK-1403 併合群における有害事象の発現率は 89.3%（284/318 例）であり，これらのうち副作用と判定された事象は 10.7%（34/318 例）であった。最も発現率が高かった有害事象は「上咽頭炎」37.4%（119/318 例）であり，副作用は「補正カルシウム減少」5.7%（18/318 例）であった。重症度別で高度と判定された有害事象の発現率は 1.9%（6/318 例），中等度と判定された有害事象の発現率は 17.6%（56/318 例）であり，これらのうち副作用と判定された事象の発現率は，高度では副作用の発現はなく，中等

度は 0.9%（3/318 例）であった。有害事象及び副作用の発現時期について，投与開始後 24 週まで 3 週間隔での時期別集計では有害事象は 20.1%～28.6%とほぼ一定の発現率で推移したが，副作用は投与開始後 1～3 週が最も高かった。

プラセボ群における有害事象の発現率は 72.0%（36/50 例）であり，これらのうち副作用と判定された事象は 8.0%（4/50 例）であった。最も発現率が高かった有害事象は「上咽頭炎」24.0%（12/50 例）であり，副作用は 2 例以上発現した事象はなかった。重症度別で高度と判定された有害事象の発現率は 2.0%（1/50 例），中等度と判定された有害事象の発現率は 14.0%（7/50 例）であり，これらのうち副作用と判定された事象の発現は高度の「慢性心不全」1 例のみであった。プラセボ群において時期別で有害事象及び副作用の最も発現率が高かった時期はいずれも投与開始後 1～3 週であった。

(3) その他の試験

1) AJ0001 試験

症状別の有害事象の発現が，SK-1403 の 0.1 mg 群において「血中ビリルビン増加」が 16.7%（1/6 例），1.0 mg 群において「嘔吐」が 16.7%（1/6 例），2.5 mg 群において「悪心」が 33.3%（2/6 例），「嘔吐」が 50.0%（3/6 例），「悪寒」が 16.7%（1/6 例）に認められ，これらのうち「悪心」，「嘔吐」，「悪寒」の全事象が副作用と判定された（2.7.6.1.5（1））。

2) AJ1001 試験

a) 単回投与

症状別の有害事象の発現が，プラセボ群において「発熱」が 6.7%（1/15 例），SK-1403 の 0.025 mg 群において「心房細動」，「悪心」，「皮膚剥脱」がいずれも 25.0%（1/4 例），0.05 mg 群において「低血糖」，「下痢」，「水疱性皮膚炎」，「血圧上昇」がいずれも 25.0%（1/4 例），0.1 mg 群において「インフルエンザ」が 25.0%（1/4 例），0.2 mg 群において「上腹部痛」が 25.0%（1/4 例），0.4 mg 群において「嘔吐」，「体温上昇」がいずれも 25.0%（1/4 例），0.6 mg 群において「低血糖」，「悪心」，「嘔吐」，「血圧上昇」がいずれも 25.0%（1/4 例），0.8 mg 群において「食欲減退」，「嘔吐」，「補正カルシウム減少」がいずれも 20.0%（1/5 例）に認められ，これらのうち「食欲減退」，「嘔吐」，「補正カルシウム減少」の全事象と 0.6 mg 群における「悪心」が副作用と判定された（2.7.6.2.5（1））。

b) 反復投与

症状別の有害事象の発現が，プラセボ群において「胃腸炎」，「帯状疱疹」，「鼻咽頭炎」，「肛門直腸不快感」，「背部痛」，「靭帯捻挫」，「腰椎骨折」がいずれも 9.1%（1/11 例），SK-1403 の 0.05 mg 群において「下痢」，「嘔吐」，「委縮性外陰膣炎」，「血中カルシウム減少」，「補正カルシウム減少」がいずれも 11.1%（1/9 例），0.1 mg 群において「鼻咽頭炎」，「感覚鈍麻」，「上室性期外収縮」，「心室性期外収縮」，「腹部不快感」，「接触性皮膚炎」，「シャント閉塞」，「挫傷」，「シャント狭窄」がいずれも 11.1%（1/9 例），

0.2 mg 群において「鼻咽頭炎」が 30.0%（3/10 例），「シャント感染」，「上室性期外収縮」，「腹部不快感」，「血中ブドウ糖減少」，「補正カルシウム減少」がいずれも 10.0%（1/10 例）に認められ，これらのうち「感覚鈍麻」，「上室性期外収縮」，「心室性期外収縮」，「腹部不快感」，「血中カルシウム減少」，「補正カルシウム減少」の全事象が副作用と判定された（2.7.6.2.5（1））。

2.7.4.2.1.2 比較的よく見られる有害事象

（1）AJ1004 試験

SK-1403 群において 5%以上に認められた有害事象は，「上咽頭炎」24.3%（25/103 例），「下痢」10.7%（11/103 例），「咽頭炎」8.7%（9/103 例），「挫傷」8.7%（9/103 例），「補正カルシウム減少」8.7%（9/103 例），「湿疹」6.8%（7/103 例）であった。これらのうち副作用と判定された事象は「補正カルシウム減少」8.7%（9/103 例）のみであった（表 2.7.4－5）。

プラセボ群において 5%以上に認められた有害事象は，「上咽頭炎」24.0%（12/50 例），「嘔吐」8.0%（4/50 例），「腹部不快感」6.0%（3/50 例），「挫傷」6.0%（3/50 例），「上気道の炎症」6.0%（3/50 例）であった。これらのうち副作用と判定された事象は「嘔吐」2.0%（1/50 例）及び「腹部不快感」2.0%（1/50 例）であった（表 2.7.4－5）。

（2）AJ1002 試験，AJ1003 試験，AJ1004 試験の併合解析

併合解析における，SK-1403 併合群において比較的よく見られる有害事象（発現率 2%以上）の発現状況を表 2.7.4.7－11 に示した。

SK-1403 併合群において 5%以上に認められた有害事象は，「上咽頭炎」37.4%（119/318 例），「下痢」12.6%（40/318 例），「上気道の炎症」7.9%（25/318 例），「関節痛」7.5%（24/318 例），「挫傷」7.2%（23/318 例），「嘔吐」6.6%（21/318），「皮膚擦過傷」6.0%（19/318），「補正カルシウム減少」5.7%（18/318），「背部痛」5.7%（18/318），「インフルエンザ」5.3%（17/318），「咽頭炎」5.0%（16/318），「湿疹」5.0%（16/318）であった。これらのうち副作用と判定された事象は「補正カルシウム減少」5.7%（18/318），「嘔吐」0.3%（1/ 318）であった。

2.7.4.2.1.3 死亡

（1）AJ1004 試験

死亡，その他の重篤な有害事象及び他の重要な有害事象及び副作用の一覧を表 2.7.4－6 に示した。

SK-1403 群における死亡に至った有害事象として，「細菌性髄膜炎」（1 例）が認められたが，副作用とは判定されなかった。死亡に至った有害事象の発現率は 1.0%（1/103 例）であった。

プラセボ群における死亡に至った有害事象はなかった。

表 2.7.4－6　死亡，その他の重篤な有害事象及び他の重要な有害事象及び副作用の一覧

	有害事象		副作用	
	SK-1403 群 (N=103)	プラセボ群 (N=50)	SK-1403 群 (N=103)	プラセボ群 (N=50)
死亡	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)
その他の重篤な有害事象	11(10.7%)	8(16.0%)	0(0.0%)	1(2.0%)
他の重要な有害事象	4(3.9%)	4(8.0%)	4(3.9%)	2(4.0%)
中止の理由となった有害事象	0(0.0%)	4(8.0%)	0(0.0%)	2(4.0%)
減量の理由となった有害事象	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
休薬の理由となった有害事象	4(3.9%)	0(0.0%)	4(3.9%)	0(0.0%)

［資料 5.3.5.1-1　表 14.3.2-1 及び表 14.3.2-2 から改変引用］

(2) AJ1002 試験，AJ1003 試験，AJ1004 試験の併合解析

併合解析における，死亡に至った有害事象の発現状況を表 2.7.4.7－12 に，重症度別発現状況を表 2.7.4.7－13 に，時期別発現状況を表 2.7.4.7－14 に，死亡した症例の一覧を表 2.7.4.7－15 に示した。

SK-1403 併合群における死亡に至った有害事象として，「細菌性髄膜炎」(1 例) が認められたが，副作用とは判定されなかった。死亡に至った有害事象の発現率は 0.3% (1/318 例) であった。時期別では投与開始後 7～9 週で認められた。

プラセボ群における死亡に至った有害事象はなかった。

(3) その他の試験

AJ0001 試験及び AJ1001 試験において，死亡に至った有害事象はなかった。

2.7.4.2.1.4　その他の重篤な有害事象

(1) AJ1004 試験

その他の重篤な有害事象は SK-1403 群で 10.7%(11/103 例)，プラセボ群で 16.0%(8/50 例) に認められた (表 2.7.4－6)。

その他の重篤な副作用は，SK-1403 群では認めず，プラセボ群で 2.0% (1/50 例) に認められた。

SK-1403 群におけるその他の重篤な有害事象として，「黄斑線維症，白内障手術」(1 例)，「末梢動脈閉塞性疾患」(1 例)，「血栓性脳梗塞」(1 例)，「狭心症」(1 例)，「脳梗塞」(1 例)，「末梢性虚血」(1 例)，「視床出血」(1 例)，「腰部脊柱管狭窄症」(1 例)，「大腿骨骨折」(1 例)，「胆管炎」(1 例)，「急性胆嚢炎，肝膿瘍，敗血症」(1 例) が認められたが，全て副作用とは判定されなかった (2.7.6.3.4 (2))。

プラセボ群におけるその他の重篤な有害事象として，「過換気」(1 例)，「慢性心不全」(1 例)，「大腿骨頚部骨折」(1 例)，「末梢動脈閉塞性疾患」(1 例)，「肺炎」(1 例)，「脳梗塞」(1 例)，「背部痛」(1 例)，「直腸出血」(1 例) が認められ，これらのうち「慢性心不全」(1 例) が副作用と判定された (2.7.6.3.4 (2))。

(2) AJ1002 試験，AJ1003 試験，AJ1004 試験の併合解析

併合解析における，その他の重篤な有害事象の発現状況を表 2.7.4.7－16 に，重症度別発現状況を表 2.7.4.7－17 に，時期別発現状況を表 2.7.4.7－18 に，その他の重篤な

有害事象を発現した症例の一覧を表 2.7.4.7－19 に示した。

SK-1403 併合群におけるその他の重篤な有害事象の発現率は 14.2%（45/318 例）であり，これらのうち副作用と判定された事象は 0.9%（3/318 例）であった。重症度別で高度と判定された有害事象の発現率は 1.6%（5/318 例），中等度と判定された有害事象の発現率は 11.6%（37/318 例）であり，これらのうち副作用と判定された事象の発現率は，高度はなく，中等度は 0.9%（3/318 例）であった。時期別で最も発現率が高かった時期は，投与開始後 10～12 週，25～38 週及び 39～52 週（いずれも 3.1%）であった。症状別有害事象の内訳は，「狭心症」（4 例），「浮動性めまい」（2 例），「脳梗塞」（2 例），「視床出血」（2 例），「胃腺癌，腺癌」（1 例），「気道感染」（1 例），「脳幹出血」（1 例），「顔面骨骨折」（1 例），「関節脱臼」（1 例），「結腸癌」（1 例），「唾液腺新生物」（1 例），「肝嚢胞感染」（1 例），「迷路性回転性めまい」（1 例），「椎骨動脈解離」（1 例），「腱断裂」（1 例），「心筋虚血，末梢動脈閉塞性疾患，大腸ポリープ」（1 例），「虫垂炎，皮膚潰瘍」（1 例），「急性心筋梗塞」（1 例），「小脳出血」（1 例），「前立腺癌」（1 例），「出血性腸憩室」（1 例），「高血圧」（1 例），「手首関節骨折，出血性十二指腸潰瘍，狭心症」（1 例），「肺炎」（1 例），「結腸癌，腹膜炎」（1 例），「橈骨骨折」（1 例），「硝子体出血」（1 例），「手根管症候群」（1 例），「損傷，背部痛」（1 例），「心筋虚血」（1 例），「急性胆嚢炎」（1 例），「黄斑線維症，白内障手術」（1 例），「末梢動脈閉塞性疾患」（1 例），「血栓性脳梗塞」（1 例），「末梢性虚血」（1 例），「腰部脊柱管狭窄症」（1 例），「大腿骨骨折」（1 例），「胆管炎」（1 例），「急性胆嚢炎，肝膿瘍，敗血症」（1 例）が認められ，これらのうち「浮動性めまい」（1 例），「急性心筋梗塞」（1 例），「高血圧」（1 例）が副作用と判定された。

プラセボ群におけるその他の重篤な有害事象の発現率は 16.0%（8/50 例）であり，これらのうち副作用と判定された事象の発現率は 2.0%（1/50 例）であった。重症度別で高度と判定された有害事象の発現率は 2.0%（1/50 例），中等度と判定された有害事象の発現率は 12.0%（6/50 例）であり，これらのうち副作用と判定された事象の発現率は高度 2.0%（1/50 例）であり，中等度はなかった。時期別で最も発現率が高かった時期は投与開始後 16～18 週（8.0%）であった。症状別有害事象の内訳は，「過換気」（1 例），「慢性心不全」（1 例），「大腿骨頚部骨折」（1 例），「末梢動脈閉塞性疾患」（1 例），「肺炎」（1 例），「脳梗塞」（1 例），「背部痛」（1 例），「直腸出血」（1 例）が認められ，これらのうち「慢性心不全」（1 例）が副作用と判定された。

(3) その他の試験

AJ0001 試験及び AJ1001 試験単回投与において，その他の重篤な有害事象は認められなかった。AJ1001 試験の反復投与においては，プラセボ群で「腰椎骨折」（1 例），SK-1403 の 0.1 mg 群で「シャント閉塞」（1 例），「シャント狭窄」（1 例）がそれぞれ認められたが，いずれも副作用と判定されなかった。

2.7.4.2.1.5 他の重要な有害事象

(1) AJ1004 試験

他の重要な有害事象は SK-1403 群で 3.9%（4/103 例），プラセボ群で 8.0%（4/50 例）

に認められた（表 2.7.4－6）。その内訳は，SK-1403 群では全て休薬の理由となった有害事象であり，全て「補正カルシウム減少」であった。SK-1403 群で中止及び減量の理由となった有害事象は認められなかった。プラセボ群では全て中止の理由となった有害事象であり，「心窩部不快感」が 1 例，「甲状腺機能低下症」が 1 例，「腹部不快感」が 1 例，「補正カルシウム増加」が 1 例及び「血中副甲状腺ホルモン増加」が 1 例であった（「補正カルシウム増加」と「血中副甲状腺ホルモン増加」は同一症例で発現）。プラセボ群で休薬及び減量の理由となった有害事象は認められなかった。

他の重要な有害事象のうち副作用と判定された事象は，SK-1403 群では全ての事象 4 例（3.9%），プラセボ群では 2 例（4.0%）であった。プラセボ群で副作用と判定された事象は，「心窩部不快感」1 例及び「腹部不快感」1 例であった（2.7.6.3.4 (2)）。

(2) AJ1002 試験，AJ1003 試験，AJ1004 試験の併合解析

併合解析における，中止の理由となった有害事象，休薬の理由となった有害事象及び減量の理由となった有害事象について，それぞれの発現状況を表 2.7.4.7－20，表 2.7.4.7－21 及び表 2.7.4.7－22 に，重症度別発現状況を表 2.7.4.7－23，表 2.7.4.7－24 及び表 2.7.4.7－25 に，時期別発現状況を表 2.7.4.7－26，表 2.7.4.7－27 及び表 2.7.4.7－28 に，他の重要な有害事象を発現した症例の一覧を表 2.7.4.7－29 に示した。

1) 中止の理由となった有害事象

SK-1403 併合群における中止の理由となった有害事象の発現率は 0.9%（3/318 例）であり，これらのうち副作用と判定された事象は 0.9%（3/318 例）であった。重症度別では全て軽度と判定された。時期別で最も発現率が高かった時期は投与開始後 19～21 週，25～38 週及び 39～52 週（いずれも 0.3%）であった。症状別の内訳は，「嘔吐」（1 例），「肝機能異常」（1 例），「心電図 QT 延長」（1 例）が認められ，全て副作用と判定された。

プラセボ群における中止の理由となった有害事象の発現率は 8.0%（4/50 例）であり，これらのうち副作用と判定された事象は 4.0%（2/50 例）であった。重症度別では全て軽度と判定された。時期別で最も発現率が高かった時期は投与開始後 1～3 週（4.0%）であった。症状別の内訳は，「心窩部不快感」（1 例），「甲状腺機能低下症」（1 例），「腹部不快感」（1 例），「補正カルシウム増加，血中副甲状腺ホルモン増加」（1 例）が認められ，これらのうち「心窩部不快感」（1 例），「腹部不快感」（1 例）が副作用と判定された。

2) 休薬の理由となった有害事象

SK-1403 併合群における休薬の理由となった有害事象の発現率は 4.4%（14/318 例）であり，これらのうち副作用と判定された事象は 4.1%（13/318 例）であった。重症度は全て軽度と判定された。時期別で最も発現率が高かった時期は投与開始後 1～3 週（2.5%）であった。症状別の内訳は，「補正カルシウム減少」（10 例），「補正カルシウム減少，心電図 QT 延長」（1 例），「心電図 QT 延長」（1 例）「口渇，顔面浮腫」（1 例），「肝機能異常」（1 例）が認められ，これらのうち「肝機能異常」（1 例）以外は全て副

作用と判定された。

プラセボ群における休薬の理由となった有害事象はなかった。

3）減量の理由となった有害事象

SK-1403 併合群における減量の理由となった有害事象及び副作用の発現率は 0.3%（1/318 例）であった。重症度は軽度と判定され，発現時期は投与開始後 39～52 週であった。症状別の内訳は，「心電図 QT 延長」（1 例）が認められ，副作用と判定された。

プラセボ群における減量の理由となった有害事象はなかった。

（3）その他の試験

AJ0001 試験及び AJ1001 試験単回投与において，他の重要な有害事象はなかった。AJ1001 試験反復投与においては，SK-1403 の 0.05 mg 群及び 0.2 mg 群で「補正カルシウム減少」がそれぞれ 1 例に認められた。いずれも治験薬の中止の理由となった有害事象であり，副作用と判定された。

2.7.4.2.1.6　器官別又は症候群別有害事象の解析（特に留意した有害事象）

併合解析において，特に留意した有害事象である「低カルシウム血症」，「骨代謝障害」，「胃腸障害」，「QT 延長」及び「水晶体混濁」に関連する有害事象について検討し，発現状況を表 2.7.4.7－30 に，重症度別発現状況を表 2.7.4.7－31 に，時期別発現状況を表 2.7.4.7－32 に示した。

（1）「低カルシウム血症」に関連する有害事象

SK-1403 併合群における「低カルシウム血症」に関連する有害事象の発現率は 5.7%（18/318 例）であった。症状別の内訳は，全て「補正カルシウム減少」（臨床検査値の異常）であり，症候性の「低カルシウム血症」の発現は認められなかった。重症度別では全て軽度と判定された。時期別で最も発現率が高かった時期は投与開始後 1～3 週（3.1%）であった。「補正カルシウム減少」（18 例）は全て副作用と判定された。

プラセボ群における「低カルシウム血症」に関連する有害事象は認められなかった。

（2）血清補正 Ca 濃度低下の状況

併合解析における，治療期の最低血清補正 Ca 濃度別の被験者割合を表 2.7.4.7－33 に示した。

SK-1403 併合群及びプラセボ群において治療期の血清補正 Ca の最低濃度が 7.0 mg/dL 未満の被験者は認められず，7.0 mg/dL 以上 7.5 mg/dL 未満であった被験者は SK-1403 併合群で 11 例であり，プラセボ群では認められなかった。

併合解析における，血清補正 Ca 濃度 7.5 mg/dL 未満による休薬状況及び症例一覧を表 2.7.4.7－34 及び表 2.7.4.7－35 に示した。

SK-1403 併合群における血清補正 Ca 濃度 7.5 mg/dL 未満による休薬は，解析対象被験者 318 例に対して 11 例（3.5%）12 件発現した。

プラセボ群において血清補正 Ca 濃度 7.5 mg/dL 未満による休薬はなかった。

SK-1403 併合群における血清補正 Ca 濃度が 7.5 mg/dL 未満による休薬症例の内訳は，AJ1002 試験では 9 例 10 件発現し，全例が血清補正 Ca 濃度の初期値が 9.0 mg/dL 未満の被験者であり，休薬前の投与量は 9 件が 50 μg，1 件が 25 μg であった。また，7 件は投与開始後 1 週又は 2 週で発現しており，投与初期に多く発現した。休薬した 10 件全てが休薬開始後 1 週で血清補正 Ca 濃度が 7.5 mg/dL 以上へ回復した。AJ1003 試験では休薬症例はなかった。AJ1004 試験では 2 例 2 件発現し，血清補正 Ca 濃度の初期値は 1 例が 9.0 mg/dL 未満，1 例は 9.0 mg/dL 以上であった。休薬前の投与量は 1 例が 25 μg，1 例が 200 μg であった。いずれの症例も休薬開始後 1 週で血清補正 Ca 濃度が 7.5 mg/dL 以上へ回復した。

(3) 「骨代謝障害」に関連する有害事象

SK-1403 併合群及びプラセボ群における「骨代謝障害」に関連する有害事象は認められなかった。

(4) 「胃腸障害」に関連する有害事象

SK-1403 併合群における「胃腸障害」に関連する有害事象が 36.5%（116/318 例）に認められ，最も発現率が高かった事象は「下痢」12.6%（40/318 例）であった。副作用と判定された事象の発現率は 0.9%（3/318 例）であり，「便秘」1 例，「悪心」1 例，「嘔吐」1 例であった。重症度別で高度と判定された事象はなく，中等度と判定された事象の発現率は 2.5%（8/318 例）であり，これらのうち副作用と判定された事象はなかった。時期別で最も発現率が高かった時期は投与開始後 38～52 週（9.4%）であったが，全ての時期で発現率に大きな違いは認められなかった。

プラセボ群における「胃腸障害」に関連する有害事象が 26.0%（13/50 例）に認められ，最も発現率が高かった事象は「嘔吐」8.0%（4/50 例）であった。副作用と判定された事象の発現率は 6.0%（3/50 例）であり，「腹部不快感」1 例，「嘔吐」1 例，「心窩部不快感」1 例であった。重症度別で高度と判定された事象はなく，中等度と判定された事象の発現率は 4.0%（2/50 例）であり，これらのうち副作用と判定された事象はなかった。プラセボ群において時期別で最も発現率が高かった時期は投与開始後 1～3 週（8.0%）であった。

(5) 「QT 延長」に関連する有害事象

SK-1403 併合群における「QT 延長」に関連する有害事象の発現率は 1.9%（6/318 例）であり，これらのうち副作用と判定された事象は 1.3%（4/318 例）であった。重症度は全て軽度と判定された。時期別で最も発現率が高かった時期は投与開始後 25～38 週及び 39～52 週（いずれも 0.6%）であった。症状別の内訳は，「心電図 QT 延長」（5 例），「心室性頻脈」（1 例）で，これらのうち「心電図 QT 延長」（4 例）が副作用と判定された。

プラセボ群における「QT 延長」に関連する有害事象は認められなかった。

（6）「水晶体混濁」に関連する有害事象

SK-1403 併合群における「水晶体混濁」に関連する有害事象の発現率は 2.5%（8/318 例）であり，これらのうち副作用と判定された事象は 0.6%（2/318 例）であった。重症度別で高度と判定された事象はなく，中等度と判定された事象の発現率は 0.3%（1/318 例）であったが，副作用とは判定されなかった。時期別で最も発現率が高かった時期は投与開始後 22～24 週，25～38 週及び 39～52 週（いずれも 0.6%）であった。症状別の内訳は，「白内障」（3 例），「白内障手術」（3 例），「水晶体混濁」（2 例）で，これらのうち「水晶体混濁」（2 例）が副作用と判定された。

プラセボ群における「水晶体混濁」に関連する有害事象は認められなかった。

2.7.4.2.2　個別有害事象の文章による説明

各試験における死亡に至った有害事象及びその他の重篤な有害事象の個別の説明は 2.7.6 においてそれぞれの試験に記載した。

2.7.4.3　臨床検査値の評価

2.7.4.3.1　臨床検査値の変動

SK-1403 併合解析における，血液学的検査値（白血球数，赤血球数，ヘモグロビン，ヘマトクリット，血小板数）の要約を表 2.7.4.7－36 に，血液生化学検査値［総蛋白，AST（GOT），ALT（GPT），LD（LDH），総ビリルビン，直接ビリルビン，ALP，γ-GTP，CPK，アミラーゼ，BUN，クレアチニン，尿酸，Na，Cl，K，Ca，補正 Ca，P，Mg，総コレステロール，トリグリセライド，グルコース］，骨代謝マーカー（BAP，total PINP，TRACP-5b）及び血清 P 及び Ca 濃度調節関連因子（iFGF23）の要約を表 2.7.4.7－37 に示した。

SK-1403 併合群における臨床検査値平均値の変動について，血液学的検査値の変動は認められず，血液生化学的検査値では ALP，P，iFGF23，BAP，total PINP 及び TRACP-5b の低下が認められた。その他の項目については臨床検査値の大きな変動は認められなかった。

2.7.4.3.2　SOC「臨床検査」に分類される有害事象

併合解析における，SOC「臨床検査」に分類される有害事象の発現状況を表 2.7.4.7－38 に，重症度別発現状況を表 2.7.4.7－39 に，時期別発現状況を表 2.7.4.7－40 に示した。

SK-1403 併合群における SOC「臨床検査」に分類される有害事象の発現率は 11.9%（38/318 例）であった。重症度別で高度及び中等度と判定された事象はなかった。時期別で最も発現率が高かった時期は投与開始後 1～3 週（3.5%）であった。症状別の内訳は，「補正カルシウム減少」（18 例，5.7%），「心電図 QT 延長」（5 例，1.6%），「血中クレアチンホスホキナーゼ増加」（3 例，0.9%），「血中カリウム増加」（3 例，0.9%），「ヘモグロビン減少」（2 例，0.6%），「血中ビリルビン増加」（1 例，0.3%），「血圧上昇」（1 例，0.3%），「血中尿酸増加」（1 例，0.3%），「γ－グルタミルトランスフェラーゼ増加」（1 例，0.3%），「プロトロンビン時間延長」（1 例，0.3%），「白血球数減少」（1 例，0.3%），「血中アルカリホスファターゼ増加」（1 例，0.3%），「便潜血陽性」（1 例，0.3%），「肝機能検査値上昇」（1 例，0.3%）であった。これら

のうち副作用と判定された事象は 6.6%（21/318 例）であり，「補正カルシウム減少」（18 例，5.7%）及び「心電図 QT 延長」（4 例，1.3%）であった。

プラセボ群における SOC「臨床検査」に分類される有害事象の発現率は 8.0%（4/50 例）であった。重症度別で高度及び中等度と判定された事象はなかった。時期別で最も発現率が高かった時期は投与開始後 10～12 週（4.0%）であった。症状別の内訳は，「便潜血陽性」（2 例，4.0%）「血中副甲状腺ホルモン増加，補正カルシウム増加」（1 例，2.0%），「脳性ナトリウム利尿ペプチド増加」（1 例，2.0%）であった。全ての事象が副作用と判定されなかった。

2.7.4.4　バイタルサイン，身体的所見及び安全性に関連する他の観察項目

2.7.4.4.1　血圧，脈拍数

併合解析における，収縮期血圧，拡張期血圧，脈拍数の要約を表 2.7.4.7－41 に示した。

SK-1403 併合群での 0 週, 12 週及び 52 週における収縮期血圧はそれぞれ 150.8 mmHg, 151.4 mmHg 及び 151.1 mmHg，拡張期血圧はそれぞれ 82.1 mmHg，82.1 mmHg 及び 81.3 mmHg，脈拍数はそれぞれ 75.3 回/分，75.1 回/分及び 75.9 回/分であった。

プラセボ群の 0 週及び 18 週における収縮期血圧はそれぞれ 151.6 mmHg 及び 149.2 mmHg，拡張期血圧はそれぞれ 81.0 mmHg 及び 80.3 mmHg，脈拍数はそれぞれ 74.9 回/分及び 74.5 回/分であった。

両群とも大きな変動は認められなかった。

2.7.4.4.2　安静時 12 誘導心電図

併合解析における，安静時 12 誘導心電図検査結果の要約を表 2.7.4.7－42 に，安静時 12 誘導心電図のシフトテーブルを表 2.7.4.7－43 に，QT 間隔，QTcF，QRS 間隔，RR 間隔，PR 間隔の要約を表 2.7.4.7－44 に，QTcF のカテゴリ別集計を表 2.7.4.7－45 に，QTcF 変化量のカテゴリ別集計を表 2.7.4.7－46 に示した。

SK-1403 併合群の 24 週及び 52 週における安静時 12 誘導心電図検査において，臨床的に問題となる異常を示した症例はそれぞれ 3.7%（9/242 例），1.6%（3/190 例）であった。また，0 週において正常であり，24 週において異常を示した症例は 2 例，52 週において異常を示した症例は 2 例であった。24 週及び 52 週における QT 間隔，QTcF，QRS 間隔，RR 間隔及び PR 間隔の変化量はそれぞれ，8.6 ms（95%信頼区間：6.2 ms – 11.0 ms）及び 9.3 ms（95%信頼区間：6.8 ms – 11.9 ms），8.8 ms（95%信頼区間：7.1 ms – 10.5 ms）及び 9.6 ms（95%信頼区間：7.8 ms – 11.5 ms），-0.4 ms 及び-0.4 ms，2.3 ms 及び 2.0 ms 並びに-0.6 ms 及び 0.5 ms であり，QTcF 変化量のカテゴリ別集計では 24 週，52 週いずれにおいても 30 ms 以下の症例が最も多かった［24 週：92.1%（223/242 例），52 週：92.1%（174/189 例）］。

プラセボ群の 24 週における安静時 12 誘導心電図検査において，臨床的に問題となる異常を示した症例は 15.4%（6/39 例）であった。また，0 週において正常であり，24 週において異常を示した症例は 1 例であった。24 週における QT 間隔，QTcF，QRS 間隔，RR 間隔及び PR 間隔の変化量はそれぞれ，-0.6 ms（95%信頼区間：-6.1 ms – 4.9 ms），0.8 ms（95%信頼区間：-3.7 ms – 5.3 ms），-1.8 ms，-7.4 ms，2.0 ms であり，QTcF 変化量のカテゴリ別集計では

30 ms 以下の症例が 97.4%（38/39 例）で最も多かった。

2.7.4.4.3　SOC「心臓障害」に分類される有害事象

併合解析における，SOC「心臓障害」に分類される有害事象の発現状況を表 2.7.4.7－47 に，重症度別発現状況を表 2.7.4.7－48 に，時期別発現状況を表 2.7.4.7－49 に示した。

SK-1403 併合群における SOC「心臓障害」に分類される有害事象の発現率は 5.3%（17/318 例）であり，これらのうち副作用と判定された事象の発現率は 0.3%（1/318 例）であり，症状名は「急性心筋梗塞」であった。重症度別で高度と判定された有害事象はなく，中等度と判定された有害事象の発現率は 2.5%（8/318 例）であり，これらのうち副作用と判定された事象の発現率は 0.3%（1/318 例）であった。時期別で最も有害事象の発現率が高かった時期は投与開始後 10～12 週及び 39～52 週であった（いずれも 1.6%）。

プラセボ群における SOC「心臓障害」に分類される有害事象の発現率は 4.0%（2/50 例）であり，これらのうち副作用と判定された事象の発現率は 2.0%（1/50 例）であり，症状名は「心房細動，慢性心不全」であった。重症度別で高度と判定された有害事象の発現率は 2.0%（1/50 例），中等度と判定された有害事象はなく，高度と判定された事象は副作用と判定され，発現率は 2.0%（1/50 例）であった。プラセボ群において時期別で最も有害事象の発現率が高かった時期は投与開始後 10～12 週，16～18 週及び 25～38 週であった（いずれも 2.0%，1 例は 2 件の事象を発現）。

2.7.4.4.4　眼科学的検査

AJ1001 試験及び AJ1002 試験においては水晶体の混濁が悪化した症例はなかった。

AJ1003 試験及び AJ1004 試験における水晶体検査結果の要約を表 2.7.4－7 及び表 2.7.4－8 に示した。AJ1003 試験において，24 週時に水晶体の混濁が悪化した症例はなかったが，52 週時又は中止時における水晶体の混濁の悪化した率は，右眼 0.8%（1/119 眼）及び左眼 0.8%（1/119 眼）であった（2.7.6.5.4（5）3)）。AJ1004 試験の 24 週又は中止時における SK-1403 群における水晶体の混濁の悪化した率は，右眼 2.9%（2/69 眼）及び左眼 2.9%（2/69 眼）であった。AJ1004 試験のプラセボ群においては水晶体の混濁が悪化した症例はなかった（2.7.6.3.4（5）3)）。

表 2.7.4－7　水晶体検査結果の要約（AJ1003 試験）

		時期	スクリーニング時	治療期 24 週時	治療期 52 週時又は中止時
水晶体の状態	右眼	無水晶体	1（0.6%）	-	-
	(N=157)	人工水晶体	37（23.6%）	-	-
		有水晶体	119（75.8%）	-	-
	左眼	無水晶体	0（0.0%）	-	-
	(N=156)	人工水晶体	37（23.7%）	-	-
		有水晶体	119（76.3%）	-	-
水晶体の混濁の有無	右眼	有	75（63.0%）	-	-
	(N=119)	無	44（37.0%）	-	-
	左眼	有	76（63.9%）	-	-
	(N=119)	無	43（36.1%）	-	-
水晶体の混濁の悪化	右眼	有	-	0（0.0%）	1（0.8%）
	(N=119)	無	-	107（89.9%）	110（92.4%）
	左眼	有	-	0（0.0%）	1（0.8%）
	(N=119)	無	-	105（88.2%）	108（90.8%）

［5.3.5.2-2 表 14.3.5-11 から改変引用］

表 2.7.4－8　水晶体検査結果の要約（AJ1004 試験）

				SK-1403 群			プラセボ群	
		時期		スクリーニング時	治療期 24 週時又は中止時		スクリーニング時	治療期 24 週時又は中止時
水晶体の状態	右眼	無水晶体	N=103	0（0.0%）	-	N=49	0（0.0%）	-
		人工水晶体		33（32.0%）	-		9（18.4%）	-
		有水晶体		69（67.0%）	-		39（79.6%）	-
		不明		1（1.0%）	-		1（2.0%）	-
	左眼	無水晶体	N=103	0（0.0%）	-	N=49	1（2.0%）	-
		人工水晶体		34（33.0%）	-		8（16.3%）	-
		有水晶体		69（67.0%）	-		40（81.6%）	-
		不明		0（0.0%）	-		0（0.0%）	-
水晶体の混濁の有無	右眼	有	N=69	46（66.7%）	-	N=39	28（71.8%）	-
		無		23（33.3%）	-		11（28.2%）	-
	左眼	有	N=69	46（66.7%）	-	N=40	30（75.0%）	-
		無		23（33.3%）	-		10（25.0%）	-
水晶体の混濁の悪化	右眼	有	N=69	-	2（2.9%）	N=39	-	0（0.0%）
		無		-	61（88.4%）		-	36（92.3%）
	左眼	有	N=69	-	2（2.9%）	N=40	-	0（0.0%）
		無		-	62（89.9%）		-	37（92.5%）

［5.3.5.1-1 表 14.3.5-11 から改変引用］

2.7.4.4.5　その他の観察項目

併合解析における，透析後体重の要約を表 2.7.4.7－50 に示した。

SK-1403 併合群での 0 週, 24 週及び 52 週における透析後体重はそれぞれ 63.53 kg, 64.26 kg 及び 63.93 kg であった。

プラセボ群の 0 週及び 24 週における透析後体重はそれぞれ 59.84 kg 及び 60.29 kg であった。

両群とも大きな変動は認められなかった。

2.7.4.5　特別な患者集団及び状況下における安全性

SK-1403 併合群において，内因性要因及び外因性要因による部分集団解析を行った。

2.7.4.5.1　内因性要因

併合解析における，全有害事象，死亡に至った有害事象，その他の重篤な有害事象，他の重要な有害事象（中止の理由となった有害事象，休薬の理由となった有害事象，減量の理由となった有害事象），「低カルシウム血症」に関連する有害事象，「骨代謝障害」に関連する有害事象，「胃腸障害」に関連する有害事象，「QT 延長」に関連する有害事象，「水晶体混濁」に関連する有害事象について，性別，年齢，原疾患，透析期間，血清 iPTH 濃度ベースライン値，血清補正 Ca 濃度ベースライン値，血清 P 濃度ベースライン値による部分集団解析結果を表 2.7.4.7－51，表 2.7.4.7－52，表 2.7.4.7－53，表 2.7.4.7－54，表 2.7.4.7－55，表 2.7.4.7－56，表 2.7.4.7－57，表 2.7.4.7－58，表 2.7.4.7－59，表 2.7.4.7－60，表 2.7.4.7－61 に示した。

（1）全有害事象

SK-1403 併合群において，有害事象の発現率は 89.3%（284/318 例）であり，これらのうち副作用と判定された事象の発現率は 10.7%（34/318 例）であった。

部分集団別の有害事象の発現率は，男性 88.0%（212/241 例），女性 93.5%（72/77 例），年齢 65 歳未満 90.7%（156/172 例），65 歳以上 87.7%（128/146 例），原疾患が慢性糸球体腎炎 88.7%（102/115 例），糖尿病性腎症 90.0%（72/80 例），腎硬化症 84.2%（32/38 例），多発性嚢胞腎 84.2%（16/19 例），その他 93.9%（62/66 例），透析期間が 5 年未満 89.7%（87/97 例），5 年以上 10 年未満 93.3%（83/89 例），10 年以上 20 年未満 86.6%（84/97 例），20 年以上 85.7%（30/35 例），血清 iPTH 濃度ベースライン値 240 pg/mL 以下 94.3%（33/35 例），240 pg/mL 超 500 pg/mL 未満 87.7%（186/212 例），500 pg/mL 以上 91.5%（65/71 例），血清補正 Ca 濃度ベースライン値 8.4 mg/dL 未満 100.0%（2/2 例），8.4 mg/dL 以上 9.0 mg/dL 未満 88.0%（66/75 例），9.0 mg/dL 以上 10.0 mg/dL 以下 88.3%（159/180 例），10.0 mg/dL 超 93.4%（57/61 例），血清 P 濃度ベースライン値 3.5 mg/dL 未満 75.0%（3/4 例），3.5 mg/dL 以上 6.0 mg/dL 以下 89.1%（172/193 例），6.0 mg/dL 超 90.1%（109/121 例）であった。

部分集団別の副作用の発現率は，男性 9.1%（22/241 例），女性 15.6%（12/77 例），年齢 65 歳未満 11.0%（19/172 例），65 歳以上 10.3%（15/146 例），原疾患が慢性糸球体腎炎 9.6%（11/115 例），糖尿病性腎症 11.3%（9/80 例），腎硬化症 7.9%（3/38 例），多発性嚢胞腎 5.3%（1/19 例），その他 15.2%（10/66 例），透析期間が 5 年未満 13.4%（13/97 例），5 年以上 10 年未満 13.5%（12/89 例），10 年以上 20 年未満 7.2%（7/97 例），20 年以上 5.7%（2/35 例），血清 iPTH 濃度ベースライン値 240 pg/mL 以下 20.0%（7/35 例），240 pg/mL 超 500 pg/mL 未満 10.8%（23/212 例），500 pg/mL 以上 5.6%（4/71 例），血清補正 Ca 濃度ベースライン値 8.4 mg/dL 未満 0.0%（0/2 例），8.4 mg/dL 以上 9.0 mg/dL 未満 21.3%（16/75 例），9.0 mg/dL 以上 10.0 mg/dL 以下 7.2%（13/180 例），10.0 mg/dL 超 8.2%（5/61 例），血清 P 濃度ベースライン値 3.5 mg/dL 未満 0.0%（0/4 例），3.5 mg/dL 以上 6.0 mg/dL 以下 11.9%（23/193 例），6.0 mg/dL 超 9.1%（11/121 例）であった。

全有害事象の発現率と比較して，明らかに発現率が高くなる部分集団は認められなかった。一方，副作用発現率については，血清補正 Ca 濃度ベースライン値による部分集団解析において，8.4 mg/dL 以上 9.0 mg/dL 未満の部分集団の発現率は 21.3%であ

り，全副作用発現率 10.7%と比較して高かった。その他に全副作用発現率と比較して副作用発現率が高くなる部分集団は認められなかった。

(2) 死亡に至った有害事象

死亡に至った有害事象は 1 例のみであり，部分集団別の検討はできなかった。

(3) その他の重篤な有害事象

SK-1403 併合群において，その他の重篤な有害事象の発現率は 14.2%（45/318 例）であった。

部分集団別のその他の重篤な有害事象の発現率は，男性 15.4%（37/241 例），女性 10.4%（8/77 例），年齢 65 歳未満 10.5%（18/172 例），65 歳以上 18.5%（27/146 例），原疾患が慢性糸球体腎炎 10.4%（12/115 例），糖尿病性腎症 23.8%（19/80 例），腎硬化症 13.2%（5/38 例），多発性嚢胞腎 21.1%（4/19 例），その他 7.6%（5/66 例），透析期間が 5 年未満 13.4%（13/97 例），5 年以上 10 年未満 14.6%（13/89 例），10 年以上 20 年未満 14.4%（14/97 例），20 年以上 14.3%（5/35 例），血清 iPTH 濃度ベースライン値 240 pg/mL 以下 22.9%（8/35 例），240 pg/mL 超 500 pg/mL 未満 13.7%（29/212 例），500 pg/mL 以上 11.3%（8/71 例），血清補正 Ca 濃度ベースライン値 8.4 mg/dL 未満 0.0%（0/2 例），8.4 mg/dL 以上 9.0 mg/dL 未満 14.7%（11/75 例），9.0 mg/dL 以上 10.0 mg/dL 以下 13.3%（24/180 例），10.0 mg/dL 超 16.4%（10/61 例），血清 P 濃度ベースライン値 3.5 mg/dL 未満 25.0%（1/4 例），3.5 mg/dL 以上 6.0 mg/dL 以下 12.4%（24/193 例），6.0 mg/dL 超 16.5%（20/121 例）であった。

その他の重篤な有害事象の全体の発現率と比較して，明らかに発現率が高くなる部分集団は認められなかった。

(4) 中止の理由となった有害事象

中止の理由となった有害事象は 3 例と少数であるため，部分集団別の検討はできなかった。

(5) 休薬の理由となった有害事象

SK-1403 併合解析において，休薬の理由となった有害事象の発現率は 4.4%（14/318 例）であった。

部分集団別の休薬の理由となった有害事象の発現率は，男性 2.5%（6/241 例），女性 10.4%（8/77 例），年齢 65 歳未満 4.7%（8/172 例），65 歳以上 4.1%（6/146 例），原疾患が慢性糸球体腎炎 4.3%（5/115 例），糖尿病性腎症 6.3%（5/80 例），腎硬化症 2.6%（1/38 例），多発性嚢胞腎 0.0%（0/19 例），その他 4.5%（3/66 例），透析期間が 5 年未満 7.2%（7/97 例），5 年以上 10 年未満 5.6%（5/89 例），10 年以上 20 年未満 2.1%（2/97 例），20 年以上 0.0%（0/35 例），血清 iPTH 濃度ベースライン値 240 pg/mL 以下 5.7%（2/35 例），240 pg/mL 超 500 pg/mL 未満 4.7%（10/212 例），500 pg/mL 以上 2.8%（2/71 例），血清補正 Ca 濃度ベースライン値 8.4 mg/dL 未満 0.0%（0/2 例），8.4 mg/dL 以上 9.0 mg/dL 未満 14.7%（11/75 例），9.0 mg/dL 以上 10.0 mg/dL 以下 1.7%（3/180 例），10.0 mg/dL

超 0.0%（0/61 例），血清 P 濃度ベースライン値 3.5 mg/dL 未満 0.0%（0/4 例），3.5 mg/dL 以上 6.0 mg/dL 以下 6.2%（12/193 例），6.0 mg/dL 超 1.7%（2/121 例）であった。

性別及び血清補正 Ca 濃度ベースライン値による部分集団解析において，休薬理由となった有害事象の発現率は女性で 10.4%, 血清補正 Ca 濃度ベースライン値 8.4 mg/dL 以上 9.0 mg/dL 未満の部分集団で 14.7%と全体の発現率 4.4%と比較して高かった。その他に，休薬の理由となった有害事象の全体の発現率と比較して明らかに発現率が高くなる部分集団は認められなかった。

(6) 減量の理由となった有害事象

減量の理由になった有害事象は 1 例のみであり部分集団別の検討はできなかった。

(7) 「低カルシウム血症」に関連する有害事象

SK-1403 併合解析において，「低カルシウム血症」に関連する有害事象の発現率は 5.7%（18/318 例）であった。

部分集団別の「低カルシウム血症」に関連する有害事象の発現率は, 男性 4.1%（10/241 例），女性 10.4%（8/77 例），年齢 65 歳未満 5.2%（9/172 例），65 歳以上 6.2%（9/146 例），原疾患が慢性糸球体腎炎 2.6%（3/115 例），糖尿病性腎症 8.8%（7/80 例），腎硬化症 5.3%（2/38 例），多発性嚢胞腎 0.0%（0/19 例），その他 9.1%（6/66 例），透析期間が 5 年未満 9.3%（9/97 例），5 年以上 10 年未満 5,6%（5/89 例），10 年以上 20 年未満 3.1%（3/97 例），20 年以上 2.9%（1/35 例），血清 iPTH 濃度ベースライン値 240 pg/mL 以下 5.7%（2/35 例），240 pg/mL 超 500 pg/mL 未満 7.1%（15/212 例），500 pg/mL 以上 1.4%（1/71 例）, 血清補正 Ca 濃度ベースライン値 8.4 mg/dL 未満 0.0%（0/2 例）, 8.4 mg/dL 以上 9.0 mg/dL 未満 17.3%（13/75 例）, 9.0 mg/dL 以上 10.0 mg/dL 以下 2.8%（5/180 例），10.0 mg/dL 超 0.0%（0/61 例）, 血清 P 濃度ベースライン値 3.5 mg/dL 未満 0.0%（0/4 例），3.5 mg/dL 以上 6.0 mg/dL 以下 7.3%（14/193 例），6.0 mg/dL 超 3.3%（4/121 例）であった。

血清補正 Ca 濃度ベースライン値による部分集団解析において，8.4 mg/dL 以上 9.0 mg/dL 未満の部分集団で「低カルシウム血症」に関連する有害事象の発現率は 17.3%と全体の発現率 5.7%と比較して高かった。その他に，「低カルシウム血症」に関連する有害事象の全体の発現率と比較して明らかに発現率が高くなる部分集団は認められなかった。

(8) 「骨代謝障害」に関連する有害事象

「骨代謝障害」に関連する有害事象は認められなかった。

(9) 「胃腸障害」に関連する有害事象

SK-1403 併合解析において，「胃腸障害」に関連する有害事象の発現率は 36.5%（116/318 例）であった。

部分集団別の「胃腸障害」に関連する有害事象の発現率は, 男性 35.3%（85/241 例），女性 40.3%（31/77 例），年齢 65 歳未満 35.5%（61/172 例），65 歳以上 37.7%（55/146

例），原疾患が慢性糸球体腎炎 34.8%（40/115 例），糖尿病性腎症 33.8%（27/80 例），腎硬化症 31.6%（12/38 例），多発性嚢胞腎 26.3%（5/19 例），その他 48.5%（32/66 例），透析期間が 5 年未満 26.8%（26/97 例），5 年以上 10 年未満 42.7%（38/89 例），10 年以上 20 年未満 39.2%（38/97 例），20 年以上 40.0%（14/35 例），血清 iPTH 濃度ベースライン値 240 pg/mL 以下 37.1%（13/35 例），240 pg/mL 超 500 pg/mL 未満 35.8%（76/212 例），500 pg/mL 以上 38.0%（27/71 例），血清補正 Ca 濃度ベースライン値 8.4 mg/dL 未満 0.0%（0/2 例），8.4 mg/dL 以上 9.0 mg/dL 未満 33.3%（25/75 例），9.0 mg/dL 以上 10.0 mg/dL 以下 39.4%（71/180 例），10.0 mg/dL 超 32.8%（20/61 例），血清 P 濃度ベースライン値 3.5 mg/dL 未満 0.0%（0/4 例），3.5 mg/dL 以上 6.0 mg/dL 以下 36.8%（71/193 例），6.0 mg/dL 超 37.2%（45/121 例）であった。

「胃腸障害」に関連する有害事象の全体の発現率と比較して，明らかに発現率が高くなる部分集団は認められなかった。

（10）「QT 延長」に関連する有害事象

SK-1403 併合解析において，「QT 延長」に関連する有害事象の発現率は 1.9%（6/318 例）であった。

部分集団別の「QT 延長」に関連する有害事象の発現率は，男性 2.1%（5/241 例），女性 1.3%（1/77 例），年齢 65 歳未満 1.7%（3/172 例），65 歳以上 2.1%（3/146 例），原疾患が慢性糸球体腎炎 3.5%（4/115 例），糖尿病性腎症 1.3%（1/80 例），腎硬化症 2.6%（1/38 例），多発性嚢胞腎 0.0%（0/19 例），その他 0.0%（0/66 例），透析期間が 5 年未満 1.0%（1/97 例），5 年以上 10 年未満 3.4%（3/89 例），10 年以上 20 年未満 2.1%（2/97 例），20 年以上 0.0%（0/35 例），血清 iPTH 濃度ベースライン値 240 pg/mL 以下 5.7%（2/35 例），240 pg/mL 超 500 pg/mL 未満 1.4%（3/212 例），500 pg/mL 以上 1.4%（1/71 例），血清補正 Ca 濃度ベースライン値 8.4 mg/dL 未満 0.0%（0/2 例），8.4 mg/dL 以上 9.0 mg/dL 未満 4.0%（3/75 例），9.0 mg/dL 以上 10.0 mg/dL 以下 1.1%（2/180 例），10.0 mg/dL 超 1.6%（1/61 例），血清 P 濃度ベースライン値 3.5 mg/dL 未満 0.0%（0/4 例），3.5 mg/dL 以上 6.0 mg/dL 以下 1.6%（3/193 例），6.0 mg/dL 超 2.5%（3/121 例）であった。

血清 iPTH 濃度ベースライン値及び血清補正 Ca 濃度ベースライン値による部分集団解析において，血清 iPTH 濃度ベースライン値 240 pg/mL 以下及び血清補正 Ca 濃度ベースライン値 8.4 mg/dL 以上 9.0 mg/dL 未満の部分集団で「QT 延長」に関連する有害事象の発現率は 5.7%及び 4.0%であり，全体の発現率 1.9%と比較して高かった。その他に，「QT 延長」に関連する有害事象の全体の発現率と比較して，明らかに発現率が高くなる部分集団は認められなかった。

（11）「水晶体混濁」に関連する有害事象

SK-1403 併合解析において，「水晶体混濁」に関連する有害事象の発現率は 2.5%（8/318 例）であった。

部分集団別の「水晶体混濁」に関連する有害事象の発現率は，男性 2.1%（5/241 例），女性 3.9%（3/77 例），年齢 65 歳未満 1.7%（3/172 例），65 歳以上 3.4%（5/146 例），原疾患が慢性糸球体腎炎 3.5%（4/115 例），糖尿病性腎症 1.3%（1/80 例），腎硬化症 5.3%

（2/38 例），多発性嚢胞腎 0.0%（0/19 例），その他 1.5%（1/66 例），透析期間が 5 年未満 5.2%（5/97 例），5 年以上 10 年未満 2.2%（2/89 例），10 年以上 20 年未満 1.0%（1/97 例），20 年以上 0.0%（0/35 例），血清 iPTH 濃度ベースライン値 240 pg/mL 以下 5.7%（2/35 例），240 pg/mL 超 500 pg/mL 未満 2.8%（6/212 例），500 pg/mL 以上 0.0%（0/71 例），血清補正 Ca 濃度ベースライン値 8.4 mg/dL 未満 0.0%（0/2 例），8.4 mg/dL 以上 9.0 mg/dL 未満 4.0%（3/75 例），9.0 mg/dL 以上 10.0 mg/dL 以下 2.8%（5/180 例），10.0 mg/dL 超 0.0%（0/61 例），血清 P 濃度ベースライン値 3.5 mg/dL 未満 0.0%（0/4 例），3.5 mg/dL 以上 6.0 mg/dL 以下 3.1%（6/193 例），6.0 mg/dL 超 1.7%（2/121 例）であった。

原疾患，透析期間及び血清 iPTH 濃度ベースライン値による部分集団解析において，腎硬化症，透析期間が 5 年未満及び血清 iPTH 濃度ベースライン値 240 pg/mL 以下の部分集団で「水晶体混濁」に関連する有害事象の発現率は 5.3%，5.2%及び 5.7%と全体の発現率 2.5%と比較して高かった。その他に，「水晶体混濁」に関連する有害事象の全体発現率と比較してが明らかに発現率が高くなる部分集団は認められなかった。

2.7.4.5.2　外因性要因

併合解析における，全有害事象，死亡に至った有害事象，その他の重篤な有害事象，他の重要な有害事象（中止の理由となった有害事象，休薬の理由となった有害事象，減量の理由となった有害事象），「低カルシウム血症」に関連する有害事象，「骨代謝障害」に関連する有害事象，「胃腸障害」に関連する有害事象，「QT 延長」に関連する有害事象，「水晶体混濁」に関連する有害事象について，活性型ビタミン D 製剤投与，透析液 Ca 濃度，透析方法による部分集団解析結果を表 2.7.4.7－62，表 2.7.4.7－63，表 2.7.4.7－64，表 2.7.4.7－65，表 2.7.4.7－66，表 2.7.4.7－67，表 2.7.4.7－68，表 2.7.4.7－69，表 2.7.4.7－70，表 2.7.4.7－71，表 2.7.4.7－72 に示した。

（1）全有害事象

SK-1403 併合群において，有害事象の発現率は 89.3%（284/318 例）であり，これらのうち副作用と判定された事象の発現率は 10.7%（34/318 例）であった。

部分集団別の有害事象の発現率は，透析方法が血液透析 90.4%（141/156 例），血液濾過透析 88.3%（143/162 例），透析液 Ca 濃度が 2.5 mEq/L 91.0%（111/122 例），2.75 mEq/L 86.1%（87/101 例），3.0 mEq/L 90.5%（86/95 例），活性型ビタミン D 製剤無 90.2%（55/61 例），有 89.1%（229/257 例）であった。

部分集団別の副作用の発現率は，透析方法が血液透析 12.2%（19/156 例），血液濾過透析 9.3%（15/162 例），透析液 Ca 濃度が 2.5 mEq/L 8.2%（10/122 例），2.75 mEq/L 9.9%（10/101 例），3.0 mEq/L 14.7%（14/95 例），活性型ビタミン D 製剤無 13.1%（8/61 例），有 10.1%（26/257 例）であった。

全有害事象の発現率と比較して明らかに発現率が高くなる部分集団は認められなかった。

（2）死亡に至った有害事象

死亡に至った有害事象は 1 例のみであり，部分集団別の検討はできなかった。

(3) その他の重篤な有害事象

SK-1403 併合群において，その他の重篤な有害事象の発現率は 14.2%（45/318 例）であった。

部分集団別のその他重篤な有害事象の発現率は，透析方法が血液透析 14.1%（22/156 例），血液濾過透析 14.2%（23/162 例），透析液 Ca 濃度が 2.5 mEq/L 15.6%（19/122 例），2.75 mEq/L 11.9%（12/101 例），3.0 mEq/L 14.7%（14/95 例），活性型ビタミン D 製剤無 16.4%（10/61 例），有 13.6%（35/257 例）であった。

その他重篤な有害事象の全体の発現率と比較して明らかに発現率が高くなる部分集団は認められなかった。

(4) 中止の理由となった有害事象

中止の理由となった有害事象は 3 例と少数であるため，部分集団別の検討はできなかった。

(5) 休薬の理由となった有害事象

SK-1403 併合解析において，休薬の理由となった有害事象の発現率は 4.4%（14/318 例）であった。

部分集団別の休薬の理由となった有害事象の発現率は，透析方法が血液透析 5.1%（8/156 例），血液濾過透析 3.7%（6/162 例），透析液 Ca 濃度が 2.5 mEq/L 4.9%（6/122 例），2.75 mEq/L 5.0%（5/101 例），3.0 mEq/L 3.2%（3/95 例），活性型ビタミン D 製剤無 4.9%（3/61 例），有 4.3%（11/257 例）であった。

休薬の理由となった有害事象の全体の発現率と比較して明らかに発現率が高くなる部分集団は認められなかった。

(6) 減量の理由となった有害事象

減量の理由になった有害事象は 1 例のみであり，部分集団別の検討はできなかった。

(7) 「低カルシウム血症」に関連する有害事象

SK-1403 併合解析において，「低カルシウム血症」に関連する有害事象の発現率は 5.7%（18/318 例）であった。

部分集団別の「低カルシウム血症」に関連する有害事象の発現率は，透析方法が血液透析 7.7%（12/156 例），血液濾過透析 3.7%（6/162 例），透析液 Ca 濃度が 2.5 mEq/L 5.7%（7/122 例），2.75 mEq/L 5.0%（5/101 例），3.0 mEq/L 6.3%（6/95 例），活性型ビタミン D 製剤無 9.8%（6/61 例），有 4.7%（12/257 例）であった。

「低カルシウム血症」に関連する有害事象の全体の発現率と比較して明らかに発現率が高くなる部分集団は認められなかった。

(8) 「骨代謝障害」に関連する有害事象

「骨代謝障害」に関連する有害事象は認められなかった。

（9）「胃腸障害」に関連する有害事象

SK-1403 併合解析において，「胃腸障害」に関連する有害事象の発現率は 36.5%（116/318 例）であった。

部分集団別の「胃腸障害」に関連する有害事象の発現率は，透析方法が血液透析 33.3%（52/156 例），血液濾過透析 39.5%（64/162 例），透析液 Ca 濃度が 2.5 mEq/L 35.2%（43/122 例），2.75 mEq/L 35.6%（36/101 例），3.0 mEq/L 38.9%（37/95 例），活性型ビタミン D 製剤無 26.2%（16/61 例），有 38.9%（100/257 例）であった。

「胃腸障害」に関連する有害事象の全体の発現率と比較して明らかに発現率が高くなる部分集団は認められなかった。

（10）「QT 延長」に関連する有害事象

SK-1403 併合解析において，「QT 延長」に関連する有害事象の発現率は 1.9%（6/318 例）であった。

部分集団別の「QT 延長」に関連する有害事象の発現率は，透析方法が血液透析 1.9%（3/156 例），血液濾過透析 1.9%（3/162 例），透析液 Ca 濃度が 2.5 mEq/L 1.6%（2/122 例），2.75 mEq/L 1.0%（1/101 例），3.0 mEq/L 3.2%（3/95 例），活性型ビタミン D 製剤無 0.0%（0/61 例），有 2.3%（6/257 例）であった。

全体の「QT 延長」に関連する有害事象の発現率と比較して明らかに発現率が高くなる部分集団は認められなかった。

（11）「水晶体混濁」に関連する有害事象

SK-1403 併合解析において，「水晶体混濁」に関連する有害事象の発現率は 2.5%（8/318 例）であった。

部分集団別の「水晶体混濁」に関連する有害事象の発現率は，透析方法が血液透析 3.8%（6/156 例），血液濾過透析 1.2%（2/162 例），透析液 Ca 濃度が 2.5 mEq/L 3.3%（4/122 例），2.75 mEq/L 0.0%（0/101 例），3.0 mEq/L 4.2%（4/95 例），活性型ビタミン D 製剤無 0.0%（0/61 例），有 3.1%（8/257 例）であった。

「水晶体混濁」に関連する有害事象の全体の発現率と比較して明らかに発現率が高くなる部分集団は認められなかった。

2.7.4.5.3　薬物相互作用

SK-1403 と他の薬剤との薬物相互作用を評価する試験は実施していない。

SK-1403 は主要なシトクロム P450（以下，CYP）分子種に対する阻害作用及び誘導作用を示さなかった（2.7.2.2.1.3，2.7.2.2.1.4）。

SK-1403 は MDR1 及び BCRP の基質ではなく，また各種トランスポーター（MDR1, BCRP, OATP1B1，OATP1B3，OAT1，OAT3，OCT2，MATE1 及び MATE2-K）に対する阻害活性を示さなかった（2.7.2.2.1.5）。

2.7.4.5.4　妊娠及び授乳時の使用

SK-1403 の開発段階において妊娠及び授乳時の使用経験はない。

ラット受胎能及び着床までの初期胚発生に関する試験では，親動物の一般毒性学的影響及び生殖機能に及ぼす影響は認められなかった。初期胚発生に及ぼす影響は認められなかった（2.6.6.6.1.1）。

ラット胚・胎児発生に関する試験では，母動物に及ぼす一般毒性学的影響として，300 mg/kg/日以上で体重増加抑制及び摂餌量の減少が見られた。母動物の生殖機能に及ぼす影響及び胚・胎児発生に及ぼす影響は認められなかった（2.6.6.6.2.2）。

ウサギ胚・胎児発生に関する試験では，母動物に及ぼす一般毒性学的影響として，100 mg/kg/日で排糞量の減少，体重増加抑制，摂餌量の減少及び腎臓の退色が見られた。母動物の生殖機能に及ぼす影響として，100 mg/kg/日の 1 例に SK-1403 投与の二次的な影響（母動物への一般毒性学的影響に起因する全身状態の悪化に伴う変化）と考えられる流産が認められた。胚・胎児発生に及ぼす影響は認められなかった（2.6.6.6.2.4）。

ラット出生前及び出生後の発生並びに母体の機能に関する試験では，母動物に及ぼす一般毒性学的影響として，300 mg/kg/日以上で妊娠期の摂餌量の減少，1000 mg/kg/日で妊娠期の体重増加抑制が見られた。母動物の生殖機能に及ぼす影響は認められなかった。出生児に及ぼす影響として，100 mg/kg/日以上で発育抑制（体重増加抑制），生後初期の生存性低下，水晶体前皮質及び核に限局性混濁，1000 mg/kg/日で死産児数の高値，血中 Ca 濃度の低下，オープンフィールド内での総行動距離及び立ち上がり回数の増加が見られた。しかし，外表分化，感覚・反射機能，学習機能及び生殖機能に対する影響は認められなかった（2.6.6.6.3.2）。

胎盤通過性の検討では，妊娠 18 日目の妊娠ラットに[^{14}C]SK-1403 を単回静脈内投与したとき，SK-1403 由来物質がわずかに胎児へ移行したものの経時的に消失し，投与後 24 時間の胎児の放射能分布率は 0.0120%と低く，残留性はないと考えられた（2.6.4.4.6）。また，授乳中ラットに[^{14}C]SK-1403 を単回静脈内投与したとき，SK-1403 由来物質が乳汁へ移行することが示された（2.6.4.6.3）。

2.7.4.5.5　過量投与

SK-1403 の申請する用法及び用量において，1 回投与量及び週投与回数はそれぞれ 1 回 25～300 μg，週 3 回である。

維持血液透析下の SHPT 患者を対象として SK-1403 の安全性を評価した主要な試験である AJ1002 試験，AJ1003 試験及び AJ1004 試験では，1 回 25～300 μg，週 3 回の投与を行い，SK-1403 の安全性が確認された。

AJ0001 試験において，健康成人に対する SK-1403 の単回投与では最大で 2500 μg までの投与が行われ，死亡及びその他の重篤な有害事象は認められなかった。

AJ1001 試験の単回投与パートにおいて，維持血液透析下の SHPT 患者に対する SK-1403 の単回投与では最大で 800 μg までの投与が行われ，死亡及びその他の重篤な有害事象は認められなかった。

AJ1001 試験の反復投与パートにおいて，SK-1403 の反復投与では最大で 200 μg，週 3 回までの投与が行われ，重篤な有害事象が 100 μg 群で「シャント閉塞」（1 例）及び「シャント狭窄」（1 例）が認められたが，いずれも治験薬との因果関係は否定された。一方，0.05 mg

群 1 例に 2 回，0.1 mg 群 1 例に 1 回の過量投与が発生し，いずれも SK-1403 1000 μg が投与された。これらの症例において「感覚鈍麻」1 例，「血中カルシウム減少」1 例の有害事象が発現し，いずれも副作用と判定された。重篤性及び重症度はいずれも非重篤で軽度な事象であった。なお，AJ1001 試験では治験薬としてプレフィルドシリンジ製剤でなく，バイアル製剤が用いられた。

SK-1403 を血液透析患者に投与した際には，SK-1403 の 90%以上が未変化体で血中に存在し，その主要排泄経路は透析液への排出であり，SK-1403 は血液透析により血中から除去される。このため，過量投与に対する救済処置として血液透析を実施することは有用であると考えられるが，SK-1403 の開発段階において救済処置を実施した経験はない。

2.7.4.5.6　薬物乱用

SK-1403 の開発段階において，薬物乱用の可能性を示唆する所見は得られていない。

2.7.4.5.7　離脱症状及び反跳現象

SK-1403 の開発段階において，離脱症状及び反跳現象を示唆する所見は得られていない。

2.7.4.5.8　自動車運転及び機械操作に対する影響又は精神機能の障害

AJ1002 試験, AJ1003 試験及び AJ1004 試験の 3 試験で SK-1403 を投与された 318 例において，SOC「神経系障害」に分類される有害事象の発現率は 12.9%（41 例）で，これらのうち副作用と判定された事象は「浮動性めまい」(1 例)，「パーキンソン病」(1 例）であった。「浮動性めまい」の重症度は中等度で，重篤な事象であった。「パーキンソン病」の重症度は軽度で非重篤な事象であった。SOC「精神障害」に分類される有害事象の発現率は 3.1%（10/318 例）であり，これらのうち副作用と判定された事象はなかった。

以上より，「神経系障害」に分類される副作用は 2 例に発現したものの，症状としてはそれぞれ 1 例のみの発現であること，「精神障害」に分類される副作用はなかったことから，自動車運転及び機械操作又は精神機能の障害に対する影響は低いものと考えられた。

2.7.4.6　市販後データ

SK-1403 は国内及び国外で市販されていない。

2.7.4.7　付録

表 2.7.4.7−1　治験薬の総投与量と投与期間

項目		SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
総投与量(μg)	n	318	58	157	103	50
	Mean	13542.1	16340.5	17071.5	6586.7	10771.0
	SD	11431.2	13036.8	11991.9	4325.7	4909.0
	Min	25	400	200	25	200
	Median	9300.0	9750.0	13550.0	6550.0	13175.0
	Max	40050	40050	40050	14850	14850
投与期間(日)	n	318	58	157	103	50
	Mean	280.5	339.3	337.6	160.3	146.1
	SD	103.8	73.8	73.6	23.8	40.9
	Min	1	17	17	1	8
	Median	362.0	362.0	362.0	166.0	166.0
	Max	363	363	362	167	167
投与期間(日)　カテゴリ	1≤ - <22	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	1(2.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	2(4.0%)
	64≤ - <85	5(1.6%)	0(0.0%)	3(1.9%)	2(1.9%)	1(2.0%)
	85≤ - <106	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	3(6.0%)
	106≤ - <127	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	3(6.0%)
	127≤ - <148	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)
	148≤ - <169	101(31.8%)	0(0.0%)	4(2.5%)	97(94.2%)	39(78.0%)
	169≤ - <267	4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)
	267≤ - <365	194(61.0%)	53(91.4%)	141(89.8%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

投与期間 = 治験薬の投与終了日 - 治験薬の投与開始日 +1
カテゴリの項目は例数(割合(%))

表 2.7.4.7－2　治験薬の最大投与量別の被験者割合

		SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004
		(N=318)	(N=58)	(N=157)	(N=103)	(N=50)
最大投与量	25 μg	24(7.5%)	0(0.0%)	8(5.1%)	16(15.5%)	1(2.0%)
	50 μg	82(25.8%)	24(41.4%)	33(21.0%)	25(24.3%)	2(4.0%)
	100 μg	68(21.4%)	9(15.5%)	39(24.8%)	20(19.4%)	3(6.0%)
	150 μg	46(14.5%)	6(10.3%)	25(15.9%)	15(14.6%)	2(4.0%)
	200 μg	29(9.1%)	5(8.6%)	14(8.9%)	10(9.7%)	4(8.0%)
	250 μg	18(5.7%)	2(3.4%)	9(5.7%)	7(6.8%)	8(16.0%)
	300 μg	51(16.0%)	12(20.7%)	29(18.5%)	10(9.7%)	30(60.0%)

例数(割合(%))

表 2.7.4.7－3　治験薬の最終投与量別の被験者割合

		SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004
		(N=318)	(N=58)	(N=157)	(N=103)	(N=50)
最終投与量	25 μg	73(23.0%)	14(24.1%)	31(19.7%)	28(27.2%)	1(2.0%)
	50 μg	67(21.1%)	14(24.1%)	36(22.9%)	17(16.5%)	3(6.0%)
	100 μg	50(15.7%)	7(12.1%)	26(16.6%)	17(16.5%)	2(4.0%)
	150 μg	37(11.6%)	5(8.6%)	17(10.8%)	15(14.6%)	2(4.0%)
	200 μg	26(8.2%)	4(6.9%)	13(8.3%)	9(8.7%)	4(8.0%)
	250 μg	17(5.3%)	4(6.9%)	6(3.8%)	7(6.8%)	8(16.0%)
	300 μg	48(15.1%)	10(17.2%)	28(17.8%)	10(9.7%)	30(60.0%)

例数(割合(%))

表 2.7.4.7－4　治験薬の減量状況

	投与群	試験名	対象被験者数	例数(割合(%))	件数
減量	SK-1403 群	併合	318	119(37.4%)	198
		AJ1002	58	30(51.7%)	41
		AJ1003	157	66(42.0%)	123
		AJ1004	103	23(22.3%)	34
	プラセボ群	AJ1004	50	2(4.0%)	4

表 2.7.4.7−5　治験薬の減量幅のシフトテーブル

投与群	試験名	減量幅	減量前の用量						
			300 μg	250 μg	200 μg	150 μg	100 μg	50 μg	25 μg
SK-1403 群	併合	25 μg	-	-	-	-	-	53	41
		50 μg	2	6	10	19	43	14	-
		100 μg	2	0	0	0	2	-	-
		150 μg	0	0	0	4	-	-	-
		200 μg	0	0	1	-	-	-	-
		250 μg	0	0	-	-	-	-	-
		300 μg	1	-	-	-	-	-	-
	AJ1002	25 μg	-	-	-	-	-	11	6
		50 μg	1	1	2	2	4	11	-
		100 μg	2	0	0	0	1	-	-
		150 μg	0	0	0	0	-	-	-
		200 μg	0	0	0	-	-	-	-
		250 μg	0	0	-	-	-	-	-
		300 μg	0	-	-	-	-	-	-
	AJ1003	25 μg	-	-	-	-	-	31	24
		50 μg	1	5	6	15	34	1	-
		100 μg	0	0	0	0	1	-	-
		150 μg	0	0	0	4	-	-	-
		200 μg	0	0	0	-	-	-	-
		250 μg	0	0	-	-	-	-	-
		300 μg	1	-	-	-	-	-	-
	AJ1004	25 μg	-	-	-	-	-	11	11
		50 μg	0	0	2	2	5	2	-
		100 μg	0	0	0	0	0	-	-
		150 μg	0	0	0	0	-	-	-
		200 μg	0	0	1	-	-	-	-
		250 μg	0	0	-	-	-	-	-
		300 μg	0	-	-	-	-	-	-

投与群	試験名	減量幅	減量前の用量						
			300 μg	250 μg	200 μg	150 μg	100 μg	50 μg	25 μg
プラセボ群	AJ1004	25 μg	-	-	-	-	-	0	2
		50 μg	0	0	0	0	1	1	-
		100 μg	0	0	0	0	0	-	-
		150 μg	0	0	0	0	-	-	-
		200 μg	0	0	0	-	-	-	-
		250 μg	0	0	-	-	-	-	-
		300 μg	0	-	-	-	-	-	-

件数

表 2.7.4.7－6　治験薬の休薬状況

	投与群	試験名	対象被験者数	例数(割合(%))	件数
休薬	SK-1403 群	併合	318	43(13.5%)	63
		AJ1002	58	15(25.9%)	18
		AJ1003	157	18(11.5%)	31
		AJ1004	103	10(9.7%)	14
	プラセボ群	AJ1004	50	2(4.0%)	3

表 2.7.4.7－7　人口統計学的特性及びその他の特性

項目		SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
性別	男	241(75.8%)	43(74.1%)	121(77.1%)	77(74.8%)	39(78.0%)
	女	77(24.2%)	15(25.9%)	36(22.9%)	26(25.2%)	11(22.0%)
年齢(歳)	n	318	58	157	103	50
	Mean	61.2	61.6	60.3	62.4	65.8
	SD	11.0	9.1	10.6	12.6	13.6
	Min	26	44	26	27	36
	Median	63.0	62.0	62.0	66.0	70.5
	Max	84	79	84	83	88
年齢　カテゴリ	<65 歳	172(54.1%)	33(56.9%)	91(58.0%)	48(46.6%)	20(40.0%)
	≥65 歳	146(45.9%)	25(43.1%)	66(42.0%)	55(53.4%)	30(60.0%)
身長(cm)	n	318	58	157	103	50
	Mean	163.69	162.72	164.24	163.40	161.30
	SD	9.07	9.53	8.54	9.60	8.43
	Min	130.0	130.0	130.3	137.1	139.0
	Median	164.75	163.70	165.20	164.70	161.75
	Max	184.0	180.8	181.3	184.0	179.5
ドライウェイト(kg)	n	318	58	157	103	49
	Mean	63.20	61.94	64.45	62.01	59.83
	SD	14.04	14.02	14.20	13.76	12.23
	Min	35.0	35.0	35.8	40.0	40.5
	Median	61.00	59.30	61.50	61.00	58.50
	Max	132.0	105.0	111.5	132.0	91.0
ドライウェイト カテゴリ	<50.0 kg	48(15.1%)	10(17.2%)	20(12.7%)	18(17.5%)	13(26.0%)
	≥50 kg - <60.0 kg	90(28.3%)	19(32.8%)	44(28.0%)	27(26.2%)	13(26.0%)
	≥60 kg - <70.0 kg	97(30.5%)	14(24.1%)	47(29.9%)	36(35.0%)	13(26.0%)
	≥70.0 kg	83(26.1%)	15(25.9%)	46(29.3%)	22(21.4%)	10(20.0%)

項目		SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
透析後体重(kg)	n	318	58	157	103	50
(治療期 0 週時)	Mean	63.53	62.09	64.82	62.37	59.84
	SD	14.24	14.03	14.49	13.92	12.50
	Min	35.0	35.0	36.4	39.9	40.6
	Median	61.60	58.75	62.00	61.90	58.15
	Max	134.4	106.1	113.5	134.4	91.3
透析後体重 カテゴリ	<50.0 kg	48(15.1%)	10(17.2%)	20(12.7%)	18(17.5%)	14(28.0%)
(治療期 0 週時)	≥50 kg - <60.0 kg	91(28.6%)	21(36.2%)	44(28.0%)	26(25.2%)	13(26.0%)
	≥60 kg - <70.0 kg	95(29.9%)	12(20.7%)	46(29.3%)	37(35.9%)	13(26.0%)
	≥70.0 kg	84(26.4%)	15(25.9%)	47(29.9%)	22(21.4%)	10(20.0%)
BMI(kg/m^2)	n	318	58	157	103	50
	Mean	23.53	23.33	23.87	23.13	22.89
	SD	4.08	4.29	4.26	3.64	3.78
	Min	16.0	16.3	16.4	16.0	15.5
	Median	22.75	22.10	23.20	22.70	22.45
	Max	39.5	35.6	38.5	39.5	32.5
BMI カテゴリ	<18.5 kg/m^2	18(5.7%)	4(6.9%)	8(5.1%)	6(5.8%)	8(16.0%)
	≥18.5 kg/m^2 - <25.0 kg/m^2	206(64.8%)	39(67.2%)	97(61.8%)	70(68.0%)	29(58.0%)
	≥25.0 kg/m^2	94(29.6%)	15(25.9%)	52(33.1%)	27(26.2%)	13(26.0%)
原疾患	慢性糸球体腎炎	115(36.2%)	20(34.5%)	59(37.6%)	36(35.0%)	24(48.0%)
	糖尿病性腎症	80(25.2%)	16(27.6%)	31(19.7%)	33(32.0%)	10(20.0%)
	腎硬化症	38(11.9%)	3(5.2%)	22(14.0%)	13(12.6%)	5(10.0%)
	多発性嚢胞腎	19(6.0%)	4(6.9%)	13(8.3%)	2(1.9%)	1(2.0%)
	その他	66(20.8%)	15(25.9%)	32(20.4%)	19(18.4%)	10(20.0%)
合併症	無	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	有	318(100.0%)	58(100.0%)	157(100.0%)	103(100.0%)	50(100.0%)

項目		SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
透析期間(年)	n	318	58	157	103	50
	Mean	9.94	9.25	10.04	10.18	8.00
	SD	7.67	6.47	7.55	8.48	6.67
	Min	0.2	0.3	0.2	0.3	0.2
	Median	8.63	8.46	8.75	8.83	5.33
	Max	37.3	27.3	36.3	37.3	27.0
透析期間　カテゴリ	<5 年	97(30.5%)	17(29.3%)	45(28.7%)	35(34.0%)	25(50.0%)
	≥5 年 - <10 年	89(28.0%)	19(32.8%)	49(31.2%)	21(20.4%)	6(12.0%)
	≥10 年 - <20 年	97(30.5%)	17(29.3%)	48(30.6%)	32(31.1%)	16(32.0%)
	≥20 年	35(11.0%)	5(8.6%)	15(9.6%)	15(14.6%)	3(6.0%)
透析方法	HD:血液透析	156(49.1%)	29(50.0%)	84(53.5%)	43(41.7%)	25(50.0%)
	HDF:血液透析ろ過	162(50.9%)	29(50.0%)	73(46.5%)	60(58.3%)	25(50.0%)
透析液 Ca 濃度	2.5 mEq/L	122(38.4%)	12(20.7%)	78(49.7%)	32(31.1%)	14(28.0%)
	2.75 mEq/L	101(31.8%)	16(27.6%)	46(29.3%)	39(37.9%)	21(42.0%)
	3.0 mEq/L	95(29.9%)	30(51.7%)	33(21.0%)	32(31.1%)	15(30.0%)
	その他	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
排尿の有無	無	158(49.7%)	33(56.9%)	82(52.2%)	43(41.7%)	14(28.0%)
	有	160(50.3%)	25(43.1%)	75(47.8%)	60(58.3%)	36(72.0%)
リン吸着薬の有無	無	22(6.9%)	3(5.2%)	11(7.0%)	8(7.8%)	4(8.0%)
	有	296(93.1%)	55(94.8%)	146(93.0%)	95(92.2%)	46(92.0%)
リン吸着薬の内容	Ca 含有	32(10.1%)	8(13.8%)	17(10.8%)	7(6.8%)	6(12.0%)
	Ca 非含有	152(47.8%)	21(36.2%)	83(52.9%)	48(46.6%)	25(50.0%)
	併用	112(35.2%)	26(44.8%)	46(29.3%)	40(38.8%)	15(30.0%)
Ca 製剤の有無	無	300(94.3%)	58(100.0%)	142(90.4%)	100(97.1%)	48(96.0%)
	有	18(5.7%)	0(0.0%)	15(9.6%)	3(2.9%)	2(4.0%)

項目		SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
活性型ビタミン D 製剤の有無	無	61(19.2%)	12(20.7%)	22(14.0%)	27(26.2%)	7(14.0%)
	有	257(80.8%)	46(79.3%)	135(86.0%)	76(73.8%)	43(86.0%)
リン吸着薬の変更状況の有無	無	140(44.0%)	19(32.8%)	79(50.3%)	42(40.8%)	33(66.0%)
	有	178(56.0%)	39(67.2%)	78(49.7%)	61(59.2%)	17(34.0%)
Ca 製剤の変更状況の有無	無	278(87.4%)	43(74.1%)	144(91.7%)	91(88.3%)	47(94.0%)
	有	40(12.6%)	15(25.9%)	13(8.3%)	12(11.7%)	3(6.0%)
活性型ビタミン D 製剤の変更状況の有無	無	164(51.6%)	25(43.1%)	45(28.7%)	94(91.3%)	41(82.0%)
	有	154(48.4%)	33(56.9%)	112(71.3%)	9(8.7%)	9(18.0%)
前治療薬の有無	無	97(30.5%)	-	52(33.1%)	45(43.7%)	23(46.0%)
	有	163(51.3%)	-	105(66.9%)	58(56.3%)	27(54.0%)
血清 iPTH 濃度ベースライン値(pg/mL)	n	318	58	157	103	50
	Mean	402.9	407.3	404.1	398.6	412.5
	SD	180.7	233.7	186.7	133.0	191.1
	Min	117	117	154	192	194
	Median	353.0	322.0	350.0	364.0	369.5
	Max	1370	1370	1040	847	1210
血清 iPTH 濃度ベースライン値　カテゴリ	≤240 pg/mL	35(11.0%)	11(19.0%)	19(12.1%)	5(4.9%)	4(8.0%)
	>240 pg/mL - <500 pg/mL	212(66.7%)	32(55.2%)	101(64.3%)	79(76.7%)	38(76.0%)
	≥500 pg/mL	71(22.3%)	15(25.9%)	37(23.6%)	19(18.4%)	8(16.0%)
血清補正 Ca 濃度ベースライン値(mg/dL)	n	318	58	157	103	50
	Mean	9.50	9.56	9.57	9.34	9.40
	SD	0.65	0.68	0.60	0.68	0.74
	Min	8.3	8.4	8.5	8.3	8.3
	Median	9.50	9.50	9.50	9.30	9.30
	Max	11.6	10.9	11.6	11.0	11.2

項目		SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
血清補正 Ca 濃度ベースライン値　カテゴリ	<8.4 mg/dL	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	2(4.0%)
	≥8.4 mg/dL - <9.0 mg/dL	75(23.6%)	14(24.1%)	24(15.3%)	37(35.9%)	15(30.0%)
	≥9.0 mg/dL - ≤10.0 mg/dL	180(56.6%)	30(51.7%)	101(64.3%)	49(47.6%)	23(46.0%)
	>10.0 mg/dL	61(19.2%)	14(24.1%)	32(20.4%)	15(14.6%)	10(20.0%)
血清 P 濃度ベースライン値(mg/dL)	n	318	58	157	103	50
	Mean	5.77	5.33	5.81	5.95	6.15
	SD	1.28	1.13	1.26	1.36	1.55
	Min	2.5	3.3	2.5	2.7	2.9
	Median	5.70	5.25	5.80	6.00	5.85
	Max	11.3	9.3	11.3	10.4	10.9
血清 P 濃度ベースライン値　カテゴリ	<3.5 mg/dL	4(1.3%)	1(1.7%)	2(1.3%)	1(1.0%)	1(2.0%)
	≥3.5 mg/dL - ≤6.0 mg/dL	193(60.7%)	43(74.1%)	94(59.9%)	56(54.4%)	26(52.0%)
	>6.0 mg/dL	121(38.1%)	14(24.1%)	61(38.9%)	46(44.7%)	23(46.0%)
血清補正 Ca×P 積ベースライン値	n	318	58	157	103	50
	Mean	54.811	51.095	55.634	55.648	57.851
	SD	12.883	12.274	12.707	13.230	15.400
	Min	22.68	30.03	23.25	22.68	26.68
	Median	53.495	48.435	55.800	54.290	57.495
	Max	115.26	90.21	115.26	94.64	95.92
血清 whole-PTH 濃度ベースライン値(pg/mL)	n	318	58	157	103	50
	Mean	238.75	222.99	251.90	227.59	241.28
	SD	106.23	110.58	117.20	81.82	113.41
	Min	70.5	70.5	99.5	89.4	118.0
	Median	210.50	197.00	222.00	211.00	225.00
	Max	729.0	729.0	643.0	491.0	765.0

項目		SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
iFGF23 ベースライン値(pg/mL)	n	318	58	157	103	50
	Mean	15648.04	13509.67	17054.83	14707.85	17795.25
	SD	26406.75	18201.65	31866.97	20551.14	21255.92
	Min	53.5	125.0	106.0	53.5	60.3
	Median	7535.00	6300.00	7450.00	8670.00	8485.00
	Max	298000.0	97500.0	298000.0	119000.0	95000.0
BAP ベースライン値(µg/L)	n	318	58	157	103	50
	Mean	17.15	18.23	16.08	18.18	18.58
	SD	9.31	13.22	7.29	9.33	11.98
	Min	5.9	6.2	5.9	7.8	7.0
	Median	14.90	14.10	14.50	15.70	15.50
	Max	82.5	82.5	49.3	57.3	80.9
total P1NP ベースライン値(ng/mL)	n	318	58	157	103	50
	Mean	366.48	402.32	337.58	390.34	390.12
	SD	245.85	288.35	241.16	223.27	276.13
	Min	41.2	53.4	41.2	68.7	51.2
	Median	308.50	322.00	276.00	356.00	330.50
	Max	1200.0	1200.0	1200.0	1200.0	1200.0
TRACP-5b ベースライン値(mU/dL)	n	318	58	157	103	50
	Mean	722.9	755.9	699.3	740.3	747.2
	SD	353.0	413.3	337.5	340.4	380.6
	Min	139	236	139	160	172
	Median	673.5	682.0	630.0	723.0	717.0
	Max	2260	2260	1500	1500	1500
開始時投与量	25 µg	50(15.7%)	0(0.0%)	23(14.6%)	27(26.2%)	13(26.0%)
	50 µg	268(84.3%)	58(100.0%)	134(85.4%)	76(73.8%)	37(74.0%)

カテゴリの項目は例数(割合(%))

表 2.7.4.7－8　有害事象の発現状況

SOC/PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
全体	284(89.3%)	55(94.8%)	141(89.8%)	88(85.4%)	36(72.0%)	34(10.7%)	12(20.7%)	10(6.4%)	12(11.7%)	4(8.0%)
血液およびリンパ系障害	10(3.1%)	1(1.7%)	6(3.8%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
貧血	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
播種性血管内凝固	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
鉄欠乏性貧血	5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
汎血球減少症	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腎性貧血	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
失血性貧血	1(0.3%)	0(0.0%)	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	17(5.3%)	3(5.2%)	12(7.6%)	2(1.9%)	2(4.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)
急性心筋梗塞	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
狭心症	5(1.6%)	1(1.7%)	3(1.9%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心房細動	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
徐脈	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
慢性心不全	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
うっ血性心不全	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心筋虚血	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
動悸	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
洞性頻脈	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上室性頻脈	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頻脈	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心室性期外収縮	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心室性頻脈	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
僧帽弁石灰化	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
先天性、家族性および遺伝性障害	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
包茎	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
耳および迷路障害	13(4.1%)	2(3.4%)	9(5.7%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
難聴	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
耳出血	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
耳鳴	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
回転性めまい	6(1.9%)	1(1.7%)	5(3.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
迷路性回転性めまい	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
頭位性回転性めまい	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
耳不快感	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
内分泌障害	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
甲状腺機能低下症	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
眼障害	30(9.4%)	5(8.6%)	16(10.2%)	9(8.7%)	2(4.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
白内障	3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
霰粒腫	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
結膜出血	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
アレルギー性結膜炎	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
糖尿病網膜症	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ドライアイ	5(1.6%)	2(3.4%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
角膜炎	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
水晶体混濁	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
網膜動脈閉塞	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
網膜出血	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
網膜裂孔	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
強膜炎	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
視力障害	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
硝子体浮遊物	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
硝子体出血	3(0.9%)	0(0.0%)	1(0.6%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
結膜充血	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
黄斑線維症	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腸障害	116(36.5%)	26(44.8%)	58(36.9%)	32(31.1%)	13(26.0%)	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	3(6.0%)
腹部不快感	6(1.9%)	3(5.2%)	1(0.6%)	2(1.9%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
腹部膨満	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹痛	6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
下腹部痛	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上腹部痛	9(2.8%)	5(8.6%)	2(1.3%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口角口唇炎	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
アフタ性潰瘍	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
慢性胃炎	3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腸炎	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
便秘	6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
齲歯	10(3.1%)	1(1.7%)	7(4.5%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
下痢	40(12.6%)	7(12.1%)	22(14.0%)	11(10.7%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
出血性腸憩室	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
出血性十二指腸潰瘍	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
十二指腸炎	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
嚥下障害	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腸炎	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃ポリープ	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃炎	4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
びらん性胃炎	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃食道逆流性疾患	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯肉痛	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	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%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
痔核	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
マロリー・ワイス症候群	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
悪心	13(4.1%)	1(1.7%)	9(5.7%)	3(2.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
耳下腺腫大	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯周病	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
直腸出血	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口内炎	6(1.9%)	1(1.7%)	5(3.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯痛	6(1.9%)	2(3.4%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
嘔吐	21(6.6%)	4(6.9%)	12(7.6%)	5(4.9%)	4(8.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)
大腸ポリープ	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心窩部不快感	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
ブルンネル腺過形成	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口の錯感覚	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
びらん性十二指腸炎	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
軟便	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	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	27(8.5%)	6(10.3%)	13(8.3%)	8(7.8%)	1(2.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
無力症	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胸部不快感	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胸痛	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
顔面浮腫	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
異常感	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
倦怠感	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
末梢性浮腫	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
疼痛	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
発熱	6(1.9%)	2(3.4%)	4(2.5%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腫脹	1(0.3%)	0(0.0%)	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(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
末梢腫脹	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ポリープ	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血管穿刺部位発疹	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝胆道系障害	7(2.2%)	1(1.7%)	4(2.5%)	2(1.9%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
胆管炎	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
急性胆嚢炎	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝機能異常	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
過形成性胆嚢症	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
免疫系障害	11(3.5%)	8(13.8%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
季節性アレルギー	10(3.1%)	7(12.1%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ヨウ素アレルギー	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
感染症および寄生虫症	184(57.9%)	42(72.4%)	92(58.6%)	50(48.5%)	16(32.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
虫垂炎	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
菌血症	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
気管支炎	8(2.5%)	1(1.7%)	7(4.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
蜂巣炎	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
結膜炎	4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
膀胱炎	4(1.3%)	0(0.0%)	1(0.6%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
感染性皮膚炎	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
爪の皮膚糸状菌症	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
憩室炎	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
精巣上体炎	1(0.3%)	1(1.7%)	0(0.0%)	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(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚真菌感染	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腸炎	12(3.8%)	4(6.9%)	6(3.8%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯肉炎	5(1.6%)	0(0.0%)	0(0.0%)	5(4.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
帯状疱疹	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
麦粒腫	4(1.3%)	0(0.0%)	2(1.3%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
膿痂疹	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
感染性皮膚潰瘍	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
インフルエンザ	17(5.3%)	4(6.9%)	11(7.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝膿瘍	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
リンパ節結核	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
細菌性髄膜炎	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上咽頭炎	119(37.4%)	29(50.0%)	65(41.4%)	25(24.3%)	12(24.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
外耳炎	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
中耳炎	5(1.6%)	2(3.4%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
急性中耳炎	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
慢性中耳炎	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯周炎	7(2.2%)	1(1.7%)	5(3.2%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹膜炎	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
咽頭炎	16(5.0%)	2(3.4%)	5(3.2%)	9(8.7%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肺炎	4(1.3%)	2(3.4%)	1(0.6%)	1(1.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
鼻炎	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
敗血症	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
副鼻腔炎	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚感染	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	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(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
足部白癬	4(1.3%)	1(1.7%)	1(0.6%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上気道感染	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ウイルス感染	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肛門膿瘍	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝嚢胞感染	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯肉膿瘍	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ヘリコバクター感染	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
シャント感染	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腎嚢胞感染	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
感染性腸炎	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
細菌性結膜炎	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
軟骨膜炎	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
気道感染	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
細菌性扁桃炎	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口腔ヘルペス	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
感染性皮膚嚢腫	4(1.3%)	1(1.7%)	3(1.9%)	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	84(26.4%)	15(25.9%)	44(28.0%)	25(24.3%)	9(18.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
動物咬傷	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
節足動物刺傷	4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上顆炎	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
顔面骨骨折	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腿骨頚部骨折	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腿骨骨折	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
足骨折	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
眼内異物	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
熱疲労	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
損傷	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節脱臼	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
靭帯捻挫	7(2.2%)	0(0.0%)	5(3.2%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
爪裂離	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
橈骨骨折	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
引っかき傷	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ストレス骨折	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮下血腫	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腱損傷	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腱断裂	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
手首関節骨折	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
挫傷	23(7.2%)	4(6.9%)	11(7.0%)	8(7.8%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
創傷	10(3.1%)	2(3.4%)	8(5.1%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
熱傷	4(1.3%)	2(3.4%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚裂傷	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
シャント血栓症	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
縫合関連合併症	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節損傷	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
靭帯損傷	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
四肢損傷	5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
処置による低血圧	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯牙破折	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
処置による疼痛	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
皮膚擦過傷	19(6.0%)	7(12.1%)	7(4.5%)	5(4.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
骨挫傷	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
熱中症	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
爪損傷	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋挫傷	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
外傷後頚部症候群	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚創傷	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
鼻部損傷	1(0.3%)	0(0.0%)	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	38(11.9%)	14(24.1%)	13(8.3%)	11(10.7%)	4(8.0%)	21(6.6%)	9(15.5%)	3(1.9%)	9(8.7%)	0(0.0%)
血中ビリルビン増加	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中クレアチンホスホキナーゼ増加	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中副甲状腺ホルモン増加	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中カリウム増加	3(0.9%)	2(3.4%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血圧上昇	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中尿酸増加	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心電図 QT 延長	5(1.6%)	3(5.2%)	2(1.3%)	0(0.0%)	0(0.0%)	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)
γ－グルタミルトランスフェラーゼ増加	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ヘモグロビン減少	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
プロトロンビン時間延長	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
白血球数減少	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳性ナトリウム利尿ペプチド増加	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	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%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
便潜血陽性	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
補正カルシウム減少	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)
肝機能検査値上昇	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
補正カルシウム増加	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
代謝および栄養障害	19(6.0%)	3(5.2%)	11(7.0%)	5(4.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
転移性石灰化	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
葉酸欠乏	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
痛風	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
高カルシウム血症	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
高血糖	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
高カリウム血症	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
高リン酸塩血症	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
高尿酸血症	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
低血糖	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
亜鉛欠乏	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脂質異常症	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
食欲減退	5(1.6%)	0(0.0%)	2(1.3%)	3(2.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
筋骨格系および結合組織障害	99(31.1%)	23(39.7%)	52(33.1%)	24(23.3%)	2(4.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
関節痛	24(7.5%)	5(8.6%)	16(10.2%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節炎	7(2.2%)	3(5.2%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
反応性関節炎	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
背部痛	18(5.7%)	1(1.7%)	12(7.6%)	5(4.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
滑液包炎	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
デュプイトラン拘縮	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
側腹部痛	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節滲出液	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節腫脹	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腰部脊柱管狭窄症	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋痙縮	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
筋骨格痛	7(2.2%)	5(8.6%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋肉痛	9(2.8%)	1(1.7%)	4(2.5%)	4(3.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頚部痛	5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
変形性関節症	5(1.6%)	2(3.4%)	3(1.9%)	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	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
四肢痛	13(4.1%)	6(10.3%)	6(3.8%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節周囲炎	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
多発性関節炎	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肩回旋筋腱板症候群	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
変形性脊椎症	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
滑液嚢腫	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
顎関節症候群	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腱鞘炎	9(2.8%)	1(1.7%)	3(1.9%)	5(4.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
弾発指	4(1.3%)	0(0.0%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
椎間板突出	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋骨格系胸痛	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
筋骨格硬直	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
結晶性関節障害	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腱痛	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脊柱管狭窄症	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	8(2.5%)	4(6.9%)	4(2.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腺癌	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腺癌	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
食道の良性新生物	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
結腸癌	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脂肪腫	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腸腺腫	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
前立腺癌	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
唾液腺新生物	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
神経系障害	41(12.9%)	11(19.0%)	22(14.0%)	8(7.8%)	2(4.0%)	2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)
脳幹出血	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
手根管症候群	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
小脳出血	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳梗塞	4(1.3%)	1(1.7%)	1(0.6%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳血管障害	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頚腕症候群	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
浮動性めまい	8(2.5%)	2(3.4%)	4(2.5%)	2(1.9%)	1(2.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
体位性めまい	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
顔面麻痺	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頭部不快感	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頭痛	12(3.8%)	2(3.4%)	9(5.7%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
意識消失	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
坐骨神経痛	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
傾眠	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頚髄神経根障害	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ラクナ梗塞	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
下肢静止不能症候群	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
視床出血	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
パーキンソン病	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
血栓性脳梗塞	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
椎骨動脈解離	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
味覚障害	2(0.6%)	2(3.4%)	0(0.0%)	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	10(3.1%)	2(3.4%)	6(3.8%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
不眠症	8(2.5%)	2(3.4%)	5(3.2%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
統合失調症様障害	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
夢遊症	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	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	4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血尿	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腎嚢胞出血	1(0.3%)	0(0.0%)	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(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
閉経期症状	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
不正子宮出血	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	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	56(17.6%)	12(20.7%)	33(21.0%)	11(10.7%)	5(10.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
喘息	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
咳嗽	5(1.6%)	2(3.4%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
呼吸困難	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
鼻出血	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
過換気	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
間質性肺疾患	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胸水	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肺うっ血	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肺水腫	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
アレルギー性鼻炎	6(1.9%)	1(1.7%)	3(1.9%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
鼻漏	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
睡眠時無呼吸症候群	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
喀痰増加	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上気道の炎症	25(7.9%)	4(6.9%)	18(11.5%)	3(2.9%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
アレルギー性気管支炎	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口腔咽頭不快感	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口腔咽頭痛	7(2.2%)	0(0.0%)	5(3.2%)	2(1.9%)	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	73(23.0%)	18(31.0%)	34(21.7%)	21(20.4%)	5(10.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
水疱	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚嚢腫	6(1.9%)	0(0.0%)	5(3.2%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
皮膚炎	4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
接触皮膚炎	9(2.8%)	2(3.4%)	5(3.2%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
薬疹	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
湿疹	16(5.0%)	2(3.4%)	7(4.5%)	7(6.8%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮脂欠乏性湿疹	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
紅斑	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
多形紅斑	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮下出血	12(3.8%)	2(3.4%)	8(5.1%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
多汗症	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
爪甲剥離症	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
点状出血	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
そう痒症	8(2.5%)	5(8.6%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
発疹	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
紅斑性皮疹	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脂漏性皮膚炎	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚びらん	4(1.3%)	1(1.7%)	0(0.0%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚剥脱	6(1.9%)	1(1.7%)	2(1.3%)	3(2.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚刺激	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚潰瘍	5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
蕁麻疹	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮脂欠乏症	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
水疱破裂	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
偽毛包炎	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
外科および内科処置	5(1.6%)	0(0.0%)	3(1.9%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
硝子体切除	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
抜歯	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
白内障手術	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯科インプラント埋込み	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血管障害	23(7.2%)	5(8.6%)	13(8.3%)	5(4.9%)	2(4.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
高血圧	8(2.5%)	0(0.0%)	6(3.8%)	2(1.9%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
起立性低血圧	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
末梢性虚血	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血栓性静脈炎	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
末梢動脈閉塞性疾患	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
大動脈硬化症	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
内出血	7(2.2%)	3(5.2%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7−9　有害事象の重症度別発現状況

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
全体		284(89.3%)	55(94.8%)	141(89.8%)	88(85.4%)	36(72.0%)	34(10.7%)	12(20.7%)	10(6.4%)	12(11.7%)	4(8.0%)
	軽度	280(88.1%)	55(94.8%)	139(88.5%)	86(83.5%)	36(72.0%)	32(10.1%)	11(19.0%)	9(5.7%)	12(11.7%)	4(8.0%)
	中等度	56(17.6%)	12(20.7%)	28(17.8%)	16(15.5%)	7(14.0%)	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)
	高度	6(1.9%)	0(0.0%)	4(2.5%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
血液およびリンパ系障害		10(3.1%)	1(1.7%)	6(3.8%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	10(3.1%)	1(1.7%)	6(3.8%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
貧血		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
播種性血管内凝固		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
鉄欠乏性貧血		5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
汎血球減少症		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腎性貧血		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
失血性貧血		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心臓障害		17(5.3%)	3(5.2%)	12(7.6%)	2(1.9%)	2(4.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)
	軽度	11(3.5%)	3(5.2%)	7(4.5%)	1(1.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	中等度	8(2.5%)	1(1.7%)	6(3.8%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
急性心筋梗塞		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
狭心症		5(1.6%)	1(1.7%)	3(1.9%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	5(1.6%)	1(1.7%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心房細動		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	軽度	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
徐脈		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
慢性心不全		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
うっ血性心不全		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
心筋虚血		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
動悸		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
洞性頻脈		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上室性頻脈		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頻脈		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心室性期外収縮		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心室性頻脈		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
僧帽弁石灰化		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
先天性、家族性および遺伝性障害		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
包茎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
耳および迷路障害		13(4.1%)	2(3.4%)	9(5.7%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	12(3.8%)	2(3.4%)	8(5.1%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
難聴		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
耳出血		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
耳鳴		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
回転性めまい		6(1.9%)	1(1.7%)	5(3.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	6(1.9%)	1(1.7%)	5(3.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
迷路性回転性めまい		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象 SK-1403 群 併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	プラセボ群 AJ1004 (N=50)	副作用 SK-1403 群 併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	プラセボ群 AJ1004 (N=50)
頭位性回転性めまい		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
耳不快感		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
内分泌障害		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
甲状腺機能低下症		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
眼障害		30(9.4%)	5(8.6%)	16(10.2%)	9(8.7%)	2(4.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	軽度	28(8.8%)	5(8.6%)	16(10.2%)	7(6.8%)	2(4.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	中等度	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
白内障		3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
霰粒腫		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
結膜出血		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
アレルギー性結膜炎		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
糖尿病網膜症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ドライアイ		5(1.6%)	2(3.4%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	5(1.6%)	2(3.4%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
角膜炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
水晶体混濁		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
網膜動脈閉塞		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
網膜出血		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
網膜裂孔		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
強膜炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
視力障害		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
硝子体浮遊物		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
硝子体出血		3(0.9%)	0(0.0%)	1(0.6%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
結膜充血		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
黄斑線維症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腸障害		116(36.5%)	26(44.8%)	58(36.9%)	32(31.1%)	13(26.0%)	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	3(6.0%)
	軽度	112(35.2%)	25(43.1%)	56(35.7%)	31(30.1%)	11(22.0%)	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	3(6.0%)
	中等度	8(2.5%)	2(3.4%)	4(2.5%)	2(1.9%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹部不快感		6(1.9%)	3(5.2%)	1(0.6%)	2(1.9%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	軽度	6(1.9%)	3(5.2%)	1(0.6%)	2(1.9%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
腹部膨満		2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹痛		6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
下腹部痛		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上腹部痛		9(2.8%)	5(8.6%)	2(1.3%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	9(2.8%)	5(8.6%)	2(1.3%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口角口唇炎		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
アフタ性潰瘍		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
慢性胃炎		3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腸炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
便秘		6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
齲歯		10(3.1%)	1(1.7%)	7(4.5%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	9(2.8%)	1(1.7%)	6(3.8%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
下痢		40(12.6%)	7(12.1%)	22(14.0%)	11(10.7%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	39(12.3%)	6(10.3%)	22(14.0%)	11(10.7%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
出血性腸憩室		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
出血性十二指腸潰瘍		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
十二指腸炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
嚥下障害		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腸炎		3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
胃ポリープ		4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃炎		4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
びらん性胃炎		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃食道逆流性疾患		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯肉痛		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血便排泄		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
痔核		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
マロリー・ワイス症候群		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
悪心		13(4.1%)	1(1.7%)	9(5.7%)	3(2.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	軽度	12(3.8%)	1(1.7%)	8(5.1%)	3(2.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
耳下腺腫大		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯周病		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
直腸出血		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口内炎		6(1.9%)	1(1.7%)	5(3.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	6(1.9%)	1(1.7%)	5(3.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯痛		6(1.9%)	2(3.4%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	5(1.6%)	2(3.4%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
嘔吐		21(6.6%)	4(6.9%)	12(7.6%)	5(4.9%)	4(8.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)
	軽度	20(6.3%)	3(5.2%)	12(7.6%)	5(4.9%)	4(8.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)
	中等度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腸ポリープ		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
心窩部不快感		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ブルンネル腺過形成		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口の錯感覚		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
びらん性十二指腸炎		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
軟便		3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
一般・全身障害および投与部位の状態		27(8.5%)	6(10.3%)	13(8.3%)	8(7.8%)	1(2.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	27(8.5%)	6(10.3%)	13(8.3%)	8(7.8%)	1(2.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
無力症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胸部不快感		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
胸痛		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
顔面浮腫		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
異常感		2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
倦怠感		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
末梢性浮腫		2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
疼痛		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
発熱		6(1.9%)	2(3.4%)	4(2.5%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	6(1.9%)	2(3.4%)	4(2.5%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腫脹		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
口渇		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
末梢腫脹		2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ポリープ		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血管穿刺部位発疹		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝胆道系障害		7(2.2%)	1(1.7%)	4(2.5%)	2(1.9%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	中等度	3(0.9%)	0(0.0%)	1(0.6%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胆管炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
急性胆嚢炎		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝機能異常		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
過形成性胆嚢症		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
免疫系障害		11(3.5%)	8(13.8%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	11(3.5%)	8(13.8%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
季節性アレルギー		10(3.1%)	7(12.1%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	10(3.1%)	7(12.1%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ヨウ素アレルギー		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
感染症および寄生虫症		184(57.9%)	42(72.4%)	92(58.6%)	50(48.5%)	16(32.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	178(56.0%)	41(70.7%)	89(56.7%)	48(46.6%)	16(32.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	13(4.1%)	2(3.4%)	8(5.1%)	3(2.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
虫垂炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
菌血症		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
気管支炎		8(2.5%)	1(1.7%)	7(4.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	8(2.5%)	1(1.7%)	7(4.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
蜂巣炎		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
結膜炎		4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
膀胱炎		4(1.3%)	0(0.0%)	1(0.6%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	0(0.0%)	1(0.6%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
感染性皮膚炎		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
爪の皮膚糸状菌症		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
憩室炎		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
精巣上体炎		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
毛包炎		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
皮膚真菌感染		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腸炎		12(3.8%)	4(6.9%)	6(3.8%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	11(3.5%)	3(5.2%)	6(3.8%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯肉炎		5(1.6%)	0(0.0%)	0(0.0%)	5(4.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	5(1.6%)	0(0.0%)	0(0.0%)	5(4.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
帯状疱疹		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
麦粒腫		4(1.3%)	0(0.0%)	2(1.3%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	0(0.0%)	2(1.3%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
膿痂疹		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
感染性皮膚潰瘍		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
インフルエンザ		17(5.3%)	4(6.9%)	11(7.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	13(4.1%)	4(6.9%)	8(5.1%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
肝膿瘍		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
リンパ節結核		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
細菌性髄膜炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上咽頭炎		119(37.4%)	29(50.0%)	65(41.4%)	25(24.3%)	12(24.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	118(37.1%)	29(50.0%)	64(40.8%)	25(24.3%)	12(24.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
外耳炎		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
中耳炎		5(1.6%)	2(3.4%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
急性中耳炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
慢性中耳炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
歯周炎		7(2.2%)	1(1.7%)	5(3.2%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	7(2.2%)	1(1.7%)	5(3.2%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹膜炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
咽頭炎		16(5.0%)	2(3.4%)	5(3.2%)	9(8.7%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	15(4.7%)	2(3.4%)	4(2.5%)	9(8.7%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肺炎		4(1.3%)	2(3.4%)	1(0.6%)	1(1.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	2(3.4%)	0(0.0%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
鼻炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
敗血症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
副鼻腔炎		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚感染		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
皮下組織膿瘍		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
足部白癬		4(1.3%)	1(1.7%)	1(0.6%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	1(1.7%)	1(0.6%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上気道感染		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ウイルス感染		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肛門膿瘍		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝嚢胞感染		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯肉膿瘍		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ヘリコバクター感染		3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
シャント感染		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腎嚢胞感染		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
感染性腸炎		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
細菌性結膜炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
軟骨膜炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
気道感染		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
細菌性扁桃炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口腔ヘルペス		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
感染性皮膚嚢腫		4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
傷害、中毒および処置合併症		84(26.4%)	15(25.9%)	44(28.0%)	25(24.3%)	9(18.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	軽度	77(24.2%)	14(24.1%)	39(24.8%)	24(23.3%)	8(16.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	中等度	10(3.1%)	2(3.4%)	7(4.5%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
動物咬傷		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
節足動物刺傷		4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上顎炎		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
顔面骨骨折		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腿骨頚部骨折		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腿骨骨折		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
足骨折		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
眼内異物		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
熱疲労		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
損傷		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節脱臼		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
靭帯捻挫		7(2.2%)	0(0.0%)	5(3.2%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	7(2.2%)	0(0.0%)	5(3.2%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
爪裂離		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
橈骨骨折		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
引っかき傷		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ストレス骨折		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮下血腫		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腱損傷		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腱断裂		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
手首関節骨折		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
挫傷		23(7.2%)	4(6.9%)	11(7.0%)	8(7.8%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	22(6.9%)	4(6.9%)	10(6.4%)	8(7.8%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
創傷		10(3.1%)	2(3.4%)	8(5.1%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	10(3.1%)	2(3.4%)	8(5.1%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
熱傷		4(1.3%)	2(3.4%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	2(3.4%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚裂傷		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
シャント血栓症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
縫合関連合併症		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節損傷		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
靭帯損傷		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
四肢損傷		5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
処置による低血圧		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
歯牙破折		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
処置による疼痛		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚擦過傷		19(6.0%)	7(12.1%)	7(4.5%)	5(4.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	19(6.0%)	7(12.1%)	7(4.5%)	5(4.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
骨挫傷		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
熱中症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
爪損傷		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋挫傷		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
外傷後頚部症候群		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
皮膚創傷		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
鼻部損傷		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
臨床検査		38(11.9%)	14(24.1%)	13(8.3%)	11(10.7%)	4(8.0%)	21(6.6%)	9(15.5%)	3(1.9%)	9(8.7%)	0(0.0%)
	軽度	38(11.9%)	14(24.1%)	13(8.3%)	11(10.7%)	4(8.0%)	21(6.6%)	9(15.5%)	3(1.9%)	9(8.7%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中ビリルビン増加		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中クレアチンホスホキナーゼ増加		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中副甲状腺ホルモン増加		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中カリウム増加		3(0.9%)	2(3.4%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	2(3.4%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血圧上昇		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
血中尿酸増加		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心電図 QT 延長		5(1.6%)	3(5.2%)	2(1.3%)	0(0.0%)	0(0.0%)	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)
	軽度	5(1.6%)	3(5.2%)	2(1.3%)	0(0.0%)	0(0.0%)	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
γ−グルタミルトランスフェラーゼ増加		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ヘモグロビン減少		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
プロトロンビン時間延長		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
白血球数減少		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳性ナトリウム利尿ペプチド増加		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(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%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
便潜血陽性		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
補正カルシウム減少		18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)
	軽度	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝機能検査値上昇		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
補正カルシウム増加		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
代謝および栄養障害		19(6.0%)	3(5.2%)	11(7.0%)	5(4.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	軽度	19(6.0%)	3(5.2%)	11(7.0%)	5(4.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
転移性石灰化		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
葉酸欠乏		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
痛風		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
高カルシウム血症		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
高血糖		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
高カリウム血症		2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
高リン酸塩血症		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
高尿酸血症		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
低血糖		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
亜鉛欠乏		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脂質異常症		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
食欲減退		5(1.6%)	0(0.0%)	2(1.3%)	3(2.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	軽度	5(1.6%)	0(0.0%)	2(1.3%)	3(2.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋骨格系および結合組織障害		99(31.1%)	23(39.7%)	52(33.1%)	24(23.3%)	2(4.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	軽度	94(29.6%)	23(39.7%)	50(31.8%)	21(20.4%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	中等度	6(1.9%)	0(0.0%)	3(1.9%)	3(2.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節痛		24(7.5%)	5(8.6%)	16(10.2%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	23(7.2%)	5(8.6%)	15(9.6%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節炎		7(2.2%)	3(5.2%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	7(2.2%)	3(5.2%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
反応性関節炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
背部痛		18(5.7%)	1(1.7%)	12(7.6%)	5(4.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	17(5.3%)	1(1.7%)	11(7.0%)	5(4.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
滑液包炎		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
デュプイトラン拘縮		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
側腹部痛		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節滲出液		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節腫脹		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腰部脊柱管狭窄症		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋痙縮		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋骨格痛		7(2.2%)	5(8.6%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	7(2.2%)	5(8.6%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋肉痛		9(2.8%)	1(1.7%)	4(2.5%)	4(3.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	9(2.8%)	1(1.7%)	4(2.5%)	4(3.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頚部痛		5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
変形性関節症		5(1.6%)	2(3.4%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	5(1.6%)	2(3.4%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
骨粗鬆症		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
四肢痛		13(4.1%)	6(10.3%)	6(3.8%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	13(4.1%)	6(10.3%)	6(3.8%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節周囲炎		2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
多発性関節炎		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肩回旋筋腱板症候群		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
変形性脊椎症		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
滑液嚢腫		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
顎関節症候群		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腱鞘炎		9(2.8%)	1(1.7%)	3(1.9%)	5(4.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	8(2.5%)	1(1.7%)	3(1.9%)	4(3.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
弾発指		4(1.3%)	0(0.0%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
椎間板突出		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋骨格系胸痛		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋骨格硬直		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
結晶性関節障害		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腱痛		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
脊柱管狭窄症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(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）		8(2.5%)	4(6.9%)	4(2.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腺癌		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腺癌		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
食道の良性新生物		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
結腸癌		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脂肪腫		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腸腺腫		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
前立腺癌		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
唾液腺新生物		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
神経系障害		41(12.9%)	11(19.0%)	22(14.0%)	8(7.8%)	2(4.0%)	2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	34(10.7%)	8(13.8%)	20(12.7%)	6(5.8%)	1(2.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	6(1.9%)	3(5.2%)	2(1.3%)	1(1.0%)	1(2.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳幹出血		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
手根管症候群		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
小脳出血		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳梗塞		4(1.3%)	1(1.7%)	1(0.6%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳血管障害		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象 SK-1403 群 併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	プラセボ群 AJ1004 (N=50)	副作用 SK-1403 群 併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	プラセボ群 AJ1004 (N=50)
頚腕症候群		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
浮動性めまい		8(2.5%)	2(3.4%)	4(2.5%)	2(1.9%)	1(2.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	6(1.9%)	0(0.0%)	4(2.5%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
体位性めまい		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
顔面麻痺		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頭部不快感		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頭痛		12(3.8%)	2(3.4%)	9(5.7%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	12(3.8%)	2(3.4%)	9(5.7%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
意識消失		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
坐骨神経痛		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
傾眠		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頚髄神経根障害		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ラクナ梗塞		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
下肢静止不能症候群		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
視床出血		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
パーキンソン病		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血栓性脳梗塞		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
椎骨動脈解離		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
味覚障害		2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
精神障害		10(3.1%)	2(3.4%)	6(3.8%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	10(3.1%)	2(3.4%)	6(3.8%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
不眠症		8(2.5%)	2(3.4%)	5(3.2%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	8(2.5%)	2(3.4%)	5(3.2%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
統合失調症様障害		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
夢遊症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腎および尿路障害		4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血尿		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腎嚢胞出血		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
生殖系および乳房障害		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
閉経期症状		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
不正子宮出血		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
呼吸器、胸郭および縦隔障害		56(17.6%)	12(20.7%)	33(21.0%)	11(10.7%)	5(10.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	56(17.6%)	12(20.7%)	33(21.0%)	11(10.7%)	5(10.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
喘息		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
咳嗽		5(1.6%)	2(3.4%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	5(1.6%)	2(3.4%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
呼吸困難		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
鼻出血		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
過換気		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
間質性肺疾患		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胸水		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肺うっ血		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肺水腫		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
アレルギー性鼻炎		6(1.9%)	1(1.7%)	3(1.9%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	6(1.9%)	1(1.7%)	3(1.9%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
鼻漏		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
睡眠時無呼吸症候群		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	重症度	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
喀痰増加		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上気道の炎症		25(7.9%)	4(6.9%)	18(11.5%)	3(2.9%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	25(7.9%)	4(6.9%)	18(11.5%)	3(2.9%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
アレルギー性気管支炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口腔咽頭不快感		3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口腔咽頭痛		7(2.2%)	0(0.0%)	5(3.2%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	7(2.2%)	0(0.0%)	5(3.2%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚および皮下組織障害		73(23.0%)	18(31.0%)	34(21.7%)	21(20.4%)	5(10.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	71(22.3%)	18(31.0%)	32(20.4%)	21(20.4%)	5(10.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	中等度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
水疱		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚嚢腫		6(1.9%)	0(0.0%)	5(3.2%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	5(1.6%)	0(0.0%)	4(2.5%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
皮膚炎		4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
接触皮膚炎		9(2.8%)	2(3.4%)	5(3.2%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	9(2.8%)	2(3.4%)	5(3.2%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
薬疹		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
湿疹		16(5.0%)	2(3.4%)	7(4.5%)	7(6.8%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	16(5.0%)	2(3.4%)	7(4.5%)	7(6.8%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮脂欠乏性湿疹		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
紅斑		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
多形紅斑		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮下出血		12(3.8%)	2(3.4%)	8(5.1%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	12(3.8%)	2(3.4%)	8(5.1%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
多汗症		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
爪甲剥離症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
点状出血		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
そう痒症		8(2.5%)	5(8.6%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	8(2.5%)	5(8.6%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
発疹		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
紅斑性皮疹		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脂漏性皮膚炎		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚びらん		4(1.3%)	1(1.7%)	0(0.0%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	1(1.7%)	0(0.0%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
皮膚剥脱		6(1.9%)	1(1.7%)	2(1.3%)	3(2.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	6(1.9%)	1(1.7%)	2(1.3%)	3(2.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚刺激		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚潰瘍		5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	1(1.7%)	1(0.6%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
蕁麻疹		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮脂欠乏症		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
水疱破裂		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
偽毛包炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
外科および内科処置		5(1.6%)	0(0.0%)	3(1.9%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象 SK-1403 群 併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	プラセボ群 AJ1004 (N=50)	副作用 SK-1403 群 併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	プラセボ群 AJ1004 (N=50)
硝子体切除		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
抜歯		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
白内障手術		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯科インプラント埋込み		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血管障害		23(7.2%)	5(8.6%)	13(8.3%)	5(4.9%)	2(4.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	19(6.0%)	5(8.6%)	11(7.0%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	4(1.3%)	0(0.0%)	2(1.3%)	2(1.9%)	2(4.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
高血圧		8(2.5%)	0(0.0%)	6(3.8%)	2(1.9%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	7(2.2%)	0(0.0%)	5(3.2%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
起立性低血圧		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
末梢性虚血		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
血栓性静脈炎		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
末梢動脈閉塞性疾患		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大動脈硬化症		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
内出血		7(2.2%)	3(5.2%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	7(2.2%)	3(5.2%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7－10　有害事象の時期別発現状況

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
全体		284(89.3%)	55(94.8%)	141(89.8%)	88(85.4%)	36(72.0%)	34(10.7%)	12(20.7%)	10(6.4%)	12(11.7%)	4(8.0%)
	1≤ - <22	71(22.3%)	12(20.7%)	32(20.4%)	27(26.2%)	11(22.0%)	12(3.8%)	7(12.1%)	0(0.0%)	5(4.9%)	2(4.0%)
	22≤ - <43	78(24.5%)	14(24.1%)	34(21.7%)	30(29.1%)	9(18.0%)	5(1.6%)	1(1.7%)	1(0.6%)	3(2.9%)	1(2.0%)
	43≤ - <64	77(24.2%)	18(31.0%)	34(21.7%)	25(24.3%)	5(10.0%)	4(1.3%)	1(1.7%)	1(0.6%)	2(1.9%)	0(0.0%)
	64≤ - <85	91(28.6%)	17(29.3%)	46(29.3%)	28(27.2%)	9(18.0%)	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	1(2.0%)
	85≤ - <106	68(21.4%)	11(19.0%)	29(18.5%)	28(27.2%)	5(10.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	106≤ - <127	64(20.1%)	11(19.0%)	28(17.8%)	25(24.3%)	10(20.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	1(2.0%)
	127≤ - <148	67(21.1%)	12(20.7%)	27(17.2%)	28(27.2%)	8(16.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	148≤ - <169	68(21.4%)	12(20.7%)	32(20.4%)	24(23.3%)	4(8.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	119(37.4%)	36(62.1%)	82(52.2%)	1(1.0%)	3(6.0%)	5(1.6%)	1(1.7%)	4(2.5%)	0(0.0%)	0(0.0%)
	267≤ - <365	108(34.0%)	33(56.9%)	75(47.8%)	0(0.0%)	0(0.0%)	3(0.9%)	2(3.4%)	1(0.6%)	0(0.0%)	0(0.0%)
	365≤	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血液およびリンパ系障害		10(3.1%)	1(1.7%)	6(3.8%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	3(0.9%)	0(0.0%)	1(0.6%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
貧血		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
播種性血管内凝固		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
鉄欠乏性貧血		5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
汎血球減少症		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腎性貧血		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
失血性貧血		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心臓障害		17(5.3%)	3(5.2%)	12(7.6%)	2(1.9%)	2(4.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	5(1.6%)	0(0.0%)	3(1.9%)	2(1.9%)	1(2.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)
	85≤ - <106	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	5(1.6%)	2(3.4%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
急性心筋梗塞		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
狭心症		5(1.6%)	1(1.7%)	3(1.9%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心房細動		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
徐脈		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
慢性心不全		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
うっ血性心不全		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心筋虚血		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
動悸		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
洞性頻脈		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上室性頻脈		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頻脈		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心室性期外収縮		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心室性頻脈		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
僧帽弁石灰化		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
先天性、家族性および遺伝性障害		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
包茎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
耳および迷路障害		13(4.1%)	2(3.4%)	9(5.7%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	3(0.9%)	2(3.4%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
難聴		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
耳出血		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
耳鳴		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
回転性めまい		6(1.9%)	1(1.7%)	5(3.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
迷路性回転性めまい		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頭位性回転性めまい		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
耳不快感		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
内分泌障害		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
甲状腺機能低下症		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
眼障害		30(9.4%)	5(8.6%)	16(10.2%)	9(8.7%)	2(4.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	5(1.6%)	0(0.0%)	3(1.9%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	6(1.9%)	1(1.7%)	2(1.3%)	3(2.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	7(2.2%)	2(3.4%)	5(3.2%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	267≤ - <365	4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
白内障		3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
霰粒腫		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
結膜出血		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
アレルギー性結膜炎		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
糖尿病網膜症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ドライアイ		5(1.6%)	2(3.4%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
角膜炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
水晶体混濁		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
網膜動脈閉塞		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
網膜出血		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
網膜裂孔		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
強膜炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
視力障害		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
硝子体浮遊物		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
硝子体出血		3(0.9%)	0(0.0%)	1(0.6%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
結膜充血		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
黄斑線維症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腸障害		116(36.5%)	26(44.8%)	58(36.9%)	32(31.1%)	13(26.0%)	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	3(6.0%)
	1≤ - <22	16(5.0%)	0(0.0%)	10(6.4%)	6(5.8%)	4(8.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	2(4.0%)
	22≤ - <43	11(3.5%)	1(1.7%)	4(2.5%)	6(5.8%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	43≤ - <64	11(3.5%)	3(5.2%)	6(3.8%)	2(1.9%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	15(4.7%)	3(5.2%)	6(3.8%)	6(5.8%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	13(4.1%)	3(5.2%)	7(4.5%)	3(2.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	8(2.5%)	2(3.4%)	1(0.6%)	5(4.9%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	11(3.5%)	3(5.2%)	3(1.9%)	5(4.9%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	14(4.4%)	2(3.4%)	7(4.5%)	5(4.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	23(7.2%)	7(12.1%)	16(10.2%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	267≤ - <365	30(9.4%)	10(17.2%)	20(12.7%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹部不快感		6(1.9%)	3(5.2%)	1(0.6%)	2(1.9%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	22≤ - <43	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹部膨満		2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹痛		6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
下腹部痛		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上腹部痛		9(2.8%)	5(8.6%)	2(1.3%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口角口唇炎		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
アフタ性潰瘍		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
慢性胃炎		3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
大腸炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
便秘		6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	267≤ - <365	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
齲歯		10(3.1%)	1(1.7%)	7(4.5%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
下痢		40(12.6%)	7(12.1%)	22(14.0%)	11(10.7%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	7(2.2%)	0(0.0%)	4(2.5%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	3(0.9%)	0(0.0%)	0(0.0%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	7(2.2%)	2(3.4%)	5(3.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	6(1.9%)	2(3.4%)	4(2.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
出血性腸憩室		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
出血性十二指腸潰瘍		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
十二指腸炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
嚥下障害		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腸炎		3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃ポリープ		4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃炎		4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
びらん性胃炎		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃食道逆流性疾患		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯肉痛		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血便排泄		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
痔核		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
マロリー・ワイス症候群		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
悪心		13(4.1%)	1(1.7%)	9(5.7%)	3(2.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	1≤ - <22	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	22≤ - <43	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
耳下腺腫大		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯周病		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
直腸出血		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口内炎		6(1.9%)	1(1.7%)	5(3.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯痛		6(1.9%)	2(3.4%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
嘔吐		21(6.6%)	4(6.9%)	12(7.6%)	5(4.9%)	4(8.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)
	1≤ - <22	5(1.6%)	0(0.0%)	5(3.2%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腸ポリープ		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心窩部不快感		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ブルンネル腺過形成		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口の錯感覚		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
びらん性十二指腸炎		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
軟便		3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
一般・全身障害および投与部位の状態		27(8.5%)	6(10.3%)	13(8.3%)	8(7.8%)	1(2.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	4(1.3%)	0(0.0%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	64≤ - <85	4(1.3%)	1(1.7%)	1(0.6%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	4(1.3%)	1(1.7%)	1(0.6%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	3(0.9%)	0(0.0%)	1(0.6%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
無力症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胸部不快感		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胸痛		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
顔面浮腫		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
異常感		2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
倦怠感		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
末梢性浮腫		2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
疼痛		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
発熱		6(1.9%)	2(3.4%)	4(2.5%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腫脹		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口渇		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
末梢腫脹		2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ポリープ		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血管穿刺部位発疹		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝胆道系障害		7(2.2%)	1(1.7%)	4(2.5%)	2(1.9%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胆管炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
急性胆嚢炎		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝機能異常		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
過形成性胆嚢症		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
免疫系障害		11(3.5%)	8(13.8%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	7(2.2%)	7(12.1%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
季節性アレルギー		10(3.1%)	7(12.1%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	6(1.9%)	6(10.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ヨウ素アレルギー		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
感染症および寄生虫症		184(57.9%)	42(72.4%)	92(58.6%)	50(48.5%)	16(32.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	25(7.9%)	3(5.2%)	13(8.3%)	9(8.7%)	4(8.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	19(6.0%)	1(1.7%)	10(6.4%)	8(7.8%)	5(10.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	29(9.1%)	8(13.8%)	13(8.3%)	8(7.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	21(6.6%)	3(5.2%)	14(8.9%)	4(3.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	13(4.1%)	5(8.6%)	4(2.5%)	4(3.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	14(4.4%)	2(3.4%)	7(4.5%)	5(4.9%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	22(6.9%)	4(6.9%)	6(3.8%)	12(11.7%)	4(8.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	22(6.9%)	6(10.3%)	7(4.5%)	9(8.7%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	44(13.8%)	14(24.1%)	30(19.1%)	0(0.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	37(11.6%)	10(17.2%)	27(17.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
虫垂炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
菌血症		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
気管支炎		8(2.5%)	1(1.7%)	7(4.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
蜂巣炎		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
結膜炎		4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
膀胱炎		4(1.3%)	0(0.0%)	1(0.6%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
感染性皮膚炎		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
爪の皮膚糸状菌症		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
憩室炎		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
精巣上体炎		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
毛包炎		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚真菌感染		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腸炎		12(3.8%)	4(6.9%)	6(3.8%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	3(0.9%)	2(3.4%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯肉炎		5(1.6%)	0(0.0%)	0(0.0%)	5(4.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
帯状疱疹		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
麦粒腫		4(1.3%)	0(0.0%)	2(1.3%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
膿痂疹		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
感染性皮膚潰瘍		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
インフルエンザ		17(5.3%)	4(6.9%)	11(7.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	5(1.6%)	0(0.0%)	5(3.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝膿瘍		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
リンパ節結核		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
細菌性髄膜炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上咽頭炎		119(37.4%)	29(50.0%)	65(41.4%)	25(24.3%)	12(24.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	15(4.7%)	2(3.4%)	9(5.7%)	4(3.9%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	10(3.1%)	1(1.7%)	6(3.8%)	3(2.9%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	16(5.0%)	5(8.6%)	9(5.7%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	8(2.5%)	1(1.7%)	5(3.2%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	6(1.9%)	3(5.2%)	2(1.3%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	7(2.2%)	1(1.7%)	4(2.5%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	12(3.8%)	3(5.2%)	2(1.3%)	7(6.8%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	12(3.8%)	4(6.9%)	4(2.5%)	4(3.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	17(5.3%)	5(8.6%)	12(7.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	16(5.0%)	4(6.9%)	12(7.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
外耳炎		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
中耳炎		5(1.6%)	2(3.4%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
急性中耳炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
慢性中耳炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯周炎		7(2.2%)	1(1.7%)	5(3.2%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹膜炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
咽頭炎		16(5.0%)	2(3.4%)	5(3.2%)	9(8.7%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	3(0.9%)	0(0.0%)	1(0.6%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	4(1.3%)	0(0.0%)	1(0.6%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肺炎		4(1.3%)	2(3.4%)	1(0.6%)	1(1.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
鼻炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
敗血症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
副鼻腔炎		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚感染		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮下組織膿瘍		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
足部白癬		4(1.3%)	1(1.7%)	1(0.6%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上気道感染		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ウイルス感染		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肛門膿瘍		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝嚢胞感染		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯肉膿瘍		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ヘリコバクター感染		3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
シャント感染		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腎嚢胞感染		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
感染性腸炎		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
細菌性結膜炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
軟骨膜炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
気道感染		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
細菌性扁桃炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口腔ヘルペス		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
感染性皮膚嚢腫		4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
傷害、中毒および処置合併症		84(26.4%)	15(25.9%)	44(28.0%)	25(24.3%)	9(18.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	1≤ - <22	6(1.9%)	0(0.0%)	4(2.5%)	2(1.9%)	2(4.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	22≤ - <43	9(2.8%)	2(3.4%)	4(2.5%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	9(2.8%)	2(3.4%)	2(1.3%)	5(4.9%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	8(2.5%)	1(1.7%)	5(3.2%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	9(2.8%)	1(1.7%)	4(2.5%)	4(3.9%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	13(4.1%)	3(5.2%)	4(2.5%)	6(5.8%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	6(1.9%)	2(3.4%)	2(1.3%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	8(2.5%)	2(3.4%)	4(2.5%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	16(5.0%)	7(12.1%)	9(5.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	15(4.7%)	3(5.2%)	12(7.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
動物咬傷		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
節足動物刺傷		4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上顎炎		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
顔面骨骨折		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腿骨頚部骨折		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腿骨骨折		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
足骨折		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
眼内異物		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
熱疲労		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
損傷		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節脱臼		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
靭帯捻挫		7(2.2%)	0(0.0%)	5(3.2%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
爪裂離		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
橈骨骨折		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
引っかき傷		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ストレス骨折		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮下血腫		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腱損傷		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腱断裂		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
手首関節骨折		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
挫傷		23(7.2%)	4(6.9%)	11(7.0%)	8(7.8%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	4(1.3%)	0(0.0%)	1(0.6%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
創傷		10(3.1%)	2(3.4%)	8(5.1%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	4(1.3%)	0(0.0%)	4(2.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
熱傷		4(1.3%)	2(3.4%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚裂傷		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
シャント血栓症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
縫合関連合併症		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節損傷		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
靭帯損傷		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
四肢損傷		5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
処置による低血圧		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯牙破折		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
処置による疼痛		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚擦過傷		19(6.0%)	7(12.1%)	7(4.5%)	5(4.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	5(1.6%)	2(3.4%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
骨挫傷		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
熱中症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
爪損傷		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋挫傷		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
外傷後頚部症候群		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚創傷		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
鼻部損傷		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
臨床検査		38(11.9%)	14(24.1%)	13(8.3%)	11(10.7%)	4(8.0%)	21(6.6%)	9(15.5%)	3(1.9%)	9(8.7%)	0(0.0%)
	1≤ - <22	11(3.5%)	7(12.1%)	0(0.0%)	4(3.9%)	1(2.0%)	10(3.1%)	7(12.1%)	0(0.0%)	3(2.9%)	0(0.0%)
	22≤ - <43	6(1.9%)	1(1.7%)	1(0.6%)	4(3.9%)	0(0.0%)	5(1.6%)	1(1.7%)	1(0.6%)	3(2.9%)	0(0.0%)
	43≤ - <64	3(0.9%)	2(3.4%)	0(0.0%)	1(1.0%)	0(0.0%)	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	2(4.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	5(1.6%)	1(1.7%)	3(1.9%)	1(1.0%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	127≤ - <148	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	6(1.9%)	0(0.0%)	6(3.8%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	267≤ - <365	5(1.6%)	4(6.9%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中ビリルビン増加		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中クレアチンホスホキナーゼ増加		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中副甲状腺ホルモン増加		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中カリウム増加		3(0.9%)	2(3.4%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血圧上昇		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
血中尿酸増加		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心電図 QT 延長		5(1.6%)	3(5.2%)	2(1.3%)	0(0.0%)	0(0.0%)	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
γ−グルタミルトランスフェラーゼ増加		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ヘモグロビン減少		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
プロトロンビン時間延長		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
白血球数減少		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳性ナトリウム利尿ペプチド増加		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(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%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
便潜血陽性		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
補正カルシウム減少		18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)
	1≤ - <22	10(3.1%)	7(12.1%)	0(0.0%)	3(2.9%)	0(0.0%)	10(3.1%)	7(12.1%)	0(0.0%)	3(2.9%)	0(0.0%)
	22≤ - <43	5(1.6%)	1(1.7%)	1(0.6%)	3(2.9%)	0(0.0%)	5(1.6%)	1(1.7%)	1(0.6%)	3(2.9%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝機能検査値上昇		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
補正カルシウム増加		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
代謝および栄養障害		19(6.0%)	3(5.2%)	11(7.0%)	5(4.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	5(1.6%)	0(0.0%)	2(1.3%)	3(2.9%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	8(2.5%)	2(3.4%)	6(3.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
転移性石灰化		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
葉酸欠乏		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
痛風		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
高カルシウム血症		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
高血糖		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
高カリウム血症		2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
高リン酸塩血症		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
高尿酸血症		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
低血糖		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
亜鉛欠乏		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脂質異常症		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
食欲減退		5(1.6%)	0(0.0%)	2(1.3%)	3(2.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋骨格系および結合組織障害		99(31.1%)	23(39.7%)	52(33.1%)	24(23.3%)	2(4.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	1≤ - <22	6(1.9%)	1(1.7%)	1(0.6%)	4(3.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	15(4.7%)	5(8.6%)	6(3.8%)	4(3.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	8(2.5%)	1(1.7%)	3(1.9%)	4(3.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	15(4.7%)	6(10.3%)	3(1.9%)	6(5.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	11(3.5%)	0(0.0%)	5(3.2%)	6(5.8%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	6(1.9%)	1(1.7%)	3(1.9%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	6(1.9%)	0(0.0%)	3(1.9%)	3(2.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	6(1.9%)	0(0.0%)	5(3.2%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	31(9.7%)	11(19.0%)	19(12.1%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	19(6.0%)	6(10.3%)	13(8.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節痛		24(7.5%)	5(8.6%)	16(10.2%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	7(2.2%)	1(1.7%)	6(3.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節炎		7(2.2%)	3(5.2%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	3(0.9%)	3(5.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
反応性関節炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
背部痛		18(5.7%)	1(1.7%)	12(7.6%)	5(4.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	4(1.3%)	1(1.7%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	5(1.6%)	0(0.0%)	5(3.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
滑液包炎		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
デュプイトラン拘縮		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
側腹部痛		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節滲出液		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
関節腫脹		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腰部脊柱管狭窄症		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋痙縮		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋骨格痛		7(2.2%)	5(8.6%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	5(1.6%)	3(5.2%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋肉痛		9(2.8%)	1(1.7%)	4(2.5%)	4(3.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頚部痛		5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
変形性関節症		5(1.6%)	2(3.4%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
骨粗鬆症		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
四肢痛		13(4.1%)	6(10.3%)	6(3.8%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節周囲炎		2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
多発性関節炎		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肩回旋筋腱板症候群		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
変形性脊椎症		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
滑液嚢腫		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
顎関節症候群		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腱鞘炎		9(2.8%)	1(1.7%)	3(1.9%)	5(4.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
弾発指		4(1.3%)	0(0.0%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
椎間板突出		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋骨格系胸痛		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋骨格硬直		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
結晶性関節障害		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腱痛		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脊柱管狭窄症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(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）		8(2.5%)	4(6.9%)	4(2.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	5(1.6%)	3(5.2%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腺癌		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腺癌		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
食道の良性新生物		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
結腸癌		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脂肪腫		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腸腺腫		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
前立腺癌		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
唾液腺新生物		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
神経系障害		41(12.9%)	11(19.0%)	22(14.0%)	8(7.8%)	2(4.0%)	2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	3(0.9%)	0(0.0%)	1(0.6%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	6(1.9%)	1(1.7%)	3(1.9%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	6(1.9%)	2(3.4%)	4(2.5%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	11(3.5%)	2(3.4%)	9(5.7%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	8(2.5%)	2(3.4%)	6(3.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳幹出血		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
手根管症候群		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
小脳出血		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳梗塞		4(1.3%)	1(1.7%)	1(0.6%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳血管障害		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頚腕症候群		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
浮動性めまい		8(2.5%)	2(3.4%)	4(2.5%)	2(1.9%)	1(2.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
体位性めまい		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
顔面麻痺		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頭部不快感		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頭痛		12(3.8%)	2(3.4%)	9(5.7%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	4(1.3%)	0(0.0%)	4(2.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
意識消失		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
坐骨神経痛		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
傾眠		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頚髄神経根障害		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ラクナ梗塞		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
下肢静止不能症候群		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
視床出血		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
パーキンソン病		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血栓性脳梗塞		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
椎骨動脈解離		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
味覚障害		2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
精神障害		10(3.1%)	2(3.4%)	6(3.8%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	5(1.6%)	2(3.4%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
不眠症		8(2.5%)	2(3.4%)	5(3.2%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
統合失調症様障害		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
夢遊症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腎および尿路障害		4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血尿		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腎嚢胞出血		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
生殖系および乳房障害		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
閉経期症状		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
不正子宮出血		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
呼吸器、胸郭および縦隔障害		56(17.6%)	12(20.7%)	33(21.0%)	11(10.7%)	5(10.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	6(1.9%)	0(0.0%)	5(3.2%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	5(1.6%)	1(1.7%)	3(1.9%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	8(2.5%)	2(3.4%)	3(1.9%)	3(2.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	5(1.6%)	2(3.4%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	7(2.2%)	0(0.0%)	5(3.2%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	4(1.3%)	0(0.0%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	10(3.1%)	4(6.9%)	6(3.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	9(2.8%)	3(5.2%)	6(3.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
喘息		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
咳嗽		5(1.6%)	2(3.4%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
呼吸困難		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
鼻出血		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
過換気		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
間質性肺疾患		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胸水		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肺うっ血		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肺水腫		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
アレルギー性鼻炎		6(1.9%)	1(1.7%)	3(1.9%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
鼻漏		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
睡眠時無呼吸症候群		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
喀痰増加		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上気道の炎症		25(7.9%)	4(6.9%)	18(11.5%)	3(2.9%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	5(1.6%)	1(1.7%)	4(2.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
アレルギー性気管支炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口腔咽頭不快感		3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口腔咽頭痛		7(2.2%)	0(0.0%)	5(3.2%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚および皮下組織障害		73(23.0%)	18(31.0%)	34(21.7%)	21(20.4%)	5(10.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	3(0.9%)	0(0.0%)	1(0.6%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	8(2.5%)	1(1.7%)	4(2.5%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	17(5.3%)	5(8.6%)	9(5.7%)	3(2.9%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	8(2.5%)	2(3.4%)	2(1.3%)	4(3.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	11(3.5%)	1(1.7%)	5(3.2%)	5(4.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	7(2.2%)	0(0.0%)	2(1.3%)	5(4.9%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	148≤ - <169	7(2.2%)	2(3.4%)	2(1.3%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	14(4.4%)	6(10.3%)	8(5.1%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	15(4.7%)	4(6.9%)	11(7.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
水疱		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
皮膚嚢腫		6(1.9%)	0(0.0%)	5(3.2%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚炎		4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
接触皮膚炎		9(2.8%)	2(3.4%)	5(3.2%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	3(0.9%)	0(0.0%)	1(0.6%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
薬疹		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
湿疹		16(5.0%)	2(3.4%)	7(4.5%)	7(6.8%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	4(1.3%)	0(0.0%)	0(0.0%)	4(3.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮脂欠乏性湿疹		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
紅斑		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
多形紅斑		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮下出血		12(3.8%)	2(3.4%)	8(5.1%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
多汗症		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
爪甲剥離症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
点状出血		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
そう痒症		8(2.5%)	5(8.6%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	3(0.9%)	2(3.4%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
発疹		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
紅斑性皮疹		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脂漏性皮膚炎		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚びらん		4(1.3%)	1(1.7%)	0(0.0%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
皮膚剥脱		6(1.9%)	1(1.7%)	2(1.3%)	3(2.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚刺激		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚潰瘍		5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
蕁麻疹		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮脂欠乏症		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
水疱破裂		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
偽毛包炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
外科および内科処置		5(1.6%)	0(0.0%)	3(1.9%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
硝子体切除		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
抜歯		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
白内障手術		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯科インプラント埋込み		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血管障害		23(7.2%)	5(8.6%)	13(8.3%)	5(4.9%)	2(4.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	4(1.3%)	0(0.0%)	2(1.3%)	2(1.9%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	5(1.6%)	1(1.7%)	4(2.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
高血圧		8(2.5%)	0(0.0%)	6(3.8%)	2(1.9%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
起立性低血圧		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
末梢性虚血		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血栓性静脈炎		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
末梢動脈閉塞性疾患		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大動脈硬化症		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
内出血		7(2.2%)	3(5.2%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7－11　比較的よく見られる有害事象の発現状況

PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
上腹部痛	9(2.8%)	5(8.6%)	2(1.3%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節痛	24(7.5%)	5(8.6%)	16(10.2%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節炎	7(2.2%)	3(5.2%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
背部痛	18(5.7%)	1(1.7%)	12(7.6%)	5(4.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
気管支炎	8(2.5%)	1(1.7%)	7(4.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
齲歯	10(3.1%)	1(1.7%)	7(4.5%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
接触皮膚炎	9(2.8%)	2(3.4%)	5(3.2%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
下痢	40(12.6%)	7(12.1%)	22(14.0%)	11(10.7%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
浮動性めまい	8(2.5%)	2(3.4%)	4(2.5%)	2(1.9%)	1(2.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
湿疹	16(5.0%)	2(3.4%)	7(4.5%)	7(6.8%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腸炎	12(3.8%)	4(6.9%)	6(3.8%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮下出血	12(3.8%)	2(3.4%)	8(5.1%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頭痛	12(3.8%)	2(3.4%)	9(5.7%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
高血圧	8(2.5%)	0(0.0%)	6(3.8%)	2(1.9%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
インフルエンザ	17(5.3%)	4(6.9%)	11(7.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
不眠症	8(2.5%)	2(3.4%)	5(3.2%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
靭帯捻挫	7(2.2%)	0(0.0%)	5(3.2%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋骨格痛	7(2.2%)	5(8.6%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋肉痛	9(2.8%)	1(1.7%)	4(2.5%)	4(3.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上咽頭炎	119(37.4%)	29(50.0%)	65(41.4%)	25(24.3%)	12(24.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
悪心	13(4.1%)	1(1.7%)	9(5.7%)	3(2.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
四肢痛	13(4.1%)	6(10.3%)	6(3.8%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯周炎	7(2.2%)	1(1.7%)	5(3.2%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
咽頭炎	16(5.0%)	2(3.4%)	5(3.2%)	9(8.7%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
そう痒症	8(2.5%)	5(8.6%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腱鞘炎	9(2.8%)	1(1.7%)	3(1.9%)	5(4.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
嘔吐	21(6.6%)	4(6.9%)	12(7.6%)	5(4.9%)	4(8.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)
季節性アレルギー	10(3.1%)	7(12.1%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上気道の炎症	25(7.9%)	4(6.9%)	18(11.5%)	3(2.9%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
挫傷	23(7.2%)	4(6.9%)	11(7.0%)	8(7.8%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
創傷	10(3.1%)	2(3.4%)	8(5.1%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚擦過傷	19(6.0%)	7(12.1%)	7(4.5%)	5(4.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
口腔咽頭痛	7(2.2%)	0(0.0%)	5(3.2%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
補正カルシウム減少	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)
内出血	7(2.2%)	3(5.2%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7－12　死亡に至った有害事象の発現状況

SOC/PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
全体	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	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	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
細菌性髄膜炎	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7－13　死亡に至った有害事象の重症度別発現状況

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
全体		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	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		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
細菌性髄膜炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7－14　死亡に至った有害事象の時期別発現状況

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
全体		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
感染症および寄生虫症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
細菌性髄膜炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7－15　死亡した症例一覧

試験名	被験者識別コード	性別	年齢	投与群	基本語(PT)	発現時の投与量(μg)	投与後日数	重篤性	重症度	治験薬の処置	転帰	持続期間	治験薬との因果関係
AJ1004	D5306	男	61	SK-1403	細菌性髄膜炎	100	59	重篤	高度	中止	死亡	11	無

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投与後日数 = 発現日 - 投与開始日 +1
持続期間 = 転帰日 - 発現日 +1

表 2.7.4.7－16　その他の重篤な有害事象の発現状況

SOC/PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
全体	45(14.2%)	10(17.2%)	24(15.3%)	11(10.7%)	8(16.0%)	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	1(2.0%)
心臓障害	8(2.5%)	1(1.7%)	6(3.8%)	1(1.0%)	1(2.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)
急性心筋梗塞	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
狭心症	5(1.6%)	1(1.7%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
慢性心不全	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
心筋虚血	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
耳および迷路障害	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
迷路性回転性めまい	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
眼障害	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
硝子体出血	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
黄斑線維症	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腸障害	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
出血性腸憩室	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
出血性十二指腸潰瘍	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
直腸出血	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腸ポリープ	1(0.3%)	0(0.0%)	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	3(0.9%)	0(0.0%)	1(0.6%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胆管炎	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
急性胆嚢炎	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	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	6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
虫垂炎	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝膿瘍	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹膜炎	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肺炎	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
敗血症	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝嚢胞感染	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
気道感染	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
傷害、中毒および処置合併症	7(2.2%)	2(3.4%)	4(2.5%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
顔面骨骨折	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腿骨頚部骨折	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腿骨骨折	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
損傷	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節脱臼	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
橈骨骨折	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腱断裂	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
手首関節骨折	1(0.3%)	0(0.0%)	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	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
背部痛	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腰部脊柱管狭窄症	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	5(1.6%)	3(5.2%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腺癌	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
胃腺癌	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
結腸癌	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
前立腺癌	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
唾液腺新生物	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
神経系障害	11(3.5%)	3(5.2%)	5(3.2%)	3(2.9%)	1(2.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
脳幹出血	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
手根管症候群	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
小脳出血	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳梗塞	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
浮動性めまい	2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
視床出血	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血栓性脳梗塞	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
椎骨動脈解離	1(0.3%)	0(0.0%)	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	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
過換気	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚および皮下組織障害	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚潰瘍	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	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(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
白内障手術	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血管障害	4(1.3%)	0(0.0%)	2(1.3%)	2(1.9%)	1(2.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
高血圧	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
末梢性虚血	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
末梢動脈閉塞性疾患	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1

例数(割合(%))

表 2.7.4.7－17　その他の重篤な有害事象の重症度別発現状況

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
全体		45(14.2%)	10(17.2%)	24(15.3%)	11(10.7%)	8(16.0%)	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	1(2.0%)
	軽度	5(1.6%)	1(1.7%)	3(1.9%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	37(11.6%)	9(15.5%)	19(12.1%)	9(8.7%)	6(12.0%)	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)
	高度	5(1.6%)	0(0.0%)	4(2.5%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
心臓障害		8(2.5%)	1(1.7%)	6(3.8%)	1(1.0%)	1(2.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	8(2.5%)	1(1.7%)	6(3.8%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
急性心筋梗塞		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
狭心症		5(1.6%)	1(1.7%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	5(1.6%)	1(1.7%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
慢性心不全		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
心筋虚血		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
耳および迷路障害		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	重症度	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
迷路性回転性めまい		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
眼障害		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
硝子体出血		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
黄斑線維症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腸障害		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
出血性腸憩室		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
出血性十二指腸潰瘍		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
直腸出血		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
大腸ポリープ		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝胆道系障害		3(0.9%)	0(0.0%)	1(0.6%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	3(0.9%)	0(0.0%)	1(0.6%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胆管炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
急性胆嚢炎		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
感染症および寄生虫症		6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	4(1.3%)	1(1.7%)	2(1.3%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
虫垂炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝膿瘍		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹膜炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
肺炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
敗血症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝嚢胞感染		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
気道感染		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
傷害、中毒および処置合併症		7(2.2%)	2(3.4%)	4(2.5%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	7(2.2%)	2(3.4%)	4(2.5%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
顔面骨骨折		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腿骨頚部骨折		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腿骨骨折		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
損傷		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節脱臼		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
橈骨骨折		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腱断裂		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
手首関節骨折		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋骨格系および結合組織障害		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
背部痛		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腰部脊柱管狭窄症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
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）		5(1.6%)	3(5.2%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腺癌		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腺癌		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
結腸癌		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
前立腺癌		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
唾液腺新生物		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
神経系障害		11(3.5%)	3(5.2%)	5(3.2%)	3(2.9%)	1(2.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	6(1.9%)	3(5.2%)	2(1.3%)	1(1.0%)	1(2.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳幹出血		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
手根管症候群		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
小脳出血		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳梗塞		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
浮動性めまい		2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
視床出血		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血栓性脳梗塞		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
椎骨動脈解離		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
呼吸器、胸郭および縦隔障害		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
過換気		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚および皮下組織障害		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚潰瘍		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
外科および内科処置		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
白内障手術		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血管障害		4(1.3%)	0(0.0%)	2(1.3%)	2(1.9%)	1(2.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	4(1.3%)	0(0.0%)	2(1.3%)	2(1.9%)	1(2.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
高血圧		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
末梢性虚血		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
末梢動脈閉塞性疾患		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7－18　その他の重篤な有害事象の時期別発現状況

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
全体		45(14.2%)	10(17.2%)	24(15.3%)	11(10.7%)	8(16.0%)	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	1(2.0%)
	1≤ - <22	4(1.3%)	0(0.0%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	10(3.1%)	0(0.0%)	6(3.8%)	4(3.9%)	1(2.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	85≤ - <106	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	6(1.9%)	2(3.4%)	3(1.9%)	1(1.0%)	4(8.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	127≤ - <148	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	4(1.3%)	1(1.7%)	2(1.3%)	1(1.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	10(3.1%)	3(5.2%)	7(4.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	10(3.1%)	3(5.2%)	7(4.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心臓障害		8(2.5%)	1(1.7%)	6(3.8%)	1(1.0%)	1(2.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
急性心筋梗塞		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
狭心症		5(1.6%)	1(1.7%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
慢性心不全		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心筋虚血		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
耳および迷路障害		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
迷路性回転性めまい		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
眼障害		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
硝子体出血		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
黄斑線維症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腸障害		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
出血性腸憩室		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
出血性十二指腸潰瘍		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
直腸出血		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腸ポリープ		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝胆道系障害		3(0.9%)	0(0.0%)	1(0.6%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胆管炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
急性胆嚢炎		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
感染症および寄生虫症		6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
虫垂炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝膿瘍		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹膜炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肺炎		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
敗血症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝嚢胞感染		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
気道感染		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
傷害、中毒および処置合併症		7(2.2%)	2(3.4%)	4(2.5%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
顔面骨骨折		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腿骨頚部骨折		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腿骨骨折		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
損傷		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
関節脱臼		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
橈骨骨折		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腱断裂		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
手首関節骨折		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
筋骨格系および結合組織障害		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
背部痛		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腰部脊柱管狭窄症		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(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）		5(1.6%)	3(5.2%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腺癌		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腺癌		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
結腸癌		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
前立腺癌		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
唾液腺新生物		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
神経系障害		11(3.5%)	3(5.2%)	5(3.2%)	3(2.9%)	1(2.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳幹出血		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
手根管症候群		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
小脳出血		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳梗塞		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
浮動性めまい		2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
視床出血		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血栓性脳梗塞		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
椎骨動脈解離		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
呼吸器、胸郭および縦隔障害		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
過換気		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚および皮下組織障害		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
皮膚潰瘍		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
外科および内科処置		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
白内障手術		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血管障害		4(1.3%)	0(0.0%)	2(1.3%)	2(1.9%)	1(2.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
高血圧		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
末梢性虚血		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
末梢動脈閉塞性疾患		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7－19　その他の重篤な有害事象を発現した症例一覧

試験名	被験者識別コード	性別	年齢	投与群	基本語(PT)	発現時の投与量(μg)	投与後日数	重篤性	重症度	治験薬の処置	転帰	持続期間	治験薬との因果関係
AJ1002	0203	男	62	SK-1403	浮動性めまい	25	24	重篤	中等度	継続	回復（消失）	10	無
	0306	男	69	SK-1403	腺癌	50	109	重篤	軽度	継続	回復（消失）	1	無
					胃腺癌	50	102	重篤	軽度	中止	未回復	35	無
	0404	男	75	SK-1403	気道感染	200	302	重篤	中等度	継続	回復（消失）	26	無
	1003	男	72	SK-1403	脳幹出血	25	261	重篤	中等度	継続	回復（消失）	4	無
	1302	男	55	SK-1403	狭心症	50	282	重篤	中等度	継続	回復（消失）	29	無
	1501	男	68	SK-1403	顔面骨骨折	300	109	重篤	中等度	継続	回復（消失）	89	無
	1502	男	60	SK-1403	浮動性めまい	300	165	重篤	中等度	継続	回復（消失）	2	有
					浮動性めまい	300	176	重篤	中等度	中止	回復（消失）	2	有
	1602	女	51	SK-1403	関節脱臼	300	349	重篤	中等度	継続	回復（消失）	20	無
	1701	男	73	SK-1403	結腸癌	50	264	重篤	中等度	継続	回復（消失）	64	無
	1703	男	66	SK-1403	唾液腺新生物	0	170	重篤	中等度	継続	回復（消失）	10	無
AJ1003	L0102	男	58	SK-1403	肝嚢胞感染	50	158	重篤	高度	継続	回復（消失）	57	無
	L0108	男	62	SK-1403	視床出血	0	362	重篤	高度	継続	未回復	49	無
	L0109	男	72	SK-1403	迷路性回転性めまい	150	313	重篤	中等度	継続	回復（消失）	53	無
	L0302	男	46	SK-1403	狭心症	300	256	重篤	中等度	継続	回復（消失）	2	無
	L0311	男	56	SK-1403	狭心症	200	67	重篤	中等度	継続	回復（消失）	38	無
	L0404	男	55	SK-1403	椎骨動脈解離	100	255	重篤	軽度	継続	回復（消失）	23	無
	L0407	男	56	SK-1403	腱断裂	250	126	重篤	中等度	継続	回復（消失）	134	無
	L0506	男	64	SK-1403	脳梗塞	50	177	重篤	中等度	継続	回復（消失）	7	無
	L0807	女	71	SK-1403	心筋虚血	25	30	重篤	中等度	継続	回復（消失）	30	無
					末梢動脈閉塞性疾患	25	110	重篤	中等度	継続	軽快	256	無
					大腸ポリープ	25	212	重篤	軽度	継続	回復（消失）	43	無
					末梢動脈閉塞性疾患	25	356	重篤	中等度	継続	回復（消失）	29	無

試験名	被験者識別コード	性別	年齢	投与群	基本語(PT)	発現時の投与量(μg)	投与後日数	重篤性	重症度	治験薬の処置	転帰	持続期間	治験薬との因果関係
	L0911	男	44	SK-1403	虫垂炎	50	20	重篤	中等度	継続	回復（消失）	18	無
					皮膚潰瘍	300	334	重篤	中等度	継続	回復（消失）	39	無
	L1109	男	67	SK-1403	急性心筋梗塞	50	65	重篤	中等度	休薬	軽快	344	有
	L1305	男	63	SK-1403	小脳出血	300	150	重篤	高度	継続	後遺症あり	40	無
	L1406	男	68	SK-1403	前立腺癌	150	190	重篤	中等度	中止	未回復	225	無
	L1503	男	63	SK-1403	出血性腸憩室	100	74	重篤	中等度	継続	回復（消失）	54	無
	L1605	女	76	SK-1403	高血圧	25	77	重篤	中等度	継続	回復（消失）	9	有
	L1704	男	56	SK-1403	手首関節骨折	50	37	重篤	中等度	継続	回復（消失）	269	無
					出血性十二指腸潰瘍	0	78	重篤	中等度	休薬	軽快	288	無
					狭心症	100	63	重篤	中等度	継続	回復（消失）	65	無
	L1713	女	71	SK-1403	肺炎	100	121	重篤	中等度	継続	回復（消失）	28	無
	L1801	男	74	SK-1403	結腸癌	300	235	重篤	中等度	継続	回復（消失）	57	無
					腹膜炎	300	286	重篤	高度	中止	回復（消失）	25	無
	L1808	男	68	SK-1403	橈骨骨折	50	263	重篤	中等度	継続	回復（消失）	16	無
	L1910	男	61	SK-1403	硝子体出血	150	75	重篤	軽度	継続	軽快	291	無
	L2003	女	66	SK-1403	手根管症候群	150	144	重篤	中等度	継続	回復（消失）	19	無
	L2009	男	64	SK-1403	損傷	25	15	重篤	中等度	継続	軽快	351	無
					背部痛	100	309	重篤	中等度	継続	軽快	57	無
	L2101	男	66	SK-1403	心筋虚血	100	331	重篤	中等度	継続	軽快	3	無
	L2306	男	57	SK-1403	急性胆嚢炎	25	321	重篤	中等度	継続	回復（消失）	47	無
AJ1004	D0105	女	45	PLACEBO	過換気	300	108	重篤	軽度	継続	回復（消失）	2	無
	D1002	女	69	SK-1403	黄斑線維症	50	93	重篤	中等度	継続	回復（消失）	45	無
					白内障手術	50	93	重篤	中等度	継続	回復（消失）	45	無
	D1006	男	75	SK-1403	末梢動脈閉塞性疾患	150	122	重篤	中等度	継続	回復（消失）	5	無
	D1405	女	73	PLACEBO	慢性心不全	200	114	重篤	高度	中止	回復（消失）	97	有
	D1902	女	65	SK-1403	血栓性脳梗塞	25	2	重篤	軽度	継続	後遺症あり	38	無
	D1903	男	77	SK-1403	狭心症	100	78	重篤	中等度	継続	軽快	92	無
	D2301	男	77	PLACEBO	大腿骨頚部骨折	0	110	重篤	中等度	継続	軽快	84	無
	D2601	男	69	PLACEBO	末梢動脈閉塞性疾患	50	40	重篤	中等度	継続	回復（消失）	29	無
	D2602	男	71	PLACEBO	肺炎	100	36	重篤	中等度	継続	回復（消失）	17	無
	D5102	男	70	SK-1403	脳梗塞	25	71	重篤	中等度	中止	後遺症あり	83	無
	D5307	男	66	SK-1403	末梢性虚血	50	68	重篤	中等度	継続	未回復	102	無
	D5401	男	76	PLACEBO	脳梗塞	200	74	重篤	中等度	継続	回復（消失）	96	無
	D5805	男	67	SK-1403	視床出血	25	140	重篤	高度	継続	未回復	93	無
	D6001	男	66	SK-1403	腰部脊柱管狭窄症	50	17	重篤	中等度	継続	回復（消失）	111	無

試験名	被験者識別コード	性別	年齢	投与群	基本語(PT)	発現時の投与量(μg)	投与後日数	重篤性	重症度	治験薬の処置	転帰	持続期間	治験薬との因果関係
	D6402	男	81	SK-1403	大腿骨骨折	25	163	重篤	中等度	継続	軽快	70	無
	D6406	男	71	SK-1403	胆管炎	25	82	重篤	中等度	継続	回復（消失）	46	無
	D6502	女	66	SK-1403	急性胆嚢炎	100	50	重篤	中等度	継続	回復（消失）	99	無
					肝膿瘍	100	52	重篤	中等度	継続	軽快	118	無
					敗血症	100	52	重篤	中等度	継続	回復（消失）	97	無
	D6504	男	81	PLACEBO	背部痛	200	144	重篤	中等度	継続	回復（消失）	10	無
	D6706	男	75	PLACEBO	直腸出血	200	115	重篤	中等度	継続	回復（消失）	3	無

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投与後日数 = 発現日 - 投与開始日 +1
持続期間 = 転帰日 - 発現日 +1

表 2.7.4.7−20　中止の理由となった有害事象の発現状況

	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
全体	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	4(8.0%)	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	2(4.0%)
内分泌障害	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
甲状腺機能低下症	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腸障害	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	2(4.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	2(4.0%)
腹部不快感	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
嘔吐	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
心窩部不快感	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
肝胆道系障害	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
肝機能異常	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
臨床検査	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
血中副甲状腺ホルモン増加	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心電図 QT 延長	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
補正カルシウム増加	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7−21　休薬の理由となった有害事象の発現状況

SOC/PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
全体	14(4.4%)	7(12.1%)	3(1.9%)	4(3.9%)	0(0.0%)	13(4.1%)	7(12.1%)	2(1.3%)	4(3.9%)	0(0.0%)
一般・全身障害および投与部位の状態	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
顔面浮腫	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
口渇	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
肝胆道系障害	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝機能異常	1(0.3%)	0(0.0%)	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	12(3.8%)	7(12.1%)	1(0.6%)	4(3.9%)	0(0.0%)	12(3.8%)	7(12.1%)	1(0.6%)	4(3.9%)	0(0.0%)
心電図 QT 延長	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)
補正カルシウム減少	11(3.5%)	7(12.1%)	0(0.0%)	4(3.9%)	0(0.0%)	11(3.5%)	7(12.1%)	0(0.0%)	4(3.9%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7−22　減量の理由となった有害事象の発現状況

SOC/PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
全体	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
臨床検査	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
心電図 QT 延長	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7−23　中止の理由となった有害事象の重症度別発現状況

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
全体		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	4(8.0%)	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	2(4.0%)
	軽度	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	4(8.0%)	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	2(4.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
内分泌障害		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
甲状腺機能低下症		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腸障害		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	2(4.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	2(4.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	2(4.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	2(4.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹部不快感		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
嘔吐		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心窩部不快感		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
肝胆道系障害		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝機能異常		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
臨床検査		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中副甲状腺ホルモン増加		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心電図 QT 延長		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
補正カルシウム増加		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7−24　休薬の理由となった有害事象の重症度別発現状況

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
全体		14(4.4%)	7(12.1%)	3(1.9%)	4(3.9%)	0(0.0%)	13(4.1%)	7(12.1%)	2(1.3%)	4(3.9%)	0(0.0%)
	軽度	14(4.4%)	7(12.1%)	3(1.9%)	4(3.9%)	0(0.0%)	13(4.1%)	7(12.1%)	2(1.3%)	4(3.9%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
一般・全身障害および投与部位の状態		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
顔面浮腫		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口渇		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝胆道系障害		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝機能異常		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
臨床検査		12(3.8%)	7(12.1%)	1(0.6%)	4(3.9%)	0(0.0%)	12(3.8%)	7(12.1%)	1(0.6%)	4(3.9%)	0(0.0%)
	軽度	12(3.8%)	7(12.1%)	1(0.6%)	4(3.9%)	0(0.0%)	12(3.8%)	7(12.1%)	1(0.6%)	4(3.9%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
心電図 QT 延長		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
補正カルシウム減少		11(3.5%)	7(12.1%)	0(0.0%)	4(3.9%)	0(0.0%)	11(3.5%)	7(12.1%)	0(0.0%)	4(3.9%)	0(0.0%)
	軽度	11(3.5%)	7(12.1%)	0(0.0%)	4(3.9%)	0(0.0%)	11(3.5%)	7(12.1%)	0(0.0%)	4(3.9%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7−25　減量の理由となった有害事象の重症度別発現状況

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
全体		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
臨床検査		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心電図 QT 延長		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7−26　中止の理由となった有害事象の時期別発現状況

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
全体		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	4(8.0%)	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	2(4.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
内分泌障害		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
甲状腺機能低下症		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腸障害		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	2(4.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	2(4.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹部不快感		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
嘔吐		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心窩部不快感		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝胆道系障害		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝機能異常		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
臨床検査		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中副甲状腺ホルモン増加		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
心電図 QT 延長		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
補正カルシウム増加		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7−27　休薬の理由となった有害事象の時期別発現状況

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
全体		14(4.4%)	7(12.1%)	3(1.9%)	4(3.9%)	0(0.0%)	13(4.1%)	7(12.1%)	2(1.3%)	4(3.9%)	0(0.0%)
	1≤ - <22	8(2.5%)	6(10.3%)	0(0.0%)	2(1.9%)	0(0.0%)	8(2.5%)	6(10.3%)	0(0.0%)	2(1.9%)	0(0.0%)
	22≤ - <43	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)
	43≤ - <64	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
一般・全身障害および投与部位の状態		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
顔面浮腫		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口渇		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝胆道系障害		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝機能異常		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
臨床検査		12(3.8%)	7(12.1%)	1(0.6%)	4(3.9%)	0(0.0%)	12(3.8%)	7(12.1%)	1(0.6%)	4(3.9%)	0(0.0%)
	1≤ - <22	8(2.5%)	6(10.3%)	0(0.0%)	2(1.9%)	0(0.0%)	8(2.5%)	6(10.3%)	0(0.0%)	2(1.9%)	0(0.0%)
	22≤ - <43	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心電図 QT 延長		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
補正カルシウム減少		11(3.5%)	7(12.1%)	0(0.0%)	4(3.9%)	0(0.0%)	11(3.5%)	7(12.1%)	0(0.0%)	4(3.9%)	0(0.0%)
	1≤ - <22	8(2.5%)	6(10.3%)	0(0.0%)	2(1.9%)	0(0.0%)	8(2.5%)	6(10.3%)	0(0.0%)	2(1.9%)	0(0.0%)
	22≤ - <43	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7−28　減量の理由となった有害事象の時期別発現状況

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
全体		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
臨床検査		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心電図 QT 延長		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7−29　他の重要な有害事象を発現した症例一覧

試験名	被験者識別コード	性別	年齢	投与群	基本語(PT)	発現時の投与量(μg)	投与後日数	重篤性	重症度	治験薬の処置	転帰	持続期間	治験薬との因果関係
AJ1002	0101	男	64	SK-1403	補正カルシウム減少	50	8	非重篤	軽度	休薬	回復（消失）	8	有
	0102	男	67	SK-1403	補正カルシウム減少	50	36	非重篤	軽度	休薬	回復（消失）	15	有
					補正カルシウム減少	50	106	非重篤	軽度	休薬	回復（消失）	8	有
	0202	男	58	SK-1403	補正カルシウム減少	50	8	非重篤	軽度	休薬	回復（消失）	8	有
	0701	男	75	SK-1403	補正カルシウム減少	50	8	非重篤	軽度	休薬	回復（消失）	8	有
	0702	女	45	SK-1403	補正カルシウム減少	50	8	非重篤	軽度	休薬	回復（消失）	8	有
	0703	女	69	SK-1403	補正カルシウム減少	50	8	非重篤	軽度	休薬	回復（消失）	8	有
					心電図 QT 延長	0	43	非重篤	軽度	休薬	軽快	323	有
	0704	女	77	SK-1403	補正カルシウム減少	50	8	非重篤	軽度	休薬	回復（消失）	8	有
	1505	男	48	SK-1403	嘔吐	100	319	非重篤	軽度	中止	回復（消失）	2	有
	1902	男	52	SK-1403	心電図 QT 延長	200	281	非重篤	軽度	減量	回復（消失）	85	有
AJ1003	L1207	女	49	SK-1403	口渇	100	61	非重篤	軽度	休薬	回復（消失）	13	有
					顔面浮腫	100	61	非重篤	軽度	休薬	回復（消失）	13	有
	L1701	男	61	SK-1403	心電図 QT 延長	100	169	非重篤	軽度	休薬	回復（消失）	17	有
	L2107	女	53	SK-1403	肝機能異常	25	127	非重篤	軽度	中止	軽快	85	有
	L2204	男	61	SK-1403	肝機能異常	150	106	非重篤	軽度	休薬	回復（消失）	78	無
					心電図 QT 延長	150	169	非重篤	軽度	中止	回復（消失）	78	有
AJ1004	D0704	女	75	PLACEBO	心窩部不快感	100	22	非重篤	軽度	中止	軽快	57	有
	D1004	女	75	SK-1403	補正カルシウム減少	25	15	非重篤	軽度	休薬	回復（消失）	22	有
	D2304	女	27	SK-1403	補正カルシウム減少	25	16	非重篤	軽度	休薬	回復（消失）	8	有
	D5605	女	52	PLACEBO	甲状腺機能低下症	150	64	非重篤	軽度	中止	軽快	22	無
	D6005	男	49	PLACEBO	腹部不快感	50	1	非重篤	軽度	中止	回復（消失）	12	有
	D6102	女	64	SK-1403	補正カルシウム減少	200	113	非重篤	軽度	休薬	回復（消失）	8	有
	D6203	男	81	PLACEBO	補正カルシウム増加	50	8	非重篤	軽度	中止	回復（消失）	78	無
					血中副甲状腺ホルモン増加	50	8	非重篤	軽度	中止	回復（消失）	78	無
	D6302	女	68	SK-1403	補正カルシウム減少	50	29	非重篤	軽度	休薬	回復（消失）	145	有

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投与後日数 = 発現日 - 投与開始日 +1

持続期間 = 転帰日 - 発現日 +1

表 2.7.4.7－30　特に留意した有害事象の発現状況

	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
低カルシウム血症(全体)	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)
補正カルシウム減少	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)
骨代謝障害(全体)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腸障害(全体)	116(36.5%)	26(44.8%)	58(36.9%)	32(31.1%)	13(26.0%)	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	3(6.0%)
腹部不快感	6(1.9%)	3(5.2%)	1(0.6%)	2(1.9%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
腹部膨満	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹痛	6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
下腹部痛	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上腹部痛	9(2.8%)	5(8.6%)	2(1.3%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口角口唇炎	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
アフタ性潰瘍	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
慢性胃炎	3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腸炎	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
便秘	6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
齲歯	10(3.1%)	1(1.7%)	7(4.5%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
下痢	40(12.6%)	7(12.1%)	22(14.0%)	11(10.7%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
出血性腸憩室	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
出血性十二指腸潰瘍	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
十二指腸炎	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
嚥下障害	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腸炎	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃ポリープ	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃炎	4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
びらん性胃炎	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃食道逆流性疾患	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯肉痛	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	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%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
痔核	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
マロリー・ワイス症候群	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
悪心	13(4.1%)	1(1.7%)	9(5.7%)	3(2.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
耳下腺腫大	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯周病	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
直腸出血	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口内炎	6(1.9%)	1(1.7%)	5(3.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯痛	6(1.9%)	2(3.4%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
嘔吐	21(6.6%)	4(6.9%)	12(7.6%)	5(4.9%)	4(8.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)
大腸ポリープ	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心窩部不快感	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
ブルンネル腺過形成	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口の錯感覚	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
びらん性十二指腸炎	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
軟便	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
QT 延長(全体)	6(1.9%)	3(5.2%)	2(1.3%)	1(1.0%)	0(0.0%)	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)
心電図 QT 延長	5(1.6%)	3(5.2%)	2(1.3%)	0(0.0%)	0(0.0%)	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)
心室性頻脈	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
水晶体混濁(全体)	8(2.5%)	1(1.7%)	4(2.5%)	3(2.9%)	0(0.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
白内障	3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
水晶体混濁	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
白内障手術	3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7−31　特に留意した有害事象の重症度別発現状況

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	重症度	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
低カルシウム血症(全体)		18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)
	軽度	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
補正カルシウム減少		18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)
	軽度	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
骨代謝障害(全体)		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腸障害(全体)		116(36.5%)	26(44.8%)	58(36.9%)	32(31.1%)	13(26.0%)	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	3(6.0%)
	軽度	112(35.2%)	25(43.1%)	56(35.7%)	31(30.1%)	11(22.0%)	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	3(6.0%)
	中等度	8(2.5%)	2(3.4%)	4(2.5%)	2(1.9%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹部不快感		6(1.9%)	3(5.2%)	1(0.6%)	2(1.9%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	軽度	6(1.9%)	3(5.2%)	1(0.6%)	2(1.9%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹部膨満		2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹痛		6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
下腹部痛		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	重症度	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
上腹部痛		9(2.8%)	5(8.6%)	2(1.3%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	9(2.8%)	5(8.6%)	2(1.3%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口角口唇炎		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
アフタ性潰瘍		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
慢性胃炎		3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腸炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
便秘		6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
齲歯		10(3.1%)	1(1.7%)	7(4.5%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	9(2.8%)	1(1.7%)	6(3.8%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
下痢		40(12.6%)	7(12.1%)	22(14.0%)	11(10.7%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	39(12.3%)	6(10.3%)	22(14.0%)	11(10.7%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	重症度	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
出血性腸憩室		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
出血性十二指腸潰瘍		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
十二指腸炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
嚥下障害		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腸炎		3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃ポリープ		4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃炎		4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
びらん性胃炎		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	重症度	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
胃食道逆流性疾患		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯肉痛		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血便排泄		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
痔核		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
マロリー・ワイス症候群		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
悪心		13(4.1%)	1(1.7%)	9(5.7%)	3(2.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	軽度	12(3.8%)	1(1.7%)	8(5.1%)	3(2.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
耳下腺腫大		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯周病		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	重症度	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
直腸出血		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口内炎		6(1.9%)	1(1.7%)	5(3.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	6(1.9%)	1(1.7%)	5(3.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯痛		6(1.9%)	2(3.4%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	5(1.6%)	2(3.4%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
嘔吐		21(6.6%)	4(6.9%)	12(7.6%)	5(4.9%)	4(8.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)
	軽度	20(6.3%)	3(5.2%)	12(7.6%)	5(4.9%)	4(8.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)
	中等度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腸ポリープ		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心窩部不快感		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ブルンネル腺過形成		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口の錯感覚		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	重症度	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
びらん性十二指腸炎		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
軟便		3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
QT 延長(全体)		6(1.9%)	3(5.2%)	2(1.3%)	1(1.0%)	0(0.0%)	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)
	軽度	6(1.9%)	3(5.2%)	2(1.3%)	1(1.0%)	0(0.0%)	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心電図 QT 延長		5(1.6%)	3(5.2%)	2(1.3%)	0(0.0%)	0(0.0%)	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)
	軽度	5(1.6%)	3(5.2%)	2(1.3%)	0(0.0%)	0(0.0%)	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心室性頻脈		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
水晶体混濁(全体)		8(2.5%)	1(1.7%)	4(2.5%)	3(2.9%)	0(0.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	軽度	7(2.2%)	1(1.7%)	4(2.5%)	2(1.9%)	0(0.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
白内障		3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
水晶体混濁		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	重症度	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
白内障手術		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7－32　特に留意した有害事象の時期別発現状況

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
低カルシウム血症(全体)		18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)
	1≤ - <22	10(3.1%)	7(12.1%)	0(0.0%)	3(2.9%)	0(0.0%)	10(3.1%)	7(12.1%)	0(0.0%)	3(2.9%)	0(0.0%)
	22≤ - <43	5(1.6%)	1(1.7%)	1(0.6%)	3(2.9%)	0(0.0%)	5(1.6%)	1(1.7%)	1(0.6%)	3(2.9%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
補正カルシウム減少		18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)
	1≤ - <22	10(3.1%)	7(12.1%)	0(0.0%)	3(2.9%)	0(0.0%)	10(3.1%)	7(12.1%)	0(0.0%)	3(2.9%)	0(0.0%)
	22≤ - <43	5(1.6%)	1(1.7%)	1(0.6%)	3(2.9%)	0(0.0%)	5(1.6%)	1(1.7%)	1(0.6%)	3(2.9%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
骨代謝障害(全体)		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃腸障害(全体)		116(36.5%)	26(44.8%)	58(36.9%)	32(31.1%)	13(26.0%)	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	3(6.0%)
	1≤ - <22	16(5.0%)	0(0.0%)	10(6.4%)	6(5.8%)	4(8.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	2(4.0%)
	22≤ - <43	11(3.5%)	1(1.7%)	4(2.5%)	6(5.8%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	43≤ - <64	11(3.5%)	3(5.2%)	6(3.8%)	2(1.9%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	15(4.7%)	3(5.2%)	6(3.8%)	6(5.8%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	13(4.1%)	3(5.2%)	7(4.5%)	3(2.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	8(2.5%)	2(3.4%)	1(0.6%)	5(4.9%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	11(3.5%)	3(5.2%)	3(1.9%)	5(4.9%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	14(4.4%)	2(3.4%)	7(4.5%)	5(4.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	23(7.2%)	7(12.1%)	16(10.2%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	267≤ - <365	30(9.4%)	10(17.2%)	20(12.7%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹部不快感		6(1.9%)	3(5.2%)	1(0.6%)	2(1.9%)	3(6.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	22≤ - <43	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹部膨満		2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腹痛		6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
下腹部痛		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上腹部痛		9(2.8%)	5(8.6%)	2(1.3%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口角口唇炎		2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
アフタ性潰瘍		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
慢性胃炎		3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腸炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
便秘		6(1.9%)	1(1.7%)	4(2.5%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	267≤ - <365	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
齲歯		10(3.1%)	1(1.7%)	7(4.5%)	2(1.9%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
下痢		40(12.6%)	7(12.1%)	22(14.0%)	11(10.7%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	7(2.2%)	0(0.0%)	4(2.5%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	3(0.9%)	0(0.0%)	0(0.0%)	3(2.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	5(1.6%)	1(1.7%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	7(2.2%)	2(3.4%)	5(3.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	6(1.9%)	2(3.4%)	4(2.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
出血性腸憩室		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
出血性十二指腸潰瘍		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
十二指腸炎		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
嚥下障害		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
腸炎		3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃ポリープ		4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃炎		4(1.3%)	0(0.0%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
びらん性胃炎		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
胃食道逆流性疾患		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯肉痛		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血便排泄		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
痔核		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
マロリー・ワイス症候群		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
悪心		13(4.1%)	1(1.7%)	9(5.7%)	3(2.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	1≤ - <22	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	22≤ - <43	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
耳下腺腫大		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯周病		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
直腸出血		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口内炎		6(1.9%)	1(1.7%)	5(3.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
歯痛		6(1.9%)	2(3.4%)	2(1.3%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
嘔吐		21(6.6%)	4(6.9%)	12(7.6%)	5(4.9%)	4(8.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)
	1≤ - <22	5(1.6%)	0(0.0%)	5(3.2%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	4(1.3%)	1(1.7%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
大腸ポリープ		2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心窩部不快感		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ブルンネル腺過形成		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
口の錯感覚		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
びらん性十二指腸炎		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
軟便		3(0.9%)	1(1.7%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
QT 延長(全体)		6(1.9%)	3(5.2%)	2(1.3%)	1(1.0%)	0(0.0%)	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心電図 QT 延長		5(1.6%)	3(5.2%)	2(1.3%)	0(0.0%)	0(0.0%)	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心室性頻脈		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
水晶体混濁(全体)		8(2.5%)	1(1.7%)	4(2.5%)	3(2.9%)	0(0.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
白内障		3(0.9%)	1(1.7%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	2(0.6%)	0(0.0%)	0(0.0%)	2(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
水晶体混濁		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
白内障手術		3(0.9%)	0(0.0%)	2(1.3%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7－33　治療期の最低血清補正 Ca 濃度別の被験者割合

	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
8.4 mg/dL 未満	233(73.3%)	48(82.8%)	105(66.9%)	80(77.7%)	9(18.0%)
8.0 mg/dL 未満	96(30.2%)	25(43.1%)	27(17.2%)	44(42.7%)	4(8.0%)
7.5 mg/dL 未満	11(3.5%)	9(15.5%)	0(0.0%)	2(1.9%)	0(0.0%)
7.0 mg/dL 未満	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

例数(割合(%))

表 2.7.4.7－34　血清補正 Ca 濃度 7.5 mg/dL 未満による休薬状況

	投与群	試験名	対象被験者数	例数(割合(%))	件数
血清補正 Ca 濃度 7.5 mg/dL 未満による休薬	SK-1403 群	併合	318	11(3.5%)	12
		AJ1002	58	9(15.5%)	10
		AJ1003	157	0(0.0%)	0
		AJ1004	103	2(1.9%)	2
	プラセボ群	AJ1004	50	0(0.0%)	0

表 2.7.4.7－35　血清補正 Ca 濃度低下による休薬症例一覧

試験名	被験者識別コード	性別	年齢	投与群	休薬した来院	休薬前の SK-1403 投与量(μg)	血清補正 Ca 値(最大透析間隔)(mg/dL)					
							初期値 (0 週)	休薬直前	休薬 1 週目	休薬 2 週目	休薬 3 週目	休薬 4 週目
AJ1002	0101	男	64	SK-1403	1 週	50	8.9	7.4	8.6	8.7	7.6	7.7
	0102	男	67	SK-1403	5 週	50	8.4	7.4	8.1	8.6	8.1	8
					15 週	50	8.4	7.4	8.5	7.9	7.9	
	0202	男	58	SK-1403	1 週	50	8.4	7.3	8.7	8.6	7.8	7.9
	0701	男	75	SK-1403	1 週	50	8.9	7.3	8.4	8.5	8	7.7
	0702	女	45	SK-1403	1 週	50	8.8	7.4	8.5	9.2	8.5	8
	0703	女	69	SK-1403	1 週	50	8.9	7.4	8.4	8.6	8	7.8
	0704	女	77	SK-1403	1 週	50	8.7	7.3	8.5	8.7	8	7.7
	1002	男	61	SK-1403	7 週	25	8.7	7.4	8	8.8	9	8
	1004	男	68	SK-1403	2 週	50	8.4	7.2	7.9	8.3	8.2	
AJ1004	D2304	女	27	SK-1403	2 週	25	8.5	7.3	9.3	8.9	8.7	8.7
	D6102	女	64	SK-1403	16 週	200	9.3	7.4	9.1	7.8	7.6	7.5

表 2.7.4.7－36　臨床検査値の要約（血液学的検査）

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
SK-1403 群	併合	赤血球数(×10^4/μL)	0 週	318	365.4	47.2	269	358.0	537
			6 週	302	364.0	46.2	251	358.5	533
			12 週	307	361.3	47.2	248	354.0	548
			18 週	304	359.6	44.2	207	353.0	513
			28 週	197	358.4	41.2	236	352.0	527
			40 週	193	363.0	42.1	265	360.0	529
			52 週	185	362.3	41.6	276	358.0	514
		白血球数(/μL)	0 週	318	5861.0	1911.0	2300	5600.0	22900
			6 週	302	5959.3	1941.5	2400	5600.0	19600
			12 週	307	6036.2	1934.4	2600	5900.0	20400
			18 週	304	6007.9	1878.7	2700	5700.0	17800
			28 週	197	5951.8	1734.1	2900	5800.0	15300
			40 週	193	6017.1	1824.9	3000	5800.0	14700
			52 週	185	5886.5	2002.0	2700	5700.0	23200
		ヘモグロビン(g/dL)	0 週	318	11.16	1.26	8.2	11.00	16.4
			6 週	302	11.10	1.19	7.7	10.90	16.1
			12 週	307	11.01	1.25	7.8	10.90	16.8
			18 週	304	10.95	1.15	7.6	10.80	15.6
			28 週	197	10.89	1.10	6.3	10.90	15.2
			40 週	193	11.08	1.08	8.0	11.10	15.1
			52 週	185	11.13	1.17	8.0	11.10	16.3
		ヘマトクリット(%)	0 週	318	34.10	3.86	25.4	33.50	49.3
			6 週	302	33.93	3.62	24.1	33.30	48.7
			12 週	307	33.68	3.79	24.6	33.40	49.7
			18 週	304	33.62	3.56	22.9	33.10	48.1
			28 週	197	33.51	3.35	20.7	33.10	47.3
			40 週	193	33.96	3.38	24.9	33.80	47.4
			52 週	185	34.10	3.64	25.5	33.90	47.9
		血小板数(×10^4/μL)	0 週	318	20.75	5.52	8.4	20.60	43.4
			6 週	302	20.73	5.54	7.3	20.15	44.6

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			12 週	306	20.97	5.81	7.8	20.40	50.0
			18 週	303	20.94	5.86	10.2	20.20	44.9
			28 週	197	20.85	5.34	9.1	20.10	40.1
			40 週	193	20.85	5.76	9.5	20.40	41.9
			52 週	184	21.02	5.67	7.5	20.35	46.3
	AJ1002	赤血球数(×10^4/μL)	0 週	58	368.2	51.1	280	359.0	516
			6 週	57	370.8	51.7	297	365.0	533
			12 週	56	368.5	53.8	286	358.5	548
			18 週	56	365.9	50.3	297	351.5	513
			28 週	53	364.2	47.3	264	358.0	527
			40 週	53	363.2	48.3	281	344.0	529
			52 週	52	363.1	47.4	276	354.0	514
		白血球数(/μL)	0 週	58	5706.9	1649.3	2700	5500.0	10100
			6 週	57	5698.2	1839.9	2900	5300.0	12400
			12 週	56	6012.5	1632.7	3100	5900.0	11200
			18 週	56	5971.4	1604.4	3200	5800.0	12100
			28 週	53	6075.5	1658.5	3400	6000.0	10900
			40 週	53	6043.4	1743.5	3100	5800.0	10400
			52 週	52	5555.8	1388.7	2900	5500.0	9600
		ヘモグロビン(g/dL)	0 週	58	11.24	1.24	9.2	11.00	14.3
			6 週	57	11.39	1.27	10.1	10.90	15.5
			12 週	56	11.31	1.30	9.2	11.00	15.5
			18 週	56	11.10	1.26	9.1	10.85	14.7
			28 週	53	11.02	1.17	7.9	10.90	15.2
			40 週	53	10.92	1.15	9.2	10.80	15.1
			52 週	52	11.17	1.30	8.7	11.05	16.3
		ヘマトクリット(%)	0 週	58	34.39	3.93	27.5	33.45	46.9
			6 週	57	34.55	3.79	29.8	33.20	48.7
			12 週	56	34.42	4.18	27.6	33.70	49.7
			18 週	56	34.43	3.82	28.4	33.75	46.9
			28 週	53	34.07	3.74	24.4	33.30	47.3
			40 週	53	33.68	3.68	27.7	33.10	47.4
			52 週	52	34.15	3.96	28.2	33.55	47.9

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
		血小板数(×10^4/μL)	0 週	58	20.46	6.39	8.4	20.90	43.4
			6 週	57	21.04	6.56	9.3	20.70	44.6
			12 週	56	21.62	7.25	9.4	21.50	50.0
			18 週	56	21.16	7.20	10.2	20.75	44.9
			28 週	53	20.58	6.09	9.1	21.00	40.1
			40 週	53	20.95	6.34	9.5	21.40	41.9
			52 週	52	20.96	6.78	7.5	20.90	46.3
	AJ1003	赤血球数(×10^4/μL)	0 週	157	363.7	41.5	281	361.0	537
			6 週	143	358.8	39.3	262	357.0	513
			12 週	152	353.7	43.6	248	351.0	483
			18 週	150	353.3	38.3	207	351.0	470
			28 週	144	356.3	38.7	236	351.0	495
			40 週	140	362.9	39.7	265	362.0	473
			52 週	133	362.0	39.3	277	358.0	460
		白血球数(/μL)	0 週	157	5740.8	1553.6	2300	5700.0	10800
			6 週	143	5886.7	1727.9	2400	5700.0	13600
			12 週	152	5909.2	1755.0	2600	5800.0	11600
			18 週	150	5913.3	1801.4	2700	5600.0	14200
			28 週	144	5906.3	1764.5	2900	5750.0	15300
			40 週	140	6007.1	1860.8	3000	5750.0	14700
			52 週	133	6015.8	2186.8	2700	5800.0	23200
		ヘモグロビン(g/dL)	0 週	157	11.18	1.12	8.2	11.10	15.4
			6 週	143	11.02	1.01	7.7	11.00	15.4
			12 週	152	10.85	1.19	7.8	10.80	16.1
			18 週	150	10.80	1.06	7.6	10.70	15.6
			28 週	144	10.84	1.07	6.3	10.80	13.9
			40 週	140	11.15	1.06	8.0	11.10	14.0
			52 週	133	11.11	1.12	8.0	11.10	15.8
		ヘマトクリット(%)	0 週	157	34.06	3.47	25.5	33.80	47.6
			6 週	143	33.58	3.13	24.1	33.40	45.9
			12 週	152	33.10	3.63	24.6	33.30	46.1
			18 週	150	33.03	3.28	22.9	32.80	45.1

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			28 週	144	33.30	3.19	20.7	33.10	43.2
			40 週	140	34.06	3.26	24.9	34.15	42.6
			52 週	133	34.08	3.52	25.5	34.00	45.6
		血小板数(×10^4/μL)	0 週	157	20.90	5.37	9.8	20.30	36.5
			6 週	143	20.78	5.38	10.6	20.10	39.7
			12 週	151	20.97	5.54	11.2	20.20	39.6
			18 週	150	20.78	5.55	10.7	19.70	41.7
			28 週	144	20.96	5.06	11.3	19.85	37.6
			40 週	140	20.82	5.55	10.2	20.05	39.3
			52 週	132	21.04	5.20	11.2	20.25	38.7
	AJ1004	赤血球数(×10^4/μL)	0 週	103	366.5	53.0	269	356.0	523
			6 週	102	367.4	51.3	251	360.5	509
			12 週	99	368.9	47.2	262	355.0	490
			18 週	98	365.8	47.9	258	355.5	502
		白血球数(/μL)	0 週	103	6131.1	2455.4	2800	5600.0	22900
			6 週	102	6206.9	2247.7	2700	5800.0	19600
			12 週	99	6244.4	2317.9	3100	5900.0	20400
			18 週	98	6173.5	2130.3	3400	5800.0	17800
		ヘモグロビン(g/dL)	0 週	103	11.07	1.46	8.3	10.70	16.4
			6 週	102	11.05	1.35	8.2	10.90	16.1
			12 週	99	11.09	1.29	8.1	10.90	16.8
			18 週	98	11.10	1.20	8.4	11.00	15.3
		ヘマトクリット(%)	0 週	103	34.00	4.38	25.4	33.20	49.3
			6 週	102	34.09	4.12	24.2	33.30	48.1
			12 週	99	34.16	3.69	25.5	33.70	47.0
			18 週	98	34.05	3.70	25.4	33.60	48.1
		血小板数(×10^4/μL)	0 週	103	20.67	5.28	11.9	20.50	34.9
			6 週	102	20.48	5.17	7.3	19.95	35.2
			12 週	99	20.60	5.30	7.8	20.70	33.6
			18 週	97	21.05	5.53	11.1	21.10	34.9

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
プラセボ群	AJ1004	赤血球数(×10^4/μL)	0 週	50	356.8	42.9	274	354.5	451
			6 週	49	349.4	46.6	220	351.0	456
			12 週	45	348.4	43.0	253	347.0	445
			18 週	40	348.0	36.0	266	353.5	432
		白血球数(/μL)	0 週	50	5722.0	1758.0	2900	5500.0	9800
			6 週	49	5671.4	1922.6	2900	5100.0	10400
			12 週	45	5493.3	1508.2	2900	5300.0	9200
			18 週	40	5620.0	1470.1	3100	5350.0	9800
		ヘモグロビン(g/dL)	0 週	50	11.07	1.10	9.2	11.15	14.2
			6 週	49	10.79	1.25	7.0	10.80	14.3
			12 週	45	10.82	1.19	8.3	10.60	14.5
			18 週	40	10.84	1.10	7.9	10.80	14.1
		ヘマトクリット(%)	0 週	50	33.79	3.42	26.6	33.80	41.9
			6 週	49	33.16	4.00	21.1	33.30	42.2
			12 週	45	33.10	3.67	25.3	33.10	42.6
			18 週	40	33.01	3.40	24.1	33.15	40.9
		血小板数(×10^4/μL)	0 週	50	19.35	5.06	11.8	19.30	33.7
			6 週	49	18.84	4.50	10.7	17.90	31.4
			12 週	45	19.45	5.29	9.6	18.20	36.7
			18 週	40	19.86	4.92	11.7	19.40	32.1

表 2.7.4.7－37　臨床検査値の要約（血液生化学的検査，骨代謝マーカー，血清 P 及び Ca 濃度調節関連因子）

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
SK-1403 群	併合	総蛋白(g/dL)	0 週	318	6.34	0.43	5.2	6.35	7.7
			6 週	314	6.39	0.45	5.4	6.40	7.6
			12 週	308	6.37	0.42	5.3	6.35	7.5
			18 週	303	6.37	0.45	4.7	6.40	7.7
			28 週	196	6.40	0.47	5.3	6.40	7.9
			40 週	193	6.42	0.47	5.1	6.40	7.9
			52 週	191	6.33	0.44	5.0	6.30	7.4
		AST(GOT)(U/L)	0 週	318	12.6	5.7	2	11.5	46
			6 週	314	12.4	5.4	1	12.0	34
			12 週	308	12.9	10.1	3	11.0	147
			18 週	304	12.6	7.2	3	11.0	71
			28 週	197	12.5	6.9	2	12.0	65
			40 週	193	11.5	5.6	2	11.0	50
			52 週	191	12.7	7.4	2	12.0	77
		ALT(GPT)(U/L)	0 週	318	12.5	7.6	3	11.0	73
			6 週	314	11.5	6.4	3	10.0	60
			12 週	308	12.2	11.2	3	10.0	149
			18 週	304	11.7	10.3	2	10.0	136
			28 週	197	11.5	7.5	4	10.0	80
			40 週	193	11.3	6.4	3	10.0	67
			52 週	191	12.4	8.5	3	11.0	75
		LD(LDH)(U/L)	0 週	318	169.2	39.1	77	164.5	356
			6 週	304	181.3	40.5	87	176.0	363
			12 週	308	179.9	39.5	87	174.0	333
			18 週	304	179.2	40.9	80	171.5	366
			28 週	197	177.3	39.1	83	173.0	320
			40 週	193	173.6	34.6	70	168.0	297
			52 週	186	176.2	38.7	71	171.0	302
		総ビリルビン(mg/dL)	0 週	318	0.28	0.13	0.1	0.30	1.5
			6 週	314	0.28	0.15	0.1	0.30	1.3

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			12 週	308	0.29	0.16	0.1	0.30	1.8
			18 週	304	0.28	0.14	0.1	0.30	1.9
			28 週	197	0.28	0.18	0.1	0.20	2.1
			40 週	193	0.30	0.16	0.1	0.30	1.8
			52 週	191	0.29	0.19	0.1	0.30	2.3
		直接ビリルビン(mg/dL)	0 週	318	0.11	0.07	0.0	0.10	1.2
			6 週	314	0.11	0.08	0.0	0.10	1.1
			12 週	308	0.12	0.11	0.0	0.10	1.5
			18 週	304	0.11	0.10	0.0	0.10	1.6
			28 週	197	0.12	0.13	0.0	0.10	1.8
			40 週	193	0.12	0.12	0.0	0.10	1.6
			52 週	191	0.12	0.15	0.0	0.10	2.0
		ALP(U/L)	0 週	318	258.5	112.1	104	233.0	933
			6 週	314	275.2	121.5	104	244.0	830
			12 週	308	259.5	112.3	102	239.5	834
			18 週	304	244.0	109.6	91	212.0	763
			28 週	197	218.8	92.4	89	194.0	590
			40 週	193	204.8	85.2	73	190.0	579
			52 週	191	206.2	84.3	68	191.0	612
		γ-GTP(U/L)	0 週	318	22.8	20.5	6	17.0	186
			6 週	314	23.2	27.1	5	17.0	358
			12 週	308	23.2	24.4	4	16.0	203
			18 週	304	22.9	23.3	5	16.0	232
			28 週	197	21.8	19.4	4	16.0	143
			40 週	193	21.3	16.8	6	16.0	122
			52 週	191	22.2	20.9	6	15.0	194
		CPK(U/L)	0 週	318	117.8	110.0	15	88.5	1264
			6 週	314	123.7	91.6	23	101.5	887
			12 週	308	117.4	80.1	17	97.0	543
			18 週	304	122.6	87.3	26	99.0	696
			28 週	197	117.6	81.0	25	98.0	517
			40 週	193	127.8	104.9	22	95.0	936

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			52 週	191	128.0	103.2	23	102.0	678
		アミラーゼ(U/L)	0 週	318	120.2	51.7	22	110.5	542
			6 週	314	124.6	46.0	23	117.0	312
			12 週	308	121.2	41.2	24	115.0	282
			18 週	304	122.3	47.5	22	117.0	448
			28 週	197	116.2	39.3	25	113.0	301
			40 週	193	115.1	41.6	24	110.0	269
			52 週	191	114.7	43.3	22	109.0	319
		BUN(mg/dL)	0 週	318	62.14	13.48	28.1	62.00	105.3
			6 週	314	62.85	13.90	25.2	62.75	122.0
			12 週	308	62.38	13.39	17.4	62.25	107.9
			18 週	304	62.10	12.97	25.5	62.00	102.0
			28 週	197	61.89	13.38	23.6	61.90	102.2
			40 週	193	61.15	14.10	20.0	61.90	110.3
			52 週	191	61.54	13.12	30.6	60.70	103.5
		クレアチニン(mg/dL)	0 週	318	11.887	2.457	4.78	11.900	19.74
			6 週	314	11.858	2.371	4.28	11.925	19.62
			12 週	308	11.865	2.401	4.00	11.845	19.49
			18 週	304	11.841	2.410	4.25	11.880	18.96
			28 週	197	11.892	2.393	4.61	12.010	18.61
			40 週	193	12.126	2.493	4.41	12.210	19.31
			52 週	191	12.070	2.370	4.48	12.330	19.73
		尿酸(mg/dL)	0 週	318	7.23	1.39	2.7	7.30	11.2
			6 週	314	7.24	1.50	2.7	7.30	11.3
			12 週	308	7.20	1.35	2.6	7.20	11.0
			18 週	304	7.27	1.45	2.6	7.30	11.7
			28 週	197	7.35	1.45	3.1	7.40	11.7
			40 週	193	7.38	1.34	3.6	7.40	11.0
			52 週	191	7.26	1.32	3.5	7.40	10.5
		Na(mEq/L)	0 週	318	140.3	2.8	131	140.0	148
			6 週	314	140.5	2.8	130	141.0	151

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			12 週	308	140.3	2.7	130	141.0	147
			18 週	304	140.0	2.7	130	140.0	146
			28 週	197	140.5	2.7	131	141.0	149
			40 週	193	140.2	2.7	129	140.0	146
			52 週	191	140.1	2.7	130	141.0	146
		Cl(mEq/L)	0 週	318	101.6	3.6	91	102.0	113
			6 週	314	102.2	3.7	91	102.0	111
			12 週	308	101.8	3.5	90	102.0	110
			18 週	304	102.3	3.8	90	102.0	115
			28 週	197	102.6	3.8	91	102.0	115
			40 週	193	102.9	4.0	90	103.0	112
			52 週	191	101.9	3.7	90	102.0	112
		K(mEq/L)	0 週	318	4.87	0.69	2.9	4.90	7.6
			6 週	314	4.89	0.65	3.4	4.90	7.7
			12 週	308	4.91	0.71	2.6	4.90	7.2
			18 週	304	4.87	0.69	3.3	4.90	7.2
			28 週	197	4.91	0.70	3.1	4.90	7.1
			40 週	193	4.79	0.67	3.2	4.80	6.3
			52 週	191	4.79	0.67	3.3	4.80	6.8
		Ca(mg/dL)	0 週	318	9.15	0.66	7.4	9.10	11.0
			6 週	314	8.39	0.60	6.5	8.40	10.5
			12 週	308	8.37	0.57	6.8	8.35	10.1
			18 週	304	8.44	0.62	6.6	8.40	10.7
			28 週	197	8.67	0.64	7.2	8.60	10.7
			40 週	193	8.74	0.64	7.5	8.70	12.1
			52 週	191	8.77	0.62	7.3	8.70	11.3
		補正 Ca(mg/dL)	0 週	318	9.50	0.65	8.3	9.50	11.6
			6 週	314	8.72	0.57	7.5	8.70	10.9
			12 週	308	8.71	0.56	7.6	8.60	10.9
			18 週	303	8.75	0.58	7.6	8.70	10.7
			28 週	196	8.99	0.58	7.8	8.90	10.8
			40 週	193	9.04	0.60	7.9	9.00	12.8

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			52 週	191	9.10	0.59	7.9	9.00	11.8
		P(mg/dL)	0 週	318	5.77	1.28	2.5	5.70	11.3
			6 週	314	5.30	1.33	1.4	5.20	10.7
			12 週	308	5.11	1.36	1.8	5.00	8.8
			18 週	304	5.10	1.44	1.7	5.00	10.7
			28 週	197	5.41	1.34	2.0	5.30	12.9
			40 週	193	5.35	1.30	1.9	5.20	11.4
			52 週	191	5.19	1.17	2.6	5.10	8.8
		Mg(mg/dL)	0 週	318	2.56	0.37	1.7	2.50	4.9
			6 週	314	2.51	0.37	1.5	2.50	4.6
			12 週	308	2.48	0.37	1.6	2.50	4.8
			18 週	304	2.48	0.37	1.6	2.50	4.6
			28 週	197	2.48	0.38	1.7	2.40	4.6
			40 週	193	2.47	0.37	1.7	2.40	4.8
			52 週	191	2.45	0.37	1.7	2.40	4.8
		総コレステロール(mg/dL)	0 週	318	155.1	31.1	75	152.5	262
			6 週	314	155.7	30.1	82	152.0	243
			12 週	308	156.1	33.0	72	152.0	251
			18 週	304	155.0	32.8	71	154.0	244
			28 週	197	156.1	33.4	69	156.0	248
			40 週	193	155.5	32.4	69	153.0	236
			52 週	191	155.9	29.6	72	153.0	256
		トリグリセライド(mg/dL)	0 週	318	121.9	85.8	19	98.0	546
			6 週	314	119.8	90.8	23	92.5	803
			12 週	308	124.2	98.1	25	95.0	801
			18 週	304	123.9	122.5	28	91.0	1721
			28 週	197	121.8	136.4	20	92.0	1670
			40 週	193	122.3	83.5	22	97.0	594
			52 週	191	117.0	81.0	20	92.0	508
		グルコース(mg/dL)	0 週	318	126.2	40.5	71	113.5	288
			6 週	314	120.8	36.3	44	113.0	351

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			12 週	308	119.8	40.5	62	109.5	430
			18 週	304	119.5	36.7	39	111.0	387
			28 週	197	115.5	29.8	69	108.0	277
			40 週	193	115.7	28.8	67	108.0	229
			52 週	191	117.8	32.2	43	108.0	255
		iFGF23(ng/L)	0 週	318	15648.04	26406.75	53.5	7535.00	298000.0
			6 週	314	9795.19	17623.18	20.2	4010.00	194000.0
			12 週	308	8427.60	15509.49	21.7	3100.00	133000.0
			18 週	304	8996.81	16917.69	12.1	3090.00	143000.0
			28 週	54	11755.02	20197.72	30.0	4110.00	105000.0
			40 週	53	10320.25	16158.95	28.0	3900.00	84000.0
			52 週	191	10333.41	14606.58	56.0	4350.00	96600.0
		BAP(μg/L)	0 週	318	17.15	9.31	5.9	14.90	82.5
			6 週	57	20.99	14.14	8.1	17.20	73.3
			12 週	308	17.15	9.32	6.4	14.65	60.6
			18 週	56	16.21	11.17	6.6	12.15	69.6
			28 週	54	12.71	7.92	5.8	11.15	53.2
			40 週	53	11.50	7.04	4.9	10.00	47.8
			52 週	191	10.92	4.39	4.3	9.70	33.5
		total P1NP(μg/L)	0 週	318	366.48	245.85	41.2	308.50	1200.0
			6 週	55	329.31	259.08	79.0	271.00	1200.0
			12 週	308	288.47	184.46	37.3	243.50	1200.0
			18 週	56	266.75	221.01	66.6	204.50	1200.0
			28 週	54	245.72	205.63	77.1	197.00	1200.0
			40 週	53	212.01	152.03	58.9	167.00	955.0
			52 週	191	194.81	134.35	32.7	159.00	1020.0
		TRACP-5b(mU/dL)	0 週	318	722.9	353.0	139	673.5	2260
			6 週	57	539.0	303.4	157	473.0	1640
			12 週	308	450.2	252.8	82	410.5	1620
			18 週	56	480.0	264.4	164	420.5	1550
			28 週	54	455.2	272.9	140	398.0	1550
			40 週	53	422.0	252.0	136	342.0	1290

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			52 週	191	350.5	184.3	85	326.0	978
	AJ1002	総蛋白(g/dL)	0 週	58	6.32	0.38	5.4	6.40	7.2
			6 週	57	6.42	0.44	5.4	6.40	7.4
			12 週	57	6.44	0.42	5.3	6.50	7.4
			18 週	55	6.40	0.47	4.7	6.40	7.5
			28 週	52	6.42	0.42	5.3	6.40	7.5
			40 週	53	6.40	0.43	5.3	6.40	7.9
			52 週	52	6.38	0.45	5.0	6.40	7.2
		AST(GOT)(U/L)	0 週	58	12.1	4.8	4	11.0	28
			6 週	57	12.6	4.8	5	12.0	29
			12 週	57	13.5	5.0	6	12.0	29
			18 週	56	13.4	5.3	6	12.0	31
			28 週	53	14.2	7.2	3	13.0	44
			40 週	53	12.2	4.1	4	12.0	25
			52 週	52	12.5	4.4	3	12.5	25
		ALT(GPT)(U/L)	0 週	58	11.7	6.4	3	11.0	37
			6 週	57	11.0	6.4	4	10.0	42
			12 週	57	12.2	6.5	4	11.0	45
			18 週	56	11.8	7.3	5	10.0	41
			28 週	53	11.8	6.4	4	10.0	37
			40 週	53	11.2	4.7	4	11.0	24
			52 週	52	11.2	5.1	4	10.0	24
		LD(LDH)(U/L)	0 週	58	162.1	36.1	77	159.5	280
			6 週	57	174.7	44.4	87	169.0	363
			12 週	57	173.8	36.5	87	169.0	252
			18 週	56	176.4	40.5	80	172.0	300
			28 週	53	176.2	44.0	83	168.0	320
			40 週	53	171.2	35.8	70	168.0	239
			52 週	52	176.5	42.0	71	167.0	267
		総ビリルビン(mg/dL)	0 週	58	0.29	0.19	0.1	0.30	1.5
			6 週	57	0.29	0.18	0.1	0.20	1.3
			12 週	57	0.30	0.23	0.1	0.20	1.8

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			18 週	56	0.29	0.24	0.1	0.20	1.9
			28 週	53	0.31	0.28	0.1	0.20	2.1
			40 週	53	0.31	0.24	0.1	0.30	1.8
			52 週	52	0.32	0.31	0.1	0.30	2.3
		直接ビリルビン(mg/dL)	0 週	58	0.13	0.15	0.0	0.10	1.2
			6 週	57	0.13	0.15	0.0	0.10	1.1
			12 週	57	0.14	0.19	0.0	0.10	1.5
			18 週	56	0.14	0.20	0.1	0.10	1.6
			28 週	53	0.15	0.24	0.1	0.10	1.8
			40 週	53	0.14	0.21	0.0	0.10	1.6
			52 週	52	0.15	0.27	0.0	0.10	2.0
		ALP(U/L)	0 週	58	278.7	130.5	143	239.0	724
			6 週	57	300.2	152.4	141	248.0	830
			12 週	57	268.1	109.9	110	245.0	546
			18 週	56	256.6	120.8	98	219.5	763
			28 週	53	243.8	112.2	89	202.0	590
			40 週	53	219.3	95.4	81	189.0	579
			52 週	52	215.8	86.0	77	193.0	493
		γ-GTP(U/L)	0 週	58	19.7	12.7	7	15.0	77
			6 週	57	25.6	46.7	7	16.0	358
			12 週	57	22.1	19.9	6	16.0	121
			18 週	56	20.5	13.6	7	16.5	69
			28 週	53	19.6	15.8	6	14.0	99
			40 週	53	18.2	9.9	7	14.0	54
			52 週	52	18.4	11.2	6	15.0	63
		CPK(U/L)	0 週	58	103.4	69.6	15	82.5	313
			6 週	57	101.1	52.5	23	87.0	259
			12 週	57	112.7	79.6	30	97.0	513
			18 週	56	123.9	82.4	29	105.5	439
			28 週	53	103.2	49.8	35	98.0	262
			40 週	53	113.5	74.3	22	96.0	397
			52 週	52	110.6	60.2	23	103.5	271

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
		アミラーゼ(U/L)	0 週	58	107.2	36.2	28	104.5	189
			6 週	57	114.2	39.1	23	114.0	199
			12 週	57	115.6	37.2	29	114.0	207
			18 週	56	121.9	41.2	27	120.5	304
			28 週	53	121.3	38.5	29	123.0	251
			40 週	53	112.8	36.6	32	114.0	195
			52 週	52	103.1	33.5	30	105.0	172
		BUN(mg/dL)	0 週	58	58.51	12.02	28.1	59.90	81.0
			6 週	57	61.32	16.18	29.6	62.70	122.0
			12 週	57	61.89	12.60	38.5	63.90	93.0
			18 週	56	64.12	13.24	25.5	65.05	86.9
			28 週	53	64.75	13.11	35.0	65.40	87.8
			40 週	53	65.62	17.63	20.0	64.80	110.3
			52 週	52	57.48	12.80	30.6	55.95	89.5
		クレアチニン(mg/dL)	0 週	58	11.575	2.037	4.81	11.825	16.83
			6 週	57	11.411	2.003	4.69	11.650	16.31
			12 週	57	11.534	1.889	4.87	11.590	16.15
			18 週	56	11.546	2.087	4.64	11.730	16.19
			28 週	53	11.490	2.064	4.61	11.990	16.18
			40 週	53	11.644	2.357	4.48	11.650	17.25
			52 週	52	11.555	2.255	5.46	11.975	16.22
		尿酸(mg/dL)	0 週	58	6.96	1.29	3.9	7.20	9.0
			6 週	57	6.95	1.33	3.7	7.10	9.8
			12 週	57	6.92	1.24	3.4	7.30	9.1
			18 週	56	7.16	1.36	4.4	7.25	9.8
			28 週	53	7.04	1.35	4.1	7.20	10.8
			40 週	53	7.16	1.34	3.6	7.20	9.4
			52 週	52	7.01	1.29	3.5	7.35	9.5
		Na(mEq/L)	0 週	58	139.8	2.7	132	140.0	145
			6 週	57	139.8	2.7	133	140.0	145
			12 週	57	139.5	3.1	130	140.0	145

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			18 週	56	139.7	2.6	132	140.0	144
			28 週	53	140.2	2.6	133	141.0	147
			40 週	53	139.7	2.8	131	140.0	144
			52 週	52	139.9	2.8	130	141.0	144
		Cl(mEq/L)	0 週	58	101.6	4.2	91	102.0	111
			6 週	57	100.8	4.1	91	101.0	110
			12 週	57	100.3	4.2	90	101.0	109
			18 週	56	100.0	4.0	90	101.0	109
			28 週	53	100.2	3.6	91	101.0	109
			40 週	53	100.0	3.6	90	100.0	109
			52 週	52	100.1	3.6	90	101.0	108
		K(mEq/L)	0 週	58	4.96	0.84	3.2	4.90	7.6
			6 週	57	4.87	0.60	3.4	4.90	6.2
			12 週	57	4.99	0.64	3.6	5.00	6.3
			18 週	56	4.99	0.74	3.3	5.00	7.2
			28 週	53	4.95	0.73	3.4	4.90	6.3
			40 週	53	4.86	0.77	3.2	4.90	6.3
			52 週	52	4.82	0.74	3.3	4.70	6.8
		Ca(mg/dL)	0 週	58	9.23	0.70	7.4	9.20	10.9
			6 週	57	8.37	0.57	6.5	8.40	9.6
			12 週	57	8.40	0.64	7.2	8.30	10.0
			18 週	56	8.33	0.62	6.6	8.30	10.3
			28 週	53	8.58	0.68	7.2	8.50	10.5
			40 週	53	8.62	0.63	7.5	8.50	10.2
			52 週	52	8.84	0.82	7.3	8.70	11.3
		補正 Ca(mg/dL)	0 週	58	9.56	0.68	8.4	9.50	10.9
			6 週	57	8.68	0.53	7.5	8.70	9.7
			12 週	57	8.69	0.62	7.7	8.60	10.3
			18 週	55	8.55	0.56	7.6	8.50	10.3
			28 週	52	8.82	0.65	7.8	8.60	10.6
			40 週	53	8.88	0.61	7.9	8.80	10.5
			52 週	52	9.13	0.81	7.9	8.95	11.8

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
		P(mg/dL)	0 週	58	5.33	1.13	3.3	5.25	9.3
			6 週	57	4.87	1.39	2.2	4.80	10.7
			12 週	57	4.87	1.26	2.6	4.90	8.4
			18 週	56	4.98	1.63	2.0	4.80	10.2
			28 週	53	5.53	1.59	3.1	5.40	12.9
			40 週	53	5.30	1.56	1.9	5.20	11.4
			52 週	52	4.93	1.35	2.6	4.75	8.8
		Mg(mg/dL)	0 週	58	2.48	0.33	1.8	2.50	3.4
			6 週	57	2.45	0.30	1.8	2.50	3.1
			12 週	57	2.44	0.33	1.7	2.40	3.3
			18 週	56	2.46	0.35	1.6	2.45	3.2
			28 週	53	2.49	0.38	1.7	2.50	3.4
			40 週	53	2.50	0.37	1.7	2.50	3.5
			52 週	52	2.45	0.34	1.7	2.45	3.5
		総コレステロール(mg/dL)	0 週	58	152.5	24.4	96	152.0	198
			6 週	57	156.6	24.9	90	156.0	220
			12 週	57	160.3	29.9	78	154.0	251
			18 週	56	164.9	29.5	79	163.5	229
			28 週	53	164.4	28.3	90	162.0	225
			40 週	53	156.2	29.5	86	157.0	220
			52 週	52	157.1	28.2	78	154.5	229
		トリグリセライド(mg/dL)	0 週	58	123.4	67.8	40	107.5	355
			6 週	57	121.2	71.9	40	95.0	338
			12 週	57	134.5	120.0	36	96.0	801
			18 週	56	140.6	223.4	32	86.5	1721
			28 週	53	136.2	221.3	36	95.0	1670
			40 週	53	117.7	62.6	29	102.0	303
			52 週	52	132.6	87.4	38	110.5	508
		グルコース(mg/dL)	0 週	58	127.0	38.7	82	114.0	239
			6 週	57	122.0	35.9	63	117.0	244
			12 週	57	115.5	33.4	67	110.0	226

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			18 週	56	121.0	45.6	67	110.0	376
			28 週	53	110.6	27.4	76	102.0	210
			40 週	53	118.0	31.9	67	113.0	229
			52 週	52	118.2	28.6	78	113.5	215
		iFGF23(ng/L)	0 週	58	13509.67	18201.65	125.0	6300.00	97500.0
			6 週	57	8168.65	11816.94	88.0	3200.00	46800.0
			12 週	57	8264.53	13349.64	69.0	3590.00	62500.0
			18 週	56	8787.88	13323.68	46.0	4400.00	61300.0
			28 週	53	11969.77	20328.67	30.0	4130.00	105000.0
			40 週	53	10320.25	16158.95	28.0	3900.00	84000.0
			52 週	52	8885.44	11806.72	56.0	3800.00	51700.0
		BAP(μg/L)	0 週	58	18.23	13.22	6.2	14.10	82.5
			6 週	57	20.99	14.14	8.1	17.20	73.3
			12 週	57	17.99	10.48	7.9	14.90	57.7
			18 週	56	16.21	11.17	6.6	12.15	69.6
			28 週	53	12.68	8.00	5.8	11.00	53.2
			40 週	53	11.50	7.04	4.9	10.00	47.8
			52 週	52	11.23	5.60	5.4	9.30	33.5
		total P1NP(μg/L)	0 週	58	402.32	288.35	53.4	322.00	1200.0
			6 週	55	329.31	259.08	79.0	271.00	1200.0
			12 週	57	271.36	205.89	73.8	222.00	1200.0
			18 週	56	266.75	221.01	66.6	204.50	1200.0
			28 週	53	248.57	206.52	77.1	197.00	1200.0
			40 週	53	212.01	152.03	58.9	167.00	955.0
			52 週	52	236.53	191.65	32.7	177.50	1020.0
		TRACP-5b(mU/dL)	0 週	58	755.9	413.3	236	682.0	2260
			6 週	57	539.0	303.4	157	473.0	1640
			12 週	57	502.2	285.7	166	434.0	1620
			18 週	56	480.0	264.4	164	420.5	1550
			28 週	53	452.7	274.9	140	396.0	1550
			40 週	53	422.0	252.0	136	342.0	1290
			52 週	52	405.3	205.1	172	368.0	978

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
	AJ1003	総蛋白(g/dL)	0 週	157	6.33	0.45	5.2	6.40	7.6
			6 週	155	6.36	0.46	5.4	6.30	7.6
			12 週	152	6.35	0.43	5.4	6.30	7.5
			18 週	150	6.34	0.45	5.3	6.30	7.7
			28 週	144	6.39	0.49	5.3	6.40	7.9
			40 週	140	6.42	0.48	5.1	6.40	7.7
			52 週	139	6.32	0.44	5.4	6.30	7.4
		AST(GOT)(U/L)	0 週	157	12.7	6.3	2	12.0	46
			6 週	155	12.3	5.5	1	12.0	34
			12 週	152	12.5	7.1	3	11.0	58
			18 週	150	12.5	8.5	3	11.0	71
			28 週	144	11.9	6.7	2	11.0	65
			40 週	140	11.3	6.1	2	10.5	50
			52 週	139	12.8	8.3	2	12.0	77
		ALT(GPT)(U/L)	0 週	157	13.5	8.8	4	11.0	73
			6 週	155	12.3	7.1	4	11.0	60
			12 週	152	12.3	9.9	4	10.0	79
			18 週	150	12.3	13.2	2	10.0	136
			28 週	144	11.4	7.8	4	10.0	80
			40 週	140	11.4	6.9	3	10.0	67
			52 週	139	12.8	9.4	3	11.0	75
		LD(LDH)(U/L)	0 週	157	167.4	39.9	97	164.0	349
			6 週	145	178.6	38.8	100	174.0	355
			12 週	152	178.7	38.4	108	176.5	315
			18 週	150	174.4	40.3	102	166.0	366
			28 週	144	177.7	37.2	106	174.5	295
			40 週	140	174.5	34.3	103	169.5	297
			52 週	134	176.0	37.5	102	173.0	302
		総ビリルビン(mg/dL)	0 週	157	0.28	0.10	0.1	0.30	0.7
			6 週	155	0.28	0.13	0.1	0.30	1.1
			12 週	152	0.27	0.12	0.1	0.20	0.9
			18 週	150	0.27	0.11	0.1	0.30	1.1

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			28 週	144	0.27	0.12	0.1	0.30	1.0
			40 週	140	0.29	0.12	0.1	0.30	0.9
			52 週	139	0.28	0.12	0.1	0.20	0.8
		直接ビリルビン(mg/dL)	0 週	157	0.10	0.04	0.0	0.10	0.3
			6 週	155	0.11	0.05	0.0	0.10	0.4
			12 週	152	0.10	0.05	0.0	0.10	0.5
			18 週	150	0.10	0.05	0.0	0.10	0.6
			28 週	144	0.11	0.05	0.0	0.10	0.5
			40 週	140	0.11	0.06	0.0	0.10	0.5
			52 週	139	0.12	0.06	0.0	0.10	0.5
		ALP(U/L)	0 週	157	240.2	101.6	104	217.0	933
			6 週	155	257.6	103.8	104	239.0	733
			12 週	152	249.3	102.1	102	231.0	622
			18 週	150	228.7	95.7	91	205.0	628
			28 週	144	209.6	82.6	91	190.5	563
			40 週	140	199.3	80.7	73	190.0	573
			52 週	139	202.5	83.7	68	190.0	612
		γ-GTP(U/L)	0 週	157	22.2	16.2	7	17.0	101
			6 週	155	22.1	17.0	7	17.0	126
			12 週	152	23.1	23.1	7	17.0	203
			18 週	150	23.0	23.9	6	16.0	232
			28 週	144	22.6	20.5	4	16.0	143
			40 週	140	22.5	18.7	6	17.0	122
			52 週	139	23.6	23.3	6	16.0	194
		CPK(U/L)	0 週	157	129.7	138.2	27	96.0	1264
			6 週	155	134.5	110.4	29	104.0	887
			12 週	152	119.6	82.5	26	94.0	543
			18 週	150	122.1	83.6	26	96.5	529
			28 週	144	122.9	89.4	25	97.0	517
			40 週	140	133.2	114.2	25	94.5	936
			52 週	139	134.5	114.8	29	102.0	678

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
		アミラーゼ(U/L)	0 週	157	118.9	44.0	22	111.0	284
			6 週	155	126.0	43.5	23	123.0	274
			12 週	152	121.4	39.4	24	115.5	282
			18 週	150	120.7	45.2	22	113.5	311
			28 週	144	114.3	39.5	25	108.5	301
			40 週	140	115.9	43.5	24	108.5	269
			52 週	139	119.0	45.8	22	110.0	319
		BUN(mg/dL)	0 週	157	63.62	13.24	33.5	63.10	105.3
			6 週	155	63.63	13.43	33.5	63.10	96.2
			12 週	152	63.26	13.11	27.6	62.40	97.3
			18 週	150	63.06	12.86	25.7	62.10	102.0
			28 週	144	60.84	13.36	23.6	61.55	102.2
			40 週	140	59.46	12.16	31.9	60.15	91.2
			52 週	139	63.06	12.97	31.7	62.00	103.5
		クレアチニン(mg/dL)	0 週	157	12.146	2.460	4.78	12.170	19.16
			6 週	155	12.055	2.410	4.28	11.970	19.62
			12 週	152	12.030	2.453	4.00	12.030	19.49
			18 週	150	12.022	2.402	4.25	12.120	18.54
			28 週	144	12.039	2.494	4.64	12.070	18.61
			40 週	140	12.309	2.527	4.41	12.385	19.31
			52 週	139	12.262	2.391	4.48	12.440	19.73
		尿酸(mg/dL)	0 週	157	7.41	1.33	3.4	7.40	11.2
			6 週	155	7.39	1.50	2.8	7.40	11.3
			12 週	152	7.37	1.35	3.3	7.30	11.0
			18 週	150	7.45	1.43	3.8	7.50	11.7
			28 週	144	7.47	1.48	3.1	7.40	11.7
			40 週	140	7.47	1.34	4.2	7.50	11.0
			52 週	139	7.35	1.32	4.5	7.40	10.5
		Na(mEq/L)	0 週	157	140.7	2.8	133	141.0	148
			6 週	155	141.1	2.8	133	141.0	151
			12 週	152	140.9	2.5	133	141.0	147
			18 週	150	140.4	2.6	130	141.0	146

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			28 週	144	140.6	2.7	131	141.0	149
			40 週	140	140.4	2.7	129	141.0	146
			52 週	139	140.2	2.6	130	140.0	146
		Cl(mEq/L)	0 週	157	101.7	3.8	93	102.0	113
			6 週	155	102.9	3.5	94	103.0	111
			12 週	152	102.2	3.3	93	102.0	110
			18 週	150	102.9	3.8	91	103.0	115
			28 週	144	103.4	3.4	95	103.0	115
			40 週	140	104.1	3.6	90	105.0	112
			52 週	139	102.5	3.5	90	102.0	112
		K(mEq/L)	0 週	157	4.86	0.63	3.5	4.90	6.7
			6 週	155	4.92	0.70	3.4	4.90	7.7
			12 週	152	4.87	0.68	3.2	4.85	6.4
			18 週	150	4.83	0.66	3.5	4.80	6.9
			28 週	144	4.89	0.70	3.1	4.85	7.1
			40 週	140	4.77	0.63	3.4	4.80	6.3
			52 週	139	4.78	0.64	3.3	4.80	6.3
		Ca(mg/dL)	0 週	157	9.22	0.62	7.8	9.20	11.0
			6 週	155	8.45	0.57	6.7	8.50	10.5
			12 週	152	8.46	0.53	6.9	8.40	10.1
			18 週	150	8.54	0.58	7.3	8.50	10.7
			28 週	144	8.70	0.62	7.5	8.60	10.7
			40 週	140	8.79	0.63	7.5	8.70	12.1
			52 週	139	8.75	0.53	7.5	8.70	10.5
		補正 Ca(mg/dL)	0 週	157	9.57	0.60	8.5	9.50	11.6
			6 週	155	8.80	0.55	7.6	8.70	10.9
			12 週	152	8.80	0.53	7.6	8.70	10.7
			18 週	150	8.85	0.55	7.7	8.80	10.7
			28 週	144	9.05	0.55	8.1	9.00	10.8
			40 週	140	9.10	0.59	8.0	9.00	12.8
			52 週	139	9.10	0.49	8.2	9.00	10.8

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
		P(mg/dL)	0 週	157	5.81	1.26	2.5	5.80	11.3
			6 週	155	5.47	1.25	2.4	5.30	8.9
			12 週	152	5.25	1.28	2.7	5.05	8.8
			18 週	150	5.23	1.24	1.9	5.10	10.7
			28 週	144	5.36	1.24	2.0	5.30	8.5
			40 週	140	5.37	1.19	3.1	5.20	9.1
			52 週	139	5.29	1.08	2.8	5.30	8.7
		Mg(mg/dL)	0 週	157	2.54	0.38	1.7	2.50	4.9
			6 週	155	2.48	0.38	1.5	2.50	4.6
			12 週	152	2.46	0.38	1.6	2.40	4.8
			18 週	150	2.48	0.38	1.7	2.40	4.6
			28 週	144	2.48	0.38	1.7	2.40	4.6
			40 週	140	2.46	0.38	1.8	2.40	4.8
			52 週	139	2.45	0.39	1.8	2.40	4.8
		総コレステロール(mg/dL)	0 週	157	155.2	30.4	79	153.0	243
			6 週	155	154.7	30.0	82	152.0	243
			12 週	152	154.7	32.8	78	151.0	251
			18 週	150	151.7	32.6	71	153.0	244
			28 週	144	153.0	34.7	69	147.0	248
			40 週	140	155.2	33.6	69	152.5	236
			52 週	139	155.4	30.2	72	152.0	256
		トリグリセライド(mg/dL)	0 週	157	125.7	90.8	19	97.0	546
			6 週	155	122.3	99.4	23	97.0	803
			12 週	152	124.1	90.2	25	95.5	532
			18 週	150	118.9	80.8	30	89.0	487
			28 週	144	116.6	87.1	20	91.0	668
			40 週	140	124.1	90.3	22	88.0	594
			52 週	139	111.1	78.0	20	88.0	501
		グルコース(mg/dL)	0 週	157	125.2	41.3	74	112.0	288
			6 週	155	118.3	35.2	44	108.0	255
			12 週	152	116.7	32.0	62	107.5	273
			18 週	150	117.0	31.0	39	110.0	247

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			28 週	144	117.3	30.5	69	110.0	277
			40 週	140	114.9	27.6	74	108.0	214
			52 週	139	117.6	33.6	43	106.0	255
		iFGF23(ng/L)	0 週	157	17054.83	31866.97	106.0	7450.00	298000.0
			6 週	155	10865.37	21599.61	20.2	4090.00	194000.0
			12 週	152	8774.21	17601.97	21.7	3100.00	133000.0
			18 週	150	9359.23	19711.70	24.6	2765.00	143000.0
			28 週	1	373.00	-	373.0	373.00	373.0
			52 週	139	10875.10	15528.79	269.0	4380.00	96600.0
		BAP(µg/L)	0 週	157	16.08	7.29	5.9	14.50	49.3
			12 週	152	16.47	8.16	6.7	14.75	56.3
			28 週	1	14.20	-	14.2	14.20	14.2
			52 週	139	10.80	3.85	4.3	9.90	27.7
		total P1NP(µg/L)	0 週	157	337.58	241.16	41.2	276.00	1200.0
			12 週	152	303.20	192.70	37.3	256.00	1190.0
			28 週	1	94.90	-	94.9	94.90	94.9
			52 週	139	179.20	101.86	43.0	153.00	647.0
		TRACP-5b(mU/dL)	0 週	157	699.3	337.5	139	630.0	1500
			12 週	152	435.1	234.7	88	403.5	1170
			28 週	1	590.0	-	590	590.0	590
			52 週	139	330.1	172.3	85	300.0	932
	AJ1004	総蛋白(g/dL)	0 週	103	6.35	0.43	5.4	6.30	7.7
			6 週	102	6.41	0.45	5.4	6.40	7.6
			12 週	99	6.36	0.41	5.3	6.30	7.4
			18 週	98	6.39	0.43	5.4	6.35	7.6
		AST(GOT)(U/L)	0 週	103	12.5	5.3	5	11.0	31
			6 週	102	12.3	5.8	3	11.0	34
			12 週	99	13.3	15.0	4	10.0	147
			18 週	98	12.2	6.0	4	10.5	37
		ALT(GPT)(U/L)	0 週	103	11.4	5.8	3	10.0	33

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			6 週	102	10.5	5.0	3	9.5	29
			12 週	99	11.9	14.8	3	9.0	149
			18 週	98	10.9	5.7	2	9.5	36
		LD(LDH)(U/L)	0 週	103	175.9	39.0	99	171.0	356
			6 週	102	188.8	39.8	109	182.0	345
			12 週	99	185.2	42.3	102	175.0	333
			18 週	98	188.2	40.8	113	181.0	303
		総ビリルビン(mg/dL)	0 週	103	0.28	0.13	0.1	0.30	0.9
			6 週	102	0.29	0.15	0.1	0.30	1.3
			12 週	99	0.31	0.16	0.1	0.30	1.4
			18 週	98	0.28	0.10	0.1	0.30	0.6
		直接ビリルビン(mg/dL)	0 週	103	0.11	0.05	0.0	0.10	0.4
			6 週	102	0.12	0.07	0.0	0.10	0.6
			12 週	99	0.13	0.10	0.0	0.10	1.0
			18 週	98	0.11	0.04	0.0	0.10	0.2
		ALP(U/L)	0 週	103	275.0	112.7	114	246.0	719
			6 週	102	288.0	124.4	123	249.5	751
			12 週	99	270.3	127.4	116	241.0	834
			18 週	98	260.2	120.4	98	230.0	608
		γ-GTP(U/L)	0 週	103	25.6	28.4	6	17.0	186
			6 週	102	23.6	24.9	5	17.0	170
			12 週	99	23.9	28.5	4	16.0	181
			18 週	98	24.1	26.5	5	17.0	170
		CPK(U/L)	0 週	103	107.7	72.5	22	87.0	479
			6 週	102	120.1	73.7	30	105.5	519
			12 週	99	116.7	77.3	17	99.0	455
			18 週	98	122.6	96.1	30	98.0	696
		アミラーゼ(U/L)	0 週	103	129.4	66.6	41	117.0	542
			6 週	102	128.2	52.3	41	115.0	312

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			12 週	99	124.1	45.8	46	115.0	265
			18 週	98	125.1	54.3	45	117.0	448
		BUN(mg/dL)	0 週	103	61.92	14.32	31.5	61.40	104.7
			6 週	102	62.51	13.27	25.2	62.70	93.6
			12 週	99	61.31	14.28	17.4	61.40	107.9
			18 週	98	59.49	12.72	29.7	60.40	99.9
		クレアチニン(mg/dL)	0 週	103	11.668	2.641	5.10	11.690	19.74
			6 週	102	11.808	2.484	6.47	11.790	18.35
			12 週	99	11.801	2.578	5.50	11.700	19.06
			18 週	98	11.734	2.586	5.46	11.485	18.96
		尿酸(mg/dL)	0 週	103	7.10	1.50	2.7	7.20	10.6
			6 週	102	7.18	1.55	2.7	7.30	10.5
			12 週	99	7.09	1.37	2.6	7.10	10.3
			18 週	98	7.06	1.52	2.6	7.10	11.2
		Na(mEq/L)	0 週	103	140.0	2.7	131	140.0	146
			6 週	102	140.1	2.8	130	140.0	146
			12 週	99	139.9	2.7	133	140.0	146
			18 週	98	139.6	2.8	130	140.0	146
		Cl(mEq/L)	0 週	103	101.4	3.1	94	101.0	110
			6 週	102	102.0	3.4	94	102.0	110
			12 週	99	101.9	2.9	95	102.0	109
			18 週	98	102.6	3.4	93	103.0	115
		K(mEq/L)	0 週	103	4.86	0.67	2.9	4.90	6.4
			6 週	102	4.86	0.61	3.5	4.80	6.4
			12 週	99	4.94	0.80	2.6	4.80	7.2
			18 週	98	4.85	0.69	3.3	4.80	6.4
		Ca(mg/dL)	0 週	103	9.01	0.68	7.4	8.90	10.6
			6 週	102	8.31	0.64	7.1	8.30	10.5
			12 週	99	8.23	0.57	6.8	8.30	10.0

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			18 週	98	8.37	0.65	6.8	8.30	10.0
		補正 Ca(mg/dL)	0 週	103	9.34	0.68	8.3	9.30	11.0
			6 週	102	8.64	0.61	7.6	8.60	10.7
			12 週	99	8.59	0.55	7.7	8.60	10.9
			18 週	98	8.72	0.59	7.8	8.65	10.2
		P(mg/dL)	0 週	103	5.95	1.36	2.7	6.00	10.4
			6 週	102	5.27	1.38	1.4	5.30	10.1
			12 週	99	5.05	1.51	1.8	4.80	8.6
			18 週	98	4.97	1.60	1.7	4.70	10.0
		Mg(mg/dL)	0 週	103	2.62	0.36	1.8	2.60	3.6
			6 週	102	2.58	0.36	1.7	2.55	3.6
			12 週	99	2.52	0.38	1.6	2.50	3.6
			18 週	98	2.50	0.37	1.6	2.50	3.4
		総コレステロール(mg/dL)	0 週	103	156.4	35.3	75	153.0	262
			6 週	102	156.5	33.0	84	150.0	228
			12 週	99	155.8	35.0	72	151.0	242
			18 週	98	154.4	34.1	86	147.5	231
		トリグリセライド(mg/dL)	0 週	103	115.2	87.3	26	90.0	506
			6 週	102	115.3	87.3	27	91.0	555
			12 週	99	118.3	96.5	26	92.0	728
			18 週	98	122.1	91.3	28	93.0	487
		グルコース(mg/dL)	0 週	103	127.3	40.5	71	116.0	267
			6 週	102	123.8	38.1	64	117.0	351
			12 週	99	127.1	53.3	69	113.0	430
			18 週	98	122.4	39.1	72	111.5	387
		iFGF23(ng/L)	0 週	103	14707.85	20551.14	53.5	8670.00	119000.0
			6 週	102	9077.88	13035.43	23.9	3945.00	70000.0
			12 週	99	7989.34	13187.87	26.1	2670.00	70400.0
			18 週	98	8561.48	14003.91	12.1	3270.00	88000.0

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
		BAP(μg/L)	0 週	103	18.18	9.33	7.8	15.70	57.3
			12 週	99	17.69	10.27	6.4	14.30	60.6
		total P1NP(μg/L)	0 週	103	390.34	223.27	68.7	356.00	1200.0
			12 週	99	275.72	156.47	58.9	251.00	922.0
		TRACP-5b(mU/dL)	0 週	103	740.3	340.4	160	723.0	1500
			12 週	99	443.5	258.3	82	403.0	1500
プラセボ群	AJ1004	総蛋白(g/dL)	0 週	50	6.26	0.40	5.5	6.30	7.2
			6 週	49	6.21	0.38	5.4	6.20	7.1
			12 週	45	6.20	0.41	5.5	6.20	7.2
			18 週	40	6.19	0.46	5.3	6.10	7.3
		AST(GOT)(U/L)	0 週	50	12.1	5.0	2	11.5	33
			6 週	49	12.2	5.9	3	10.0	39
			12 週	45	11.9	6.2	4	11.0	33
			18 週	40	10.9	4.9	4	9.0	25
		ALT(GPT)(U/L)	0 週	50	10.6	4.6	3	11.0	30
			6 週	49	11.8	6.7	3	11.0	35
			12 週	45	11.5	6.4	4	10.0	32
			18 週	40	10.3	4.9	4	9.5	24
		LD(LDH)(U/L)	0 週	50	176.7	31.1	108	170.5	270
			6 週	49	176.0	34.1	110	173.0	268
			12 週	45	171.8	32.0	115	166.0	247
			18 週	40	176.9	37.8	123	166.5	287
		総ビリルビン(mg/dL)	0 週	50	0.30	0.14	0.1	0.30	0.9
			6 週	49	0.27	0.13	0.1	0.20	0.8
			12 週	45	0.30	0.15	0.1	0.30	1.0
			18 週	40	0.32	0.15	0.2	0.30	0.8
		直接ビリルビン(mg/dL)	0 週	50	0.11	0.04	0.0	0.10	0.2
			6 週	49	0.11	0.04	0.0	0.10	0.2

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			12 週	45	0.12	0.05	0.1	0.10	0.3
			18 週	40	0.12	0.05	0.0	0.10	0.3
		ALP(U/L)	0 週	50	288.2	127.9	114	260.5	735
			6 週	49	307.1	146.5	124	296.0	839
			12 週	45	313.4	142.7	138	283.0	716
			18 週	40	307.4	129.6	143	281.0	684
		γ-GTP(U/L)	0 週	50	21.1	15.7	7	15.5	74
			6 週	49	21.7	18.1	6	16.0	93
			12 週	45	25.6	28.1	5	16.0	163
			18 週	40	20.8	17.4	6	15.0	87
		CPK(U/L)	0 週	50	98.1	52.9	25	87.0	236
			6 週	49	109.7	101.1	25	90.0	692
			12 週	45	100.3	57.3	25	94.0	295
			18 週	40	96.7	68.0	25	86.0	406
		アミラーゼ(U/L)	0 週	50	125.6	45.8	45	122.5	289
			6 週	49	122.1	46.1	45	115.0	250
			12 週	45	115.7	37.5	54	115.0	214
			18 週	40	114.3	32.5	60	112.0	213
		BUN(mg/dL)	0 週	50	66.19	14.47	43.4	65.60	115.3
			6 週	49	63.36	15.48	41.1	62.20	110.6
			12 週	45	62.73	13.44	36.6	61.30	93.4
			18 週	40	61.91	13.31	40.6	60.10	97.8
		クレアチニン(mg/dL)	0 週	50	11.319	2.004	7.50	11.495	15.46
			6 週	49	11.132	2.052	7.52	11.210	16.87
			12 週	45	11.343	2.009	7.93	11.180	16.12
			18 週	40	11.227	1.883	7.73	11.425	16.05
		尿酸(mg/dL)	0 週	50	7.41	1.49	3.9	7.60	11.3
			6 週	49	7.42	1.52	3.8	7.30	11.6
			12 週	45	7.56	1.25	4.3	7.30	10.3

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			18 週	40	7.45	1.19	4.0	7.40	10.2
		Na(mEq/L)	0 週	50	140.9	2.2	136	141.0	146
			6 週	49	140.8	2.9	133	141.0	146
			12 週	45	140.3	2.9	132	140.0	149
			18 週	40	140.0	2.9	128	140.5	144
		Cl(mEq/L)	0 週	50	101.4	3.5	94	101.0	111
			6 週	49	102.4	3.8	95	102.0	111
			12 週	45	101.8	3.6	95	101.0	113
			18 週	40	102.8	4.0	90	103.0	112
		K(mEq/L)	0 週	50	4.89	0.69	3.5	4.85	6.4
			6 週	49	4.92	0.78	3.7	4.80	7.2
			12 週	45	4.74	0.68	3.2	4.70	6.4
			18 週	40	4.86	0.64	3.6	4.85	7.5
		Ca(mg/dL)	0 週	50	9.06	0.71	7.9	9.00	10.5
			6 週	49	9.11	0.67	7.8	9.00	10.7
			12 週	45	9.09	0.76	7.7	8.90	11.2
			18 週	40	9.12	0.65	8.0	8.95	10.5
		補正 Ca(mg/dL)	0 週	50	9.40	0.74	8.3	9.30	11.2
			6 週	49	9.47	0.70	8.2	9.30	11.4
			12 週	45	9.49	0.79	8.0	9.30	11.3
			18 週	40	9.52	0.69	8.3	9.55	10.8
		P(mg/dL)	0 週	50	6.15	1.55	2.9	5.85	10.9
			6 週	49	5.83	1.60	2.7	5.40	11.6
			12 週	45	5.74	1.42	3.0	5.70	9.1
			18 週	40	5.86	1.63	3.1	5.45	10.9
		Mg(mg/dL)	0 週	50	2.56	0.37	1.8	2.55	3.6
			6 週	49	2.53	0.38	1.8	2.50	3.4
			12 週	45	2.46	0.37	1.8	2.40	3.2
			18 週	40	2.42	0.34	1.7	2.40	3.1

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
		総コレステロール(mg/dL)	0 週	50	157.8	30.8	101	152.5	237
			6 週	49	153.6	31.0	97	150.0	232
			12 週	45	153.3	31.1	103	148.0	233
			18 週	40	152.6	29.5	104	150.0	222
		トリグリセライド(mg/dL)	0 週	50	102.9	51.9	31	98.5	268
			6 週	49	98.6	47.6	31	90.0	264
			12 週	45	98.9	47.1	27	86.0	256
			18 週	40	100.7	46.5	33	89.0	218
		グルコース(mg/dL)	0 週	50	121.9	27.9	82	114.5	230
			6 週	49	129.2	45.6	83	111.0	316
			12 週	45	125.3	30.2	85	119.0	214
			18 週	40	123.5	35.6	76	116.5	241
		iFGF23(ng/L)	0 週	50	17795.25	21255.92	60.3	8485.00	95000.0
			6 週	49	18836.88	23661.85	140.0	8320.00	92600.0
			12 週	45	20180.44	25721.33	142.0	8790.00	106000.0
			18 週	40	21674.55	25464.05	552.0	9215.00	107000.0
		BAP(µg/L)	0 週	50	18.58	11.98	7.0	15.50	80.9
			6 週	1	11.50	-	11.5	11.50	11.5
			12 週	45	19.43	12.83	7.8	17.00	66.7
			18 週	1	9.20	-	9.2	9.20	9.2
		total P1NP(µg/L)	0 週	50	389.10	276.76	51.2	330.50	1200.0
			6 週	1	268.00	-	268.0	268.00	268.0
			12 週	45	441.02	301.09	49.9	361.00	1200.0
			18 週	1	115.00	-	115.0	115.00	115.0
		TRACP-5b(mU/dL)	0 週	50	747.2	380.6	172	717.0	1500
			6 週	1	442.0	-	442	442.0	442
			12 週	45	733.3	393.1	142	663.0	1500
			18 週	1	117.0	-	117	117.0	117

表 2.7.4.7－38　SOC「臨床検査」に分類される有害事象の発現状況

SOC/PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
臨床検査	38(11.9%)	14(24.1%)	13(8.3%)	11(10.7%)	4(8.0%)	21(6.6%)	9(15.5%)	3(1.9%)	9(8.7%)	0(0.0%)
血中ビリルビン増加	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中クレアチンホスホキナーゼ増加	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中副甲状腺ホルモン増加	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中カリウム増加	3(0.9%)	2(3.4%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血圧上昇	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中尿酸増加	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心電図 QT 延長	5(1.6%)	3(5.2%)	2(1.3%)	0(0.0%)	0(0.0%)	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)
γ－グルタミルトランスフェラーゼ増加	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ヘモグロビン減少	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
プロトロンビン時間延長	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
白血球数減少	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳性ナトリウム利尿ペプチド増加	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	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%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
便潜血陽性	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
補正カルシウム減少	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)
肝機能検査値上昇	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
補正カルシウム増加	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7－39　SOC「臨床検査」に分類される有害事象の重症度別発現状況

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
臨床検査		38(11.9%)	14(24.1%)	13(8.3%)	11(10.7%)	4(8.0%)	21(6.6%)	9(15.5%)	3(1.9%)	9(8.7%)	0(0.0%)
	軽度	38(11.9%)	14(24.1%)	13(8.3%)	11(10.7%)	4(8.0%)	21(6.6%)	9(15.5%)	3(1.9%)	9(8.7%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
血中ビリルビン増加		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中クレアチンホスホキナーゼ増加		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中副甲状腺ホルモン増加		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中カリウム増加		3(0.9%)	2(3.4%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	3(0.9%)	2(3.4%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血圧上昇		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中尿酸増加		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心電図 QT 延長		5(1.6%)	3(5.2%)	2(1.3%)	0(0.0%)	0(0.0%)	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)
	軽度	5(1.6%)	3(5.2%)	2(1.3%)	0(0.0%)	0(0.0%)	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
γ−グルタミルトランスフェラーゼ増加		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
ヘモグロビン減少		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
プロトロンビン時間延長		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
白血球数減少		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳性ナトリウム利尿ペプチド増加		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(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%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
便潜血陽性		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
補正カルシウム減少		18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)
	軽度	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝機能検査値上昇		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象 SK-1403 群 併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	プラセボ群 AJ1004 (N=50)	副作用 SK-1403 群 併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	プラセボ群 AJ1004 (N=50)
補正カルシウム増加		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7－40　SOC「臨床検査」に分類される有害事象の時期別発現状況

SOC/PT	発現時期(日)	有害事象 SK-1403 群 併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	プラセボ群 AJ1004 (N=50)	副作用 SK-1403 群 併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	プラセボ群 AJ1004 (N=50)
臨床検査		38(11.9%)	14(24.1%)	13(8.3%)	11(10.7%)	4(8.0%)	21(6.6%)	9(15.5%)	3(1.9%)	9(8.7%)	0(0.0%)
	1≤ - <22	11(3.5%)	7(12.1%)	0(0.0%)	4(3.9%)	1(2.0%)	10(3.1%)	7(12.1%)	0(0.0%)	3(2.9%)	0(0.0%)
	22≤ - <43	6(1.9%)	1(1.7%)	1(0.6%)	4(3.9%)	0(0.0%)	5(1.6%)	1(1.7%)	1(0.6%)	3(2.9%)	0(0.0%)
	43≤ - <64	3(0.9%)	2(3.4%)	0(0.0%)	1(1.0%)	0(0.0%)	2(0.6%)	1(1.7%)	0(0.0%)	1(1.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	2(4.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	5(1.6%)	1(1.7%)	3(1.9%)	1(1.0%)	1(2.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	127≤ - <148	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	6(1.9%)	0(0.0%)	6(3.8%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	267≤ - <365	5(1.6%)	4(6.9%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中ビリルビン増加		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中クレアチンホスホキナーゼ増加		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中副甲状腺ホルモン増加		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中カリウム増加		3(0.9%)	2(3.4%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血圧上昇		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血中尿酸増加		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心電図 QT 延長		5(1.6%)	3(5.2%)	2(1.3%)	0(0.0%)	0(0.0%)	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	2(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
γーグルタミルトランスフェラーゼ増加		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
ヘモグロビン減少		2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
プロトロンビン時間延長		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
白血球数減少		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
脳性ナトリウム利尿ペプチド増加		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(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%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
便潜血陽性		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
補正カルシウム減少		18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)	18(5.7%)	8(13.8%)	1(0.6%)	9(8.7%)	0(0.0%)
	1≤ - <22	10(3.1%)	7(12.1%)	0(0.0%)	3(2.9%)	0(0.0%)	10(3.1%)	7(12.1%)	0(0.0%)	3(2.9%)	0(0.0%)
	22≤ - <43	5(1.6%)	1(1.7%)	1(0.6%)	3(2.9%)	0(0.0%)	5(1.6%)	1(1.7%)	1(0.6%)	3(2.9%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
肝機能検査値上昇		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
補正カルシウム増加		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7−41　血圧及び脈拍数の要約

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
SK-1403 群	併合	収縮期血圧(mmHg)	0 週	318	150.8	20.4	87	151.5	215
			6 週	314	150.3	21.3	89	151.5	231
			12 週	308	151.4	20.9	81	151.0	213
			18 週	304	150.1	22.0	97	150.0	211
			28 週	198	150.5	20.1	100	150.5	212
			40 週	193	149.0	22.8	92	149.0	226
			52 週	191	151.1	20.7	91	151.0	225
		拡張期血圧(mmHg)	0 週	318	82.1	12.5	37	82.0	121
			6 週	314	81.3	12.1	48	80.5	122
			12 週	308	82.1	12.8	40	82.0	116
			18 週	304	81.7	13.4	36	81.0	129
			28 週	198	82.8	12.4	56	82.0	118
			40 週	193	81.1	13.4	47	80.0	120
			52 週	191	81.3	12.4	54	80.0	113
		脈拍数(回/分)	0 週	318	75.3	12.1	42	74.0	138
			6 週	314	75.2	11.0	49	74.0	138
			12 週	308	75.1	10.9	49	74.5	111
			18 週	304	75.8	11.6	47	75.0	145
			28 週	198	75.6	11.6	45	75.5	106
			40 週	193	75.6	11.1	46	76.0	110
			52 週	191	75.9	11.9	50	76.0	129
	AJ1002	収縮期血圧(mmHg)	0 週	58	149.9	18.4	102	150.5	189
			6 週	57	152.0	20.4	110	152.0	205
			12 週	57	151.5	21.0	81	150.0	213
			18 週	57	152.5	21.2	98	153.0	193
			28 週	53	153.4	20.5	102	153.0	193
			40 週	53	150.8	25.8	92	152.0	226
			52 週	52	148.6	22.2	91	150.0	225
		拡張期血圧(mmHg)	0 週	58	81.5	12.7	44	82.0	103
			6 週	57	81.5	12.6	56	81.0	112
			12 週	57	83.3	12.1	51	83.0	114

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
			18 週	57	84.3	12.8	56	84.0	110
			28 週	53	82.8	11.9	63	81.0	112
			40 週	53	81.8	16.0	47	79.0	117
			52 週	52	79.7	13.6	54	78.0	113
		脈拍数(回/分)	0 週	58	75.5	12.6	56	74.0	108
			6 週	57	74.7	10.7	54	74.0	105
			12 週	57	74.5	10.7	53	74.0	100
			18 週	57	77.1	11.4	47	77.0	103
			28 週	53	74.7	11.1	56	73.0	96
			40 週	53	74.2	10.5	55	75.0	96
			52 週	52	74.7	12.1	55	75.5	105
	AJ1003	収縮期血圧(mmHg)	0 週	157	151.1	18.8	106	153.0	215
			6 週	155	151.8	20.8	92	152.0	231
			12 週	152	154.1	20.2	112	152.0	206
			18 週	149	151.1	20.5	100	151.0	211
			28 週	145	149.4	19.9	100	150.0	212
			40 週	140	148.3	21.6	95	148.5	226
			52 週	139	152.0	20.1	98	152.0	197
		拡張期血圧(mmHg)	0 週	157	83.1	12.2	57	83.0	121
			6 週	155	83.1	11.7	54	83.0	122
			12 週	152	83.8	12.7	46	83.0	116
			18 週	149	83.2	12.4	53	81.0	129
			28 週	145	82.9	12.6	56	82.0	118
			40 週	140	80.8	12.3	51	80.0	120
			52 週	139	81.9	11.9	54	81.0	109
		脈拍数(回/分)	0 週	157	76.4	12.6	45	75.0	138
			6 週	155	76.6	11.3	49	76.0	138
			12 週	152	76.5	11.7	49	75.0	111
			18 週	149	76.9	12.7	50	78.0	145
			28 週	145	76.0	11.8	45	76.0	106
			40 週	140	76.1	11.3	46	76.0	110
			52 週	139	76.3	11.8	50	77.0	129

投与群	試験名	項目	時点	測定値					
				n	Mean	SD	Min	Median	Max
	AJ1004	収縮期血圧(mmHg)	0 週	103	150.8	23.7	87	151.0	204
			6 週	102	147.1	22.4	89	149.0	207
			12 週	99	147.1	21.5	91	151.0	190
			18 週	98	147.2	24.3	97	147.5	209
		拡張期血圧(mmHg)	0 週	103	80.9	12.9	37	82.0	110
			6 週	102	78.5	11.9	48	77.5	104
			12 週	99	78.8	13.0	40	80.0	109
			18 週	98	77.9	14.5	36	78.0	111
		脈拍数(回/分)	0 週	103	73.3	11.0	42	74.0	104
			6 週	102	73.4	10.5	50	73.0	106
			12 週	99	73.2	9.5	53	72.0	95
			18 週	98	73.6	9.4	53	74.0	114
プラセボ群	AJ1004	収縮期血圧(mmHg)	0 週	50	151.6	24.7	79	148.0	192
			6 週	49	151.6	26.4	82	149.0	213
			12 週	45	148.2	24.0	106	149.0	206
			18 週	40	149.2	20.4	106	149.0	194
		拡張期血圧(mmHg)	0 週	50	81.0	13.6	51	82.0	116
			6 週	49	80.0	12.0	56	82.0	106
			12 週	45	78.8	15.7	48	79.0	134
			18 週	40	80.3	14.0	51	80.0	129
		脈拍数(回/分)	0 週	50	74.9	12.2	55	73.0	107
			6 週	49	73.2	13.3	56	68.0	111
			12 週	45	73.3	11.2	58	70.0	102
			18 週	40	74.5	12.9	55	71.0	110

表 2.7.4.7－42　安静時 12 誘導心電図検査結果の要約

投与群	試験名	時点	対象被験者数	所見		
				正常	臨床的に問題とならない異常	臨床的に問題となる異常
SK-1403 群	併合	0 週	317	162(51.1%)	146(46.1%)	9(2.8%)
		6 週	314	149(47.5%)	154(49.0%)	11(3.5%)
		12 週	309	147(47.6%)	154(49.8%)	8(2.6%)
		18 週	305	136(44.6%)	159(52.1%)	10(3.3%)
		24 週	242	110(45.5%)	123(50.8%)	9(3.7%)
		36 週	143	61(42.7%)	81(56.6%)	1(0.7%)
		52 週	190	83(43.7%)	104(54.7%)	3(1.6%)
	AJ1002	0 週	57	30(52.6%)	27(47.4%)	0(0.0%)
		6 週	56	28(50.0%)	27(48.2%)	1(1.8%)
		12 週	56	24(42.9%)	32(57.1%)	0(0.0%)
		18 週	55	26(47.3%)	29(52.7%)	0(0.0%)
		52 週	51	23(45.1%)	27(52.9%)	1(2.0%)
	AJ1003	0 週	157	77(49.0%)	79(50.3%)	1(0.6%)
		6 週	156	70(44.9%)	85(54.5%)	1(0.6%)
		12 週	153	72(47.1%)	81(52.9%)	0(0.0%)
		18 週	152	64(42.1%)	86(56.6%)	2(1.3%)
		24 週	146	65(44.5%)	81(55.5%)	0(0.0%)
		36 週	143	61(42.7%)	81(56.6%)	1(0.7%)
		52 週	139	60(43.2%)	77(55.4%)	2(1.4%)
	AJ1004	0 週	103	55(53.4%)	40(38.8%)	8(7.8%)
		6 週	102	51(50.0%)	42(41.2%)	9(8.8%)
		12 週	100	51(51.0%)	41(41.0%)	8(8.0%)
		18 週	98	46(46.9%)	44(44.9%)	8(8.2%)
		24 週	96	45(46.9%)	42(43.8%)	9(9.4%)
プラセボ群	AJ1004	0 週	50	26(52.0%)	19(38.0%)	5(10.0%)
		6 週	49	29(59.2%)	15(30.6%)	5(10.2%)
		12 週	46	21(45.7%)	20(43.5%)	5(10.9%)
		18 週	40	20(50.0%)	15(37.5%)	5(12.5%)
		24 週	39	18(46.2%)	15(38.5%)	6(15.4%)

例数(割合(%))

表 2.7.4.7－43　安静時 12 誘導心電図検査結果のシフトテーブル

		SK-1403 群								プラセボ群	
		併合 (N=318)		AJ1002 (N=58)		AJ1003 (N=157)		AJ1004 (N=103)		AJ1004 (N=50)	
		治療期 0 週		治療期 0 週		治療期 0 週		治療期 0 週		治療期 0 週	
時点		正常	異常	正常	異常	正常	異常	正常	異常	正常	異常
6 週	正常	303	0	55	0	155	0	93	0	44	0
	異常	2	9	1	0	0	1	1	8	0	5
12 週	正常	300	1	56	0	152	1	92	0	41	0
	異常	1	7	0	0	0	0	1	7	0	5
18 週	正常	295	0	55	0	150	0	90	0	35	0
	異常	2	8	0	0	1	1	1	7	0	5
24 週	正常	232	1	-	-	145	1	87	0	33	0
	異常	2	7	-	-	0	0	2	7	1	5
36 週	正常	142	0	-	-	142	0	-	-	-	-
	異常	0	1	-	-	0	1	-	-	-	-
52 週	正常	187	0	50	0	137	0	-	-	-	-
	異常	2	1	1	0	1	1	-	-	-	-

-：測定なし

表 2.7.4.7－44 QT 間隔，QTcF，QRS 間隔，RR 間隔，PR 間隔の要約

				測定値						変化量						90%信頼区間[1]	
投与群	試験名	項目	時点	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max	下限	上限
SK-1403 群	併合	QT 間隔(ms)	0 週	316	393.8	30.8	297	392.7	506	-	-	-	-	-	-	-	-
			6 週	311	404.9	32.2	319	402.7	508	311	11.5	18.3	-70	10.7	66	9.8	13.2
			12 週	307	404.8	32.0	328	402.3	529	307	11.5	22.1	-80	11.7	82	9.4	13.5
			18 週	303	403.4	32.9	309	399.7	522	303	10.3	23.6	-67	10.0	110	8.1	12.6
			24 週	242	401.3	32.3	317	397.7	504	242	8.6	22.4	-74	11.8	63	6.2	11.0
			36 週	143	395.5	31.2	337	392.3	491	143	8.5	20.4	-81	7.3	52	5.7	11.3
			52 週	189	398.3	31.6	309	395.3	512	189	9.3	21.4	-86	9.0	82	6.8	11.9
		QTcF(ms)	0 週	316	420.1	21.6	371	419.5	506	-	-	-	-	-	-	-	-
			6 週	311	430.9	24.2	371	428.3	518	311	11.1	13.5	-29	10.3	55	9.9	12.4
			12 週	307	431.1	24.2	375	429.7	520	307	11.2	16.2	-28	11.0	66	9.7	12.8
			18 週	303	430.7	23.3	372	427.7	524	303	11.2	16.3	-36	11.0	70	9.7	12.8
			24 週	242	427.2	22.8	372	424.5	511	242	8.8	16.0	-35	9.2	73	7.1	10.5
			36 週	143	423.0	21.8	382	421.7	501	143	8.5	14.3	-28	7.7	57	6.5	10.5
			52 週	189	426.9	22.7	376	424.7	511	189	9.6	15.5	-30	8.7	69	7.8	11.5
		QRS 間隔(ms)	0 週	316	95.1	15.4	73	91.3	164	-	-	-	-	-	-	-	-
			6 週	313	94.4	14.6	74	90.7	165	313	-0.8	5.7	-23	-0.3	22	-	-
			12 週	308	95.0	17.0	72	91.0	233	308	-0.1	7.4	-26	-0.7	82	-	-
			18 週	303	94.7	15.3	73	91.0	160	303	-0.5	6.5	-28	-0.7	47	-	-
			24 週	242	95.3	15.8	75	90.7	163	242	-0.4	8.8	-35	-0.7	57	-	-
			36 週	143	95.0	15.7	77	90.7	154	143	0.4	7.5	-17	-0.7	59	-	-
			52 週	189	93.8	14.1	74	90.0	152	189	-0.4	5.7	-17	0.0	41	-	-
		RR 間隔(ms)	0 週	316	828.9	123.7	492	820.5	1249	-	-	-	-	-	-	-	-
			6 週	313	833.8	114.1	512	827.3	1250	313	5.8	72.9	-278	1.7	299	-	-
			12 週	308	832.5	116.2	548	829.2	1292	308	4.8	81.2	-341	7.2	244	-	-
			18 週	303	826.2	121.5	545	819.7	1265	303	-2.0	88.3	-354	-1.3	313	-	-
			24 週	242	834.5	123.6	511	833.0	1287	242	2.3	87.1	-332	5.8	232	-	-
			36 週	143	822.7	122.7	477	807.7	1188	143	2.7	82.8	-362	15.7	178	-	-
			52 週	189	817.5	123.1	465	794.7	1226	189	2.0	84.4	-476	1.7	233	-	-

投与群	試験名	項目	時点	測定値						変化量						90%信頼区間[1]	
				n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max	下限	上限
		PR 間隔(ms)	0 週	307	181.0	29.9	124	176.0	355	-	-	-	-	-	-	-	-
			6 週	303	179.5	28.3	132	172.7	339	303	-1.4	12.6	-140	-0.7	46	-	-
			12 週	299	179.7	28.8	125	173.7	327	298	-0.9	12.6	-141	-0.8	27	-	-
			18 週	292	179.8	28.7	129	175.7	314	292	-0.5	12.6	-124	-0.2	42	-	-
			24 週	231	179.7	29.0	133	173.7	334	231	-0.6	14.2	-151	-0.3	32	-	-
			36 週	139	177.8	25.1	135	174.0	287	139	0.6	10.5	-34	1.0	43	-	-
			52 週	184	178.4	26.0	126	174.7	266	184	0.5	10.1	-35	0.7	31	-	-
	AJ1002	QT 間隔(ms)	0 週	56	393.7	26.5	339	394.3	461	-	-	-	-	-	-	-	-
			6 週	53	412.4	30.6	347	409.3	499	53	19.4	18.5	-23	18.7	66	15.1	23.7
			12 週	54	415.2	27.8	360	413.0	489	54	22.4	20.6	-13	19.7	70	17.7	27.1
			18 週	53	417.4	32.5	352	409.3	506	53	23.5	27.5	-21	22.0	110	17.2	29.8
			52 週	50	411.8	32.2	360	406.0	512	50	16.6	24.3	-50	19.3	82	10.8	22.3
		QTcF(ms)	0 週	56	424.0	20.7	382	427.3	470	-	-	-	-	-	-	-	-
			6 週	53	439.4	25.1	388	439.3	501	53	16.2	15.5	-23	14.3	55	12.6	19.8
			12 週	54	442.3	22.4	399	439.8	485	54	18.7	17.3	-23	18.5	62	14.7	22.6
			18 週	53	446.2	21.5	394	444.0	494	53	22.8	19.7	-17	22.3	70	18.2	27.3
			52 週	50	439.1	22.9	400	434.7	511	50	14.6	20.7	-30	13.0	69	9.7	19.5
		QRS 間隔(ms)	0 週	56	93.5	13.7	73	91.7	147	-	-	-	-	-	-	-	-
			6 週	55	93.0	13.5	74	90.7	141	55	-0.6	4.6	-17	0.7	6	-	-
			12 週	55	93.1	13.2	73	91.3	146	55	-0.5	4.2	-13	0.0	7	-	-
			18 週	53	93.1	13.4	75	91.3	147	53	-0.6	4.9	-19	0.0	9	-	-
			52 週	50	93.6	12.6	74	91.7	146	50	0.3	3.5	-11	0.7	7	-	-
		RR 間隔(ms)	0 週	56	805.7	112.9	572	799.2	1074	-	-	-	-	-	-	-	-
			6 週	55	828.3	109.1	626	814.0	1064	55	23.8	66.6	-160	17.7	206	-	-
			12 週	55	832.0	111.3	633	828.0	1072	55	27.5	70.9	-103	24.0	202	-	-
			18 週	53	821.7	113.7	625	806.3	1087	53	11.8	85.6	-142	-5.7	267	-	-
			52 週	50	829.4	118.3	591	840.0	1057	50	16.6	68.2	-127	26.8	152	-	-
		PR 間隔(ms)	0 週	56	182.2	30.1	140	178.3	261	-	-	-	-	-	-	-	-
			6 週	55	180.7	28.1	138	180.7	263	55	-1.7	10.6	-35	0.0	32	-	-
			12 週	55	181.2	31.2	135	176.7	279	55	-1.2	9.8	-25	-1.3	27	-	-
			18 週	53	178.3	27.6	132	176.7	257	53	-1.2	9.9	-25	-2.0	27	-	-
			52 週	50	182.0	30.1	139	178.0	266	50	-0.6	9.4	-27	0.7	20	-	-

				測定値						変化量						90%信頼区間[1]	
投与群	試験名	項目	時点	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max	下限	上限
	AJ1003	QT 間隔(ms)	0 週	157	387.9	29.5	297	388.0	474	-	-	-	-	-	-	-	-
			6 週	156	396.7	28.6	319	394.0	489	156	9.0	17.4	-70	9.2	54	6.7	11.3
			12 週	153	397.1	31.6	328	394.3	496	153	9.6	22.4	-80	10.7	82	6.6	12.6
			18 週	152	394.4	31.3	309	393.3	485	152	7.0	21.0	-61	7.3	56	4.2	9.8
			24 週	146	397.0	32.2	317	392.8	497	146	10.1	22.3	-74	12.3	63	7.0	13.1
			36 週	143	395.5	31.2	337	392.3	491	143	8.5	20.4	-81	7.3	52	5.7	11.3
			52 週	139	393.4	30.0	309	390.7	465	139	6.7	19.6	-86	7.3	50	4.0	9.5
		QTcF(ms)	0 週	157	415.5	20.5	371	416.0	477	-	-	-	-	-	-	-	-
			6 週	156	425.7	21.5	383	425.5	485	156	10.4	12.7	-29	9.0	44	8.7	12.0
			12 週	153	425.5	23.0	375	422.7	497	153	10.2	15.6	-28	9.7	66	8.1	12.2
			18 週	152	424.1	20.8	372	422.5	478	152	8.9	14.2	-29	9.3	53	7.0	10.8
			24 週	146	424.5	21.7	372	423.3	497	146	9.8	16.1	-35	9.8	73	7.6	12.0
			36 週	143	423.0	21.8	382	421.7	501	143	8.5	14.3	-28	7.7	57	6.5	10.5
			52 週	139	422.5	21.0	376	420.7	494	139	7.8	12.8	-19	8.0	46	6.0	9.6
		QRS 間隔(ms)	0 週	157	94.3	13.7	74	92.0	155	-	-	-	-	-	-	-	-
			6 週	156	94.1	13.6	76	90.7	165	156	-0.3	5.6	-23	-0.2	22	-	-
			12 週	153	94.3	13.9	74	91.0	151	153	-0.2	5.0	-14	-0.7	14	-	-
			18 週	152	94.5	14.3	73	91.7	160	152	0.0	5.7	-14	-0.3	17	-	-
			24 週	146	95.0	14.6	78	90.7	152	146	0.3	7.2	-16	0.2	57	-	-
			36 週	143	95.0	15.7	77	90.7	154	143	0.4	7.5	-17	-0.7	59	-	-
			52 週	139	93.8	14.7	77	89.3	152	139	-0.7	6.3	-17	-0.7	41	-	-
		RR 間隔(ms)	0 週	157	818.9	124.9	492	811.7	1249	-	-	-	-	-	-	-	-
			6 週	156	814.5	111.2	512	803.8	1250	156	-4.7	71.3	-278	-1.8	299	-	-
			12 週	153	818.3	122.9	548	812.7	1292	153	0.0	83.4	-341	6.7	198	-	-
			18 週	152	809.9	126.7	545	801.0	1265	152	-8.7	88.1	-354	-2.2	272	-	-
			24 週	146	824.0	132.4	511	813.2	1287	146	5.4	86.9	-332	8.3	232	-	-
			36 週	143	822.7	122.7	477	807.7	1188	143	2.7	82.8	-362	15.7	178	-	-
			52 週	139	813.2	124.9	465	790.7	1226	139	-3.3	89.1	-476	-1.7	233	-	-
		PR 間隔(ms)	0 週	153	177.1	25.5	124	171.3	257	-	-	-	-	-	-	-	-
			6 週	152	176.1	24.9	135	169.8	253	152	-1.0	9.7	-40	-1.0	46	-	-
			12 週	150	176.2	26.3	125	169.0	255	149	-0.6	10.1	-46	-0.3	27	-	-
			18 週	147	176.6	26.9	129	169.7	278	147	-0.5	10.7	-39	-0.3	42	-	-

				測定値						変化量						90%信頼区間[1]	
投与群	試験名	項目	時点	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max	下限	上限
			24 週	142	176.6	26.0	133	172.3	270	142	-0.5	10.1	-39	-0.3	20	-	-
			36 週	139	177.8	25.1	135	174.0	287	139	0.6	10.5	-34	1.0	43	-	-
			52 週	134	177.1	24.3	126	173.2	255	134	0.9	10.3	-35	0.8	31	-	-
	AJ1004	QT 間隔(ms)	0 週	103	402.9	32.9	341	397.3	506	-	-	-	-	-	-	-	-
			6 週	102	413.5	35.2	322	407.8	508	102	11.2	18.7	-31	9.3	59	8.1	14.2
			12 週	100	410.8	32.2	344	406.5	529	100	8.4	20.7	-43	8.2	64	5.0	11.8
			18 週	98	409.8	31.7	347	407.0	522	98	8.3	22.9	-67	9.8	52	4.5	12.2
			24 週	96	407.9	31.5	333	404.8	504	96	6.4	22.6	-60	10.0	49	2.6	10.3
		QTcF(ms)	0 週	103	425.0	22.5	378	423.7	506	-	-	-	-	-	-	-	-
			6 週	102	434.5	25.9	371	429.2	518	102	9.7	13.2	-21	9.3	53	7.5	11.8
			12 週	100	433.6	24.6	381	430.3	520	100	8.9	15.3	-27	9.8	65	6.3	11.4
			18 週	98	432.7	23.8	390	431.3	524	98	8.5	14.8	-36	9.7	47	6.0	11.0
			24 週	96	431.3	24.0	387	426.8	511	96	7.1	15.7	-28	7.7	58	4.5	9.8
		QRS 間隔(ms)	0 週	103	97.0	18.5	78	90.0	164	-	-	-	-	-	-	-	-
			6 週	102	95.5	16.6	75	90.2	151	102	-1.6	6.2	-18	-1.0	13	-	-
			12 週	100	97.3	22.2	72	90.5	233	100	0.3	11.0	-26	-0.8	82	-	-
			18 週	98	95.9	17.7	77	89.7	155	98	-1.3	8.2	-28	-1.2	47	-	-
			24 週	96	95.8	17.5	75	89.7	163	96	-1.4	10.7	-35	-1.8	44	-	-
		RR 間隔(ms)	0 週	103	856.8	123.8	572	844.0	1216	-	-	-	-	-	-	-	-
			6 週	102	866.4	114.9	566	866.3	1126	102	12.1	76.6	-153	3.8	247	-	-
			12 週	100	854.5	105.6	591	851.8	1139	100	-0.5	81.8	-256	-1.7	244	-	-
			18 週	98	854.1	113.1	651	833.5	1228	98	0.9	89.8	-284	10.5	313	-	-
			24 週	96	850.5	107.5	571	856.5	1142	96	-2.5	87.7	-303	2.0	215	-	-
		PR 間隔(ms)	0 週	98	186.5	35.1	139	177.7	355	-	-	-	-	-	-	-	-
			6 週	96	184.2	32.7	132	176.3	339	96	-1.8	16.9	-140	0.0	18	-	-
			12 週	94	184.3	30.6	136	177.3	327	94	-1.3	17.1	-141	-1.0	23	-	-
			18 週	92	185.6	31.2	139	178.0	314	92	-0.2	16.4	-124	1.8	27	-	-
			24 週	89	184.7	32.8	144	177.3	334	89	-0.7	19.1	-151	0.7	32	-	-
プラセボ群	AJ1004	QT 間隔(ms)	0 週	50	402.7	28.1	341	399.3	458	-	-	-	-	-	-	-	-
			6 週	49	402.5	31.9	331	404.3	484	49	-0.2	20.2	-43	-1.7	74	-5.0	4.7
			12 週	46	405.4	32.5	319	409.2	497	46	2.2	21.4	-46	0.3	60	-3.1	7.5
			18 週	40	399.0	29.9	340	400.5	462	40	-5.4	18.4	-52	-6.7	32	-10.2	-0.5

投与群	試験名	項目	時点	測定値						変化量						90%信頼区間[1]	
				n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max	下限	上限
			24 週	39	403.9	32.2	341	404.3	492	39	-0.6	20.4	-60	2.0	33	-6.1	4.9
		QTcF(ms)	0 週	50	425.8	20.9	379	425.0	482	-	-	-	-	-	-	-	-
			6 週	49	424.3	23.6	375	421.7	487	49	-1.4	11.9	-41	-2.0	28	-4.3	1.4
			12 週	46	427.6	26.4	368	425.3	489	46	1.6	14.5	-23	1.5	43	-2.0	5.2
			18 週	40	424.7	24.1	370	423.0	490	40	-3.2	14.3	-26	-2.0	29	-7.0	0.6
			24 週	39	428.6	26.3	381	423.0	499	39	0.8	16.7	-35	1.7	51	-3.7	5.3
		QRS 間隔(ms)	0 週	50	97.9	15.7	78	94.7	145	-	-	-	-	-	-	-	-
			6 週	49	98.1	19.6	76	90.7	161	49	0.4	8.6	-34	-1.0	21	-	-
			12 週	46	96.2	16.0	77	91.8	160	46	-1.2	8.8	-33	-0.8	25	-	-
			18 週	40	97.0	16.8	79	92.8	156	40	-1.1	8.2	-32	-0.5	21	-	-
			24 週	39	96.5	17.7	79	89.3	151	39	-1.8	8.3	-37	-1.0	17	-	-
		RR 間隔(ms)	0 週	50	851.3	116.7	617	853.8	1062	-	-	-	-	-	-	-	-
			6 週	49	861.4	134.2	587	885.0	1137	49	8.9	94.3	-194	-12.3	441	-	-
			12 週	46	857.3	111.5	607	874.3	1058	46	2.9	82.3	-167	-5.3	279	-	-
			18 週	40	835.8	123.0	605	837.7	1050	40	-13.8	72.3	-171	-14.2	149	-	-
			24 週	39	844.0	130.8	588	824.7	1187	39	-7.4	70.9	-164	-21.0	158	-	-
		PR 間隔(ms)	0 週	48	177.0	34.6	123	172.7	293	-	-	-	-	-	-	-	-
			6 週	46	177.8	36.4	126	171.8	312	46	0.6	8.3	-22	0.8	20	-	-
			12 週	43	179.0	32.5	128	176.3	289	43	2.1	9.0	-22	1.7	24	-	-
			18 週	38	177.2	33.1	138	170.5	282	38	1.0	8.3	-16	-1.2	24	-	-
			24 週	37	177.7	34.5	132	174.7	302	37	2.0	9.8	-21	1.3	25	-	-

[1] 正確な両側 90%信頼区間

-：算出なし

表 2.7.4.7－45　QTcF 測定値のカテゴリ別集計

投与群	試験名	時点	対象被験者数	QTcF 測定値カテゴリ(ms)			
				450 以下	450 超 480 以下	480 超 500 以下	500 超
SK-1403 群	併合	0 週	316	284(89.9%)	30(9.5%)	1(0.3%)	1(0.3%)
		6 週	311	249(80.1%)	51(16.4%)	7(2.3%)	4(1.3%)
		12 週	307	242(78.8%)	56(18.2%)	7(2.3%)	2(0.7%)
		18 週	303	245(80.9%)	51(16.8%)	6(2.0%)	1(0.3%)
		24 週	242	210(86.8%)	27(11.2%)	3(1.2%)	2(0.8%)
		36 週	143	130(90.9%)	12(8.4%)	0(0.0%)	1(0.7%)
		52 週	189	157(83.1%)	29(15.3%)	1(0.5%)	2(1.1%)
	AJ1002	0 週	56	49(87.5%)	7(12.5%)	0(0.0%)	0(0.0%)
		6 週	53	38(71.7%)	11(20.8%)	3(5.7%)	1(1.9%)
		12 週	54	34(63.0%)	17(31.5%)	3(5.6%)	0(0.0%)
		18 週	53	33(62.3%)	16(30.2%)	4(7.5%)	0(0.0%)
		52 週	50	35(70.0%)	13(26.0%)	0(0.0%)	2(4.0%)
	AJ1003	0 週	157	150(95.5%)	7(4.5%)	0(0.0%)	0(0.0%)
		6 週	156	134(85.9%)	20(12.8%)	2(1.3%)	0(0.0%)
		12 週	153	128(83.7%)	24(15.7%)	1(0.7%)	0(0.0%)
		18 週	152	133(87.5%)	19(12.5%)	0(0.0%)	0(0.0%)
		24 週	146	131(89.7%)	13(8.9%)	2(1.4%)	0(0.0%)
		36 週	143	130(90.9%)	12(8.4%)	0(0.0%)	1(0.7%)
		52 週	139	122(87.8%)	16(11.5%)	1(0.7%)	0(0.0%)
	AJ1004	0 週	103	85(82.5%)	16(15.5%)	1(1.0%)	1(1.0%)
		6 週	102	77(75.5%)	20(19.6%)	2(2.0%)	3(2.9%)
		12 週	100	80(80.0%)	15(15.0%)	3(3.0%)	2(2.0%)
		18 週	98	79(80.6%)	16(16.3%)	2(2.0%)	1(1.0%)
		24 週	96	79(82.3%)	14(14.6%)	1(1.0%)	2(2.1%)
プラセボ群	AJ1004	0 週	50	45(90.0%)	4(8.0%)	1(2.0%)	0(0.0%)
		6 週	49	43(87.8%)	5(10.2%)	1(2.0%)	0(0.0%)
		12 週	46	37(80.4%)	7(15.2%)	2(4.3%)	0(0.0%)
		18 週	40	37(92.5%)	2(5.0%)	1(2.5%)	0(0.0%)
		24 週	39	32(82.1%)	5(12.8%)	2(5.1%)	0(0.0%)

例数(割合(%))

表 2.7.4.7－46　QTcF 変化量のカテゴリ別集計

投与群	試験名	時点	対象被験者数	ΔQTcF カテゴリ(ms)		
				30 以下	30 超 60 以下	60 超
SK-1403 群	併合	6 週	311	285(91.6%)	26(8.4%)	0(0.0%)
		12 週	307	275(89.6%)	29(9.4%)	3(1.0%)
		18 週	303	271(89.4%)	30(9.9%)	2(0.7%)
		24 週	242	223(92.1%)	18(7.4%)	1(0.4%)
		36 週	143	132(92.3%)	11(7.7%)	0(0.0%)
		52 週	189	174(92.1%)	14(7.4%)	1(0.5%)
	AJ1002	6 週	53	43(81.1%)	10(18.9%)	0(0.0%)
		12 週	54	41(75.9%)	12(22.2%)	1(1.9%)
		18 週	53	34(64.2%)	17(32.1%)	2(3.8%)
		52 週	50	40(80.0%)	9(18.0%)	1(2.0%)
	AJ1003	6 週	156	146(93.6%)	10(6.4%)	0(0.0%)
		12 週	153	140(91.5%)	12(7.8%)	1(0.7%)
		18 週	152	145(95.4%)	7(4.6%)	0(0.0%)
		24 週	146	132(90.4%)	13(8.9%)	1(0.7%)
		36 週	143	132(92.3%)	11(7.7%)	0(0.0%)
		52 週	139	134(96.4%)	5(3.6%)	0(0.0%)
	AJ1004	6 週	102	96(94.1%)	6(5.9%)	0(0.0%)
		12 週	100	94(94.0%)	5(5.0%)	1(1.0%)
		18 週	98	92(93.9%)	6(6.1%)	0(0.0%)
		24 週	96	91(94.8%)	5(5.2%)	0(0.0%)
プラセボ群	AJ1004	6 週	49	49(100.0%)	0(0.0%)	0(0.0%)
		12 週	46	44(95.7%)	2(4.3%)	0(0.0%)
		18 週	40	40(100.0%)	0(0.0%)	0(0.0%)
		24 週	39	38(97.4%)	1(2.6%)	0(0.0%)

ΔQTcF　=(各時点の QTcF の測定値) -(投与前の QTcF の測定値)
例数(割合(%))

表 2.7.4.7－47　SOC「心臓障害」に分類される有害事象の発現状況

SOC/PT	有害事象					副作用				
	SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
心臓障害	17(5.3%)	3(5.2%)	12(7.6%)	2(1.9%)	2(4.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)
急性心筋梗塞	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
狭心症	5(1.6%)	1(1.7%)	3(1.9%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心房細動	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
徐脈	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
慢性心不全	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
うっ血性心不全	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心筋虚血	3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
動悸	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
洞性頻脈	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上室性頻脈	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頻脈	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心室性期外収縮	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心室性頻脈	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
僧帽弁石灰化	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7－48　SOC「心臓障害」に分類される有害事象の重症度別発現状況

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
心臓障害		17(5.3%)	3(5.2%)	12(7.6%)	2(1.9%)	2(4.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)
	軽度	11(3.5%)	3(5.2%)	7(4.5%)	1(1.0%)	2(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	中等度	8(2.5%)	1(1.7%)	6(3.8%)	1(1.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
急性心筋梗塞		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
狭心症		5(1.6%)	1(1.7%)	3(1.9%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	5(1.6%)	1(1.7%)	3(1.9%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心房細動		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	軽度	3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
徐脈		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
慢性心不全		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	軽度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
うっ血性心不全		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心筋虚血		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
動悸		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
洞性頻脈		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	重症度	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
上室性頻脈		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頻脈		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心室性期外収縮		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心室性頻脈		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
僧帽弁石灰化		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	軽度	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	中等度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	高度	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7－49　SOC「心臓障害」に分類される有害事象の時期別発現状況

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
心臓障害		17(5.3%)	3(5.2%)	12(7.6%)	2(1.9%)	2(4.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	64≤ - <85	5(1.6%)	0(0.0%)	3(1.9%)	2(1.9%)	1(2.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)
	85≤ - <106	2(0.6%)	1(1.7%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	4(1.3%)	2(3.4%)	2(1.3%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	5(1.6%)	2(3.4%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
急性心筋梗塞		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
狭心症		5(1.6%)	1(1.7%)	3(1.9%)	1(1.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	2(0.6%)	0(0.0%)	1(0.6%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心房細動		3(0.9%)	1(1.7%)	2(1.3%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
徐脈		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
慢性心不全		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
うっ血性心不全		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心筋虚血		3(0.9%)	0(0.0%)	3(1.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	2(0.6%)	0(0.0%)	2(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
動悸		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
洞性頻脈		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
上室性頻脈		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
頻脈		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
SOC/PT	発現時期(日)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	148≤ - <169	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心室性期外収縮		1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	1(0.3%)	0(0.0%)	1(0.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
心室性頻脈		1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	1(0.3%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
僧帽弁石灰化		1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	1≤ - <22	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	22≤ - <43	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	43≤ - <64	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	64≤ - <85	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	85≤ - <106	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

SOC/PT	発現時期(日)	有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)	併合 (N=318)	AJ1002 (N=58)	AJ1003 (N=157)	AJ1004 (N=103)	AJ1004 (N=50)
	106≤ - <127	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	127≤ - <148	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	148≤ - <169	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	169≤ - <267	1(0.3%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	267≤ - <365	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	365≤	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

MedDRA/J version 22.1
例数(割合(%))

表 2.7.4.7－50　透析後体重の要約

項目	投与群	試験名	時点	測定値					
				n	Mean	SD	Min	Median	Max
体重(透析後)(kg)	SK-1403 群	併合	0 週	318	63.53	14.24	35.0	61.60	134.4
			24 週	240	64.26	14.45	36.6	62.30	132.7
			52 週	191	63.93	15.03	35.5	61.50	114.1
		AJ1002	0 週	58	62.09	14.03	35.0	58.75	106.1
			52 週	52	61.11	14.86	35.5	58.15	111.6
		AJ1003	0 週	157	64.82	14.49	36.4	62.00	113.5
			24 週	146	65.00	14.82	36.6	62.30	114.9
			52 週	139	64.99	15.01	36.6	62.20	114.1
		AJ1004	0 週	103	62.37	13.92	39.9	61.90	134.4
			24 週	94	63.11	13.86	39.8	62.25	132.7
	プラセボ群	AJ1004	0 週	50	59.84	12.50	40.6	58.15	91.3
			24 週	39	60.29	12.48	40.8	57.80	92.7

表 2.7.4.7－51　内因性要因による部分集団解析 全有害事象

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
性別	男	241	43	121	77	39	241	43	121	77	39
		212(88.0%)	40(93.0%)	108(89.3%)	64(83.1%)	27(69.2%)	22(9.1%)	9(20.9%)	7(5.8%)	6(7.8%)	2(5.1%)
	女	77	15	36	26	11	77	15	36	26	11
		72(93.5%)	15(100.0%)	33(91.7%)	24(92.3%)	9(81.8%)	12(15.6%)	3(20.0%)	3(8.3%)	6(23.1%)	2(18.2%)
年齢別	<65 歳	172	33	91	48	20	172	33	91	48	20
		156(90.7%)	32(97.0%)	84(92.3%)	40(83.3%)	15(75.0%)	19(11.0%)	8(24.2%)	5(5.5%)	6(12.5%)	1(5.0%)
	≥65 歳	146	25	66	55	30	146	25	66	55	30
		128(87.7%)	23(92.0%)	57(86.4%)	48(87.3%)	21(70.0%)	15(10.3%)	4(16.0%)	5(7.6%)	6(10.9%)	3(10.0%)
原疾患別	慢性糸球体腎炎	115	20	59	36	24	115	20	59	36	24
		102(88.7%)	18(90.0%)	52(88.1%)	32(88.9%)	15(62.5%)	11(9.6%)	5(25.0%)	4(6.8%)	2(5.6%)	4(16.7%)
	糖尿病性腎症	80	16	31	33	10	80	16	31	33	10
		72(90.0%)	15(93.8%)	29(93.5%)	28(84.8%)	8(80.0%)	9(11.3%)	3(18.8%)	1(3.2%)	5(15.2%)	0(0.0%)
	腎硬化症	38	3	22	13	5	38	3	22	13	5
		32(84.2%)	3(100.0%)	17(77.3%)	12(92.3%)	5(100.0%)	3(7.9%)	2(66.7%)	0(0.0%)	1(7.7%)	0(0.0%)
	多発性嚢胞腎	19	4	13	2	1	19	4	13	2	1
		16(84.2%)	4(100.0%)	12(92.3%)	0(0.0%)	1(100.0%)	1(5.3%)	0(0.0%)	1(7.7%)	0(0.0%)	0(0.0%)
	その他	66	15	32	19	10	66	15	32	19	10
		62(93.9%)	15(100.0%)	31(96.9%)	16(84.2%)	7(70.0%)	10(15.2%)	2(13.3%)	4(12.5%)	4(21.1%)	0(0.0%)
透析期間別	<5 年	97	17	45	35	25	97	17	45	35	25
		87(89.7%)	16(94.1%)	39(86.7%)	32(91.4%)	22(88.0%)	13(13.4%)	4(23.5%)	4(8.9%)	5(14.3%)	3(12.0%)
	≥5 年 - <10 年	89	19	49	21	6	89	19	49	21	6
		83(93.3%)	19(100.0%)	46(93.9%)	18(85.7%)	4(66.7%)	12(13.5%)	6(31.6%)	5(10.2%)	1(4.8%)	0(0.0%)
	≥10 年 - <20 年	97	17	48	32	16	97	17	48	32	16
		84(86.6%)	15(88.2%)	43(89.6%)	26(81.3%)	8(50.0%)	7(7.2%)	2(11.8%)	0(0.0%)	5(15.6%)	1(6.3%)
	≥20 年	35	5	15	15	3	35	5	15	15	3
		30(85.7%)	5(100.0%)	13(86.7%)	12(80.0%)	2(66.7%)	2(5.7%)	0(0.0%)	1(6.7%)	1(6.7%)	0(0.0%)

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
血清 iPTH 濃度	≤240 pg/mL	35	11	19	5	4	35	11	19	5	4
ベースライン値別		33(94.3%)	11(100.0%)	17(89.5%)	5(100.0%)	4(100.0%)	7(20.0%)	2(18.2%)	4(21.1%)	1(20.0%)	1(25.0%)
	>240 pg/mL - <500 pg/mL	212	32	101	79	38	212	32	101	79	38
		186(87.7%)	30(93.8%)	89(88.1%)	67(84.8%)	25(65.8%)	23(10.8%)	8(25.0%)	5(5.0%)	10(12.7%)	2(5.3%)
	≥500 pg/mL	71	15	37	19	8	71	15	37	19	8
		65(91.5%)	14(93.3%)	35(94.6%)	16(84.2%)	7(87.5%)	4(5.6%)	2(13.3%)	1(2.7%)	1(5.3%)	1(12.5%)
血清補正 Ca 濃度	<8.4 mg/dL	2	0	0	2	2	2	0	0	2	2
ベースライン値別		2(100.0%)	0(-)	0(-)	2(100.0%)	1(50.0%)	0(0.0%)	0(-)	0(-)	0(0.0%)	0(0.0%)
	≥8.4 mg/dL - <9.0 mg/dL	75	14	24	37	15	75	14	24	37	15
		66(88.0%)	13(92.9%)	21(87.5%)	32(86.5%)	14(93.3%)	16(21.3%)	7(50.0%)	3(12.5%)	6(16.2%)	1(6.7%)
	≥9.0 mg/dL - ≤10.0 mg/dL	180	30	101	49	23	180	30	101	49	23
		159(88.3%)	28(93.3%)	91(90.1%)	40(81.6%)	14(60.9%)	13(7.2%)	2(6.7%)	7(6.9%)	4(8.2%)	3(13.0%)
	>10.0 mg/dL	61	14	32	15	10	61	14	32	15	10
		57(93.4%)	14(100.0%)	29(90.6%)	14(93.3%)	7(70.0%)	5(8.2%)	3(21.4%)	0(0.0%)	2(13.3%)	0(0.0%)
血清 P 濃度	<3.5 mg/dL	4	1	2	1	1	4	1	2	1	1
ベースライン値別		3(75.0%)	1(100.0%)	1(50.0%)	1(100.0%)	1(100.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥3.5 mg/dL - ≤6.0 mg/dL	193	43	94	56	26	193	43	94	56	26
		172(89.1%)	40(93.0%)	84(89.4%)	48(85.7%)	18(69.2%)	23(11.9%)	9(20.9%)	7(7.4%)	7(12.5%)	2(7.7%)
	>6.0 mg/dL	121	14	61	46	23	121	14	61	46	23
		109(90.1%)	14(100.0%)	56(91.8%)	39(84.8%)	17(73.9%)	11(9.1%)	3(21.4%)	3(4.9%)	5(10.9%)	2(8.7%)

例数(割合(%))

表 2.7.4.7−52　内因性要因による部分集団解析 死亡に至った有害事象

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
性別	男	241	43	121	77	39	241	43	121	77	39
		1(0.4%)	0(0.0%)	0(0.0%)	1(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	女	77	15	36	26	11	77	15	36	26	11
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
年齢別	<65 歳	172	33	91	48	20	172	33	91	48	20
		1(0.6%)	0(0.0%)	0(0.0%)	1(2.1%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥65 歳	146	25	66	55	30	146	25	66	55	30
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
原疾患別	慢性糸球体腎炎	115	20	59	36	24	115	20	59	36	24
		1(0.9%)	0(0.0%)	0(0.0%)	1(2.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	糖尿病性腎症	80	16	31	33	10	80	16	31	33	10
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	腎硬化症	38	3	22	13	5	38	3	22	13	5
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	多発性嚢胞腎	19	4	13	2	1	19	4	13	2	1
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	その他	66	15	32	19	10	66	15	32	19	10
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
透析期間別	<5 年	97	17	45	35	25	97	17	45	35	25
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥5 年 - <10 年	89	19	49	21	6	89	19	49	21	6
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥10 年 - <20 年	97	17	48	32	16	97	17	48	32	16
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥20 年	35	5	15	15	3	35	5	15	15	3
		1(0.9%)	0(0.0%)	0(0.0%)	1(2.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血清 iPTH 濃度ベースライン値別	≤240 pg/mL	35	11	19	5	4	35	11	19	5	4
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	>240 pg/mL - <500 pg/mL	212	32	101	79	38	212	32	101	79	38
		1(0.9%)	0(0.0%)	0(0.0%)	1(2.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥500 pg/mL	71	15	37	19	8	71	15	37	19	8
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
血清補正 Ca 濃度ベースライン値別	<8.4 mg/dL	2	0	0	2	2	2	0	0	2	2
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥8.4 mg/dL - <9.0 mg/dL	75	14	24	37	15	75	14	24	37	15
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥9.0 mg/dL - ≤10.0 mg/dL	180	30	101	49	23	180	30	101	49	23
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	>10.0 mg/dL	61	14	32	15	10	61	14	32	15	10
		1(0.9%)	0(0.0%)	0(0.0%)	1(2.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血清 P 濃度ベースライン値別	<3.5 mg/dL	4	1	2	1	1	4	1	2	1	1
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥3.5 mg/dL - ≤6.0 mg/dL	193	43	94	56	26	193	43	94	56	26
		1(0.9%)	0(0.0%)	0(0.0%)	1(2.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	>6.0 mg/dL	121	14	61	46	23	121	14	61	46	23
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

例数(割合(%))

表 2.7.4.7－53　内因性要因による部分集団解析 その他の重篤な有害事象

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
性別	男	241	43	121	77	39	241	43	121	77	39
		37(15.4%)	9(20.9%)	20(16.5%)	8(10.4%)	6(15.4%)	2(0.8%)	1(2.3%)	1(0.8%)	0(0.0%)	0(0.0%)
	女	77	15	36	26	11	77	15	36	26	11
		8(10.4%)	1(6.7%)	4(11.1%)	3(11.5%)	2(18.2%)	1(1.3%)	0(0.0%)	1(2.8%)	0(0.0%)	1(9.1%)
年齢別	<65 歳	172	33	91	48	20	172	33	91	48	20
		18(10.5%)	4(12.1%)	14(15.4%)	0(0.0%)	1(5.0%)	1(0.6%)	1(3.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥65 歳	146	25	66	55	30	146	25	66	55	30
		27(18.5%)	6(24.0%)	10(15.2%)	11(20.0%)	7(23.3%)	2(1.4%)	0(0.0%)	2(3.0%)	0(0.0%)	1(3.3%)

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
原疾患別	慢性糸球体腎炎	115	20	59	36	24	115	20	59	36	24
		12(10.4%)	4(20.0%)	3(5.1%)	5(13.9%)	3(12.5%)	2(1.7%)	1(5.0%)	1(1.7%)	0(0.0%)	1(4.2%)
	糖尿病性腎症	80	16	31	33	10	80	16	31	33	10
		19(23.8%)	5(31.3%)	10(32.3%)	4(12.1%)	1(10.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	腎硬化症	38	3	22	13	5	38	3	22	13	5
		5(13.2%)	0(0.0%)	3(13.6%)	2(15.4%)	1(20.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	多発性嚢胞腎	19	4	13	2	1	19	4	13	2	1
		4(21.1%)	0(0.0%)	4(30.8%)	0(0.0%)	0(0.0%)	1(5.3%)	0(0.0%)	1(7.7%)	0(0.0%)	0(0.0%)
	その他	66	15	32	19	10	66	15	32	19	10
		5(7.6%)	1(6.7%)	4(12.5%)	0(0.0%)	3(30.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
透析期間別	<5 年	97	17	45	35	25	97	17	45	35	25
		13(13.4%)	4(23.5%)	4(8.9%)	5(14.3%)	4(16.0%)	1(1.0%)	0(0.0%)	1(2.2%)	0(0.0%)	1(4.0%)
	≥5 年 - <10 年	89	19	49	21	6	89	19	49	21	6
		13(14.6%)	3(15.8%)	9(18.4%)	1(4.8%)	2(33.3%)	2(2.2%)	1(5.3%)	1(2.0%)	0(0.0%)	0(0.0%)
	≥10 年 - <20 年	97	17	48	32	16	97	17	48	32	16
		14(14.4%)	2(11.8%)	9(18.8%)	3(9.4%)	1(6.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥20 年	35	5	15	15	3	35	5	15	15	3
		5(14.3%)	1(20.0%)	2(13.3%)	2(13.3%)	1(33.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血清 iPTH 濃度ベースライン値別	≤240 pg/mL	35	11	19	5	4	35	11	19	5	4
		8(22.9%)	4(36.4%)	4(21.1%)	0(0.0%)	0(0.0%)	2(5.7%)	0(0.0%)	2(10.5%)	0(0.0%)	0(0.0%)
	>240 pg/mL - <500 pg/mL	212	32	101	79	38	212	32	101	79	38
		29(13.7%)	4(12.5%)	15(14.9%)	10(12.7%)	6(15.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥500 pg/mL	71	15	37	19	8	71	15	37	19	8
		8(11.3%)	2(13.3%)	5(13.5%)	1(5.3%)	2(25.0%)	1(1.4%)	1(6.7%)	0(0.0%)	0(0.0%)	1(12.5%)
血清補正 Ca 濃度ベースライン値別	<8.4 mg/dL	2	0	0	2	2	2	0	0	2	2
		0(0.0%)	0(-)	0(-)	0(0.0%)	1(50.0%)	0(0.0%)	0(-)	0(-)	0(0.0%)	0(0.0%)
	≥8.4 mg/dL - <9.0 mg/dL	75	14	24	37	15	75	14	24	37	15
		11(14.7%)	1(7.1%)	4(16.7%)	6(16.2%)	3(20.0%)	1(1.3%)	0(0.0%)	1(4.2%)	0(0.0%)	1(6.7%)
	≥9.0 mg/dL - ≤10.0 mg/dL	180	30	101	49	23	180	30	101	49	23
		24(13.3%)	4(13.3%)	15(14.9%)	5(10.2%)	3(13.0%)	1(0.6%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)
	>10.0 mg/dL	61	14	32	15	10	61	14	32	15	10
		10(16.4%)	5(35.7%)	5(15.6%)	0(0.0%)	1(10.0%)	1(1.6%)	1(7.1%)	0(0.0%)	0(0.0%)	0(0.0%)

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
血清 P 濃度ベースライン値別	<3.5 mg/dL	4	1	2	1	1	4	1	2	1	1
		1(25.0%)	0(0.0%)	0(0.0%)	1(100.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥3.5 mg/dL - ≤6.0 mg/dL	193	43	94	56	26	193	43	94	56	26
		24(12.4%)	5(11.6%)	13(13.8%)	6(10.7%)	6(23.1%)	1(0.5%)	0(0.0%)	1(1.1%)	0(0.0%)	1(3.8%)
	>6.0 mg/dL	121	14	61	46	23	121	14	61	46	23
		20(16.5%)	5(35.7%)	11(18.0%)	4(8.7%)	2(8.7%)	2(1.7%)	1(7.1%)	1(1.6%)	0(0.0%)	0(0.0%)

例数(割合(%))

表 2.7.4.7－54　内因性要因による部分集団解析 中止の理由となった有害事象

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
性別	男	241	43	121	77	39	241	43	121	77	39
		2(0.8%)	1(2.3%)	1(0.8%)	0(0.0%)	2(5.1%)	2(0.8%)	1(2.3%)	1(0.8%)	0(0.0%)	1(2.6%)
	女	77	15	36	26	11	77	15	36	26	11
		1(1.3%)	0(0.0%)	1(2.8%)	0(0.0%)	2(18.2%)	1(1.3%)	0(0.0%)	1(2.8%)	0(0.0%)	1(9.1%)
年齢別	<65 歳	172	33	91	48	20	172	33	91	48	20
		3(1.7%)	1(3.0%)	2(2.2%)	0(0.0%)	2(10.0%)	3(1.7%)	1(3.0%)	2(2.2%)	0(0.0%)	1(5.0%)
	≥65 歳	146	25	66	55	30	146	25	66	55	30
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(6.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(3.3%)
原疾患別	慢性糸球体腎炎	115	20	59	36	24	115	20	59	36	24
		2(1.7%)	1(5.0%)	1(1.7%)	0(0.0%)	3(12.5%)	2(1.7%)	1(5.0%)	1(1.7%)	0(0.0%)	2(8.3%)
	糖尿病性腎症	80	16	31	33	10	80	16	31	33	10
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	腎硬化症	38	3	22	13	5	38	3	22	13	5
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(20.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	多発性嚢胞腎	19	4	13	2	1	19	4	13	2	1
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	その他	66	15	32	19	10	66	15	32	19	10
		1(1.5%)	0(0.0%)	1(3.1%)	0(0.0%)	0(0.0%)	1(1.5%)	0(0.0%)	1(3.1%)	0(0.0%)	0(0.0%)

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
透析期間別	<5 年	97	17	45	35	25	97	17	45	35	25
		1(1.0%)	0(0.0%)	1(2.2%)	0(0.0%)	2(8.0%)	1(1.0%)	0(0.0%)	1(2.2%)	0(0.0%)	2(8.0%)
	≥5 年 - <10 年	89	19	49	21	6	89	19	49	21	6
		2(2.2%)	1(5.3%)	1(2.0%)	0(0.0%)	0(0.0%)	2(2.2%)	1(5.3%)	1(2.0%)	0(0.0%)	0(0.0%)
	≥10 年 - <20 年	97	17	48	32	16	97	17	48	32	16
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(12.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥20 年	35	5	15	15	3	35	5	15	15	3
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血清 iPTH 濃度	≤240 pg/mL	35	11	19	5	4	35	11	19	5	4
ベースライン値別		2(5.7%)	1(9.1%)	1(5.3%)	0(0.0%)	1(25.0%)	2(5.7%)	1(9.1%)	1(5.3%)	0(0.0%)	1(25.0%)
	>240 pg/mL - <500 pg/mL	212	32	101	79	38	212	32	101	79	38
		1(0.5%)	0(0.0%)	1(1.0%)	0(0.0%)	3(7.9%)	1(0.5%)	0(0.0%)	1(1.0%)	0(0.0%)	1(2.6%)
	≥500 pg/mL	71	15	37	19	8	71	15	37	19	8
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血清補正 Ca 濃度	<8.4 mg/dL	2	0	0	2	2	2	0	0	2	2
ベースライン値別		0(0.0%)	0(-)	0(-)	0(0.0%)	0(0.0%)	0(0.0%)	0(-)	0(-)	0(0.0%)	0(0.0%)
	≥8.4 mg/dL - <9.0 mg/dL	75	14	24	37	15	75	14	24	37	15
		1(1.3%)	0(0.0%)	1(4.2%)	0(0.0%)	1(6.7%)	1(1.3%)	0(0.0%)	1(4.2%)	0(0.0%)	0(0.0%)
	≥9.0 mg/dL - ≤10.0 mg/dL	180	30	101	49	23	180	30	101	49	23
		2(1.1%)	1(3.3%)	1(1.0%)	0(0.0%)	2(8.7%)	2(1.1%)	1(3.3%)	1(1.0%)	0(0.0%)	2(8.7%)
	>10.0 mg/dL	61	14	32	15	10	61	14	32	15	10
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(10.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血清 P 濃度	<3.5 mg/dL	4	1	2	1	1	4	1	2	1	1
ベースライン値別		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥3.5 mg/dL - ≤6.0 mg/dL	193	43	94	56	26	193	43	94	56	26
		2(1.0%)	0(0.0%)	2(2.1%)	0(0.0%)	2(7.7%)	2(1.0%)	0(0.0%)	2(2.1%)	0(0.0%)	1(3.8%)
	>6.0 mg/dL	121	14	61	46	23	121	14	61	46	23
		1(0.8%)	1(7.1%)	0(0.0%)	0(0.0%)	2(8.7%)	1(0.8%)	1(7.1%)	0(0.0%)	0(0.0%)	1(4.3%)

例数(割合(%))

表 2.7.4.7－55　内因性要因による部分集団解析 休薬の理由となった有害事象

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
性別	男	241	43	121	77	39	241	43	121	77	39
		6(2.5%)	4(9.3%)	2(1.7%)	0(0.0%)	0(0.0%)	5(2.1%)	4(9.3%)	1(0.8%)	0(0.0%)	0(0.0%)
	女	77	15	36	26	11	77	15	36	26	11
		8(10.4%)	3(20.0%)	1(2.8%)	4(15.4%)	0(0.0%)	8(10.4%)	3(20.0%)	1(2.8%)	4(15.4%)	0(0.0%)
年齢別	<65 歳	172	33	91	48	20	172	33	91	48	20
		8(4.7%)	3(9.1%)	3(3.3%)	2(4.2%)	0(0.0%)	7(4.1%)	3(9.1%)	2(2.2%)	2(4.2%)	0(0.0%)
	≥65 歳	146	25	66	55	30	146	25	66	55	30
		6(4.1%)	4(16.0%)	0(0.0%)	2(3.6%)	0(0.0%)	6(4.1%)	4(16.0%)	0(0.0%)	2(3.6%)	0(0.0%)
原疾患別	慢性糸球体腎炎	115	20	59	36	24	115	20	59	36	24
		5(4.3%)	2(10.0%)	2(3.4%)	1(2.8%)	0(0.0%)	4(3.5%)	2(10.0%)	1(1.7%)	1(2.8%)	0(0.0%)
	糖尿病性腎症	80	16	31	33	10	80	16	31	33	10
		5(6.3%)	2(12.5%)	1(3.2%)	2(6.1%)	0(0.0%)	5(6.3%)	2(12.5%)	1(3.2%)	2(6.1%)	0(0.0%)
	腎硬化症	38	3	22	13	5	38	3	22	13	5
		1(2.6%)	1(33.3%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.6%)	1(33.3%)	0(0.0%)	0(0.0%)	0(0.0%)
	多発性嚢胞腎	19	4	13	2	1	19	4	13	2	1
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	その他	66	15	32	19	10	66	15	32	19	10
		3(4.5%)	2(13.3%)	0(0.0%)	1(5.3%)	0(0.0%)	3(4.5%)	2(13.3%)	0(0.0%)	1(5.3%)	0(0.0%)
透析期間別	<5 年	97	17	45	35	25	97	17	45	35	25
		7(7.2%)	4(23.5%)	0(0.0%)	3(8.6%)	0(0.0%)	7(7.2%)	4(23.5%)	0(0.0%)	3(8.6%)	0(0.0%)
	≥5 年 - <10 年	89	19	49	21	6	89	19	49	21	6
		5(5.6%)	2(10.5%)	3(6.1%)	0(0.0%)	0(0.0%)	4(4.5%)	2(10.5%)	2(4.1%)	0(0.0%)	0(0.0%)
	≥10 年 - <20 年	97	17	48	32	16	97	17	48	32	16
		2(2.1%)	1(5.9%)	0(0.0%)	1(3.1%)	0(0.0%)	2(2.1%)	1(5.9%)	0(0.0%)	1(3.1%)	0(0.0%)
	≥20 年	35	5	15	15	3	35	5	15	15	3
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
血清 iPTH 濃度	≤240 pg/mL	35	11	19	5	4	35	11	19	5	4
ベースライン値別		2(5.7%)	0(0.0%)	1(5.3%)	1(20.0%)	0(0.0%)	1(2.9%)	0(0.0%)	0(0.0%)	1(20.0%)	0(0.0%)
	>240 pg/mL - <500 pg/mL	212	32	101	79	38	212	32	101	79	38
		10(4.7%)	7(21.9%)	1(1.0%)	2(2.5%)	0(0.0%)	10(4.7%)	7(21.9%)	1(1.0%)	2(2.5%)	0(0.0%)
	≥500 pg/mL	71	15	37	19	8	71	15	37	19	8
		2(2.8%)	0(0.0%)	1(2.7%)	1(5.3%)	0(0.0%)	2(2.8%)	0(0.0%)	1(2.7%)	1(5.3%)	0(0.0%)
血清補正 Ca 濃度	<8.4 mg/dL	2	0	0	2	2	2	0	0	2	2
ベースライン値別		0(0.0%)	0(-)	0(-)	0(0.0%)	0(0.0%)	0(0.0%)	0(-)	0(-)	0(0.0%)	0(0.0%)
	≥8.4 mg/dL - <9.0 mg/dL	75	14	24	37	15	75	14	24	37	15
		11(14.7%)	7(50.0%)	1(4.2%)	3(8.1%)	0(0.0%)	11(14.7%)	7(50.0%)	1(4.2%)	3(8.1%)	0(0.0%)
	≥9.0 mg/dL - ≤10.0 mg/dL	180	30	101	49	23	180	30	101	49	23
		3(1.7%)	0(0.0%)	2(2.0%)	1(2.0%)	0(0.0%)	2(1.1%)	0(0.0%)	1(1.0%)	1(2.0%)	0(0.0%)
	>10.0 mg/dL	61	14	32	15	10	61	14	32	15	10
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血清 P 濃度	<3.5 mg/dL	4	1	2	1	1	4	1	2	1	1
ベースライン値別		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥3.5 mg/dL - ≤6.0 mg/dL	193	43	94	56	26	193	43	94	56	26
		12(6.2%)	7(16.3%)	2(2.1%)	3(5.4%)	0(0.0%)	11(5.7%)	7(16.3%)	1(1.1%)	3(5.4%)	0(0.0%)
	>6.0 mg/dL	121	14	61	46	23	121	14	61	46	23
		2(1.7%)	0(0.0%)	1(1.6%)	1(2.2%)	0(0.0%)	2(1.7%)	0(0.0%)	1(1.6%)	1(2.2%)	0(0.0%)

例数(割合(%))

表 2.7.4.7－56　内因性要因による部分集団解析 減量の理由となった有害事象

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
性別	男	241	43	121	77	39	241	43	121	77	39
		1(0.4%)	1(2.3%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.4%)	1(2.3%)	0(0.0%)	0(0.0%)	0(0.0%)
	女	77	15	36	26	11	77	15	36	26	11
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
年齢別	<65 歳	172	33	91	48	20	172	33	91	48	20
		1(0.6%)	1(3.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.6%)	1(3.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥65 歳	146	25	66	55	30	146	25	66	55	30
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
原疾患別	慢性糸球体腎炎	115	20	59	36	24	115	20	59	36	24
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	糖尿病性腎症	80	16	31	33	10	80	16	31	33	10
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	腎硬化症	38	3	22	13	5	38	3	22	13	5
		1(2.6%)	1(33.3%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.6%)	1(33.3%)	0(0.0%)	0(0.0%)	0(0.0%)
	多発性嚢胞腎	19	4	13	2	1	19	4	13	2	1
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	その他	66	15	32	19	10	66	15	32	19	10
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
透析期間別	<5 年	97	17	45	35	25	97	17	45	35	25
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥5 年 - <10 年	89	19	49	21	6	89	19	49	21	6
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥10 年 - <20 年	97	17	48	32	16	97	17	48	32	16
		1(1.0%)	1(5.9%)	0(0.0%)	0(0.0%)	0(0.0%)	1(1.0%)	1(5.9%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥20 年	35	5	15	15	3	35	5	15	15	3
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血清 iPTH 濃度ベースライン値別	≤240 pg/mL	35	11	19	5	4	35	11	19	5	4
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	>240 pg/mL - <500 pg/mL	212	32	101	79	38	212	32	101	79	38
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥500 pg/mL	71	15	37	19	8	71	15	37	19	8
		1(1.4%)	1(6.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(1.4%)	1(6.7%)	0(0.0%)	0(0.0%)	0(0.0%)

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
血清補正 Ca 濃度ベースライン値別	<8.4 mg/dL	2	0	0	2	2	2	0	0	2	2
		0(0.0%)	0(-)	0(-)	0(0.0%)	0(0.0%)	0(0.0%)	0(-)	0(-)	0(0.0%)	0(0.0%)
	≥8.4 mg/dL - <9.0 mg/dL	75	14	24	37	15	75	14	24	37	15
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥9.0 mg/dL - ≤10.0 mg/dL	180	30	101	49	23	180	30	101	49	23
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	>10.0 mg/dL	61	14	32	15	10	61	14	32	15	10
		1(1.6%)	1(7.1%)	0(0.0%)	0(0.0%)	0(0.0%)	1(1.6%)	1(7.1%)	0(0.0%)	0(0.0%)	0(0.0%)
血清 P 濃度ベースライン値別	<3.5 mg/dL	4	1	2	1	1	4	1	2	1	1
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥3.5 mg/dL - ≤6.0 mg/dL	193	43	94	56	26	193	43	94	56	26
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	>6.0 mg/dL	121	14	61	46	23	121	14	61	46	23
		1(0.8%)	1(7.1%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.8%)	1(7.1%)	0(0.0%)	0(0.0%)	0(0.0%)

例数(割合(%))

表 2.7.4.7−57　内因性要因による部分集団解析　「低カルシウム血症」に関連する有害事象

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
性別	男	241	43	121	77	39	241	43	121	77	39
		10(4.1%)	5(11.6%)	1(0.8%)	4(5.2%)	0(0.0%)	10(4.1%)	5(11.6%)	1(0.8%)	4(5.2%)	0(0.0%)
	女	77	15	36	26	11	77	15	36	26	11
		8(10.4%)	3(20.0%)	0(0.0%)	5(19.2%)	0(0.0%)	8(10.4%)	3(20.0%)	0(0.0%)	5(19.2%)	0(0.0%)
年齢別	<65 歳	172	33	91	48	20	172	33	91	48	20
		9(5.2%)	4(12.1%)	0(0.0%)	5(10.4%)	0(0.0%)	9(5.2%)	4(12.1%)	0(0.0%)	5(10.4%)	0(0.0%)
	≥65 歳	146	25	66	55	30	146	25	66	55	30
		9(6.2%)	4(16.0%)	1(1.5%)	4(7.3%)	0(0.0%)	9(6.2%)	4(16.0%)	1(1.5%)	4(7.3%)	0(0.0%)

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
原疾患別	慢性糸球体腎炎	115	20	59	36	24	115	20	59	36	24
		3(2.6%)	2(10.0%)	0(0.0%)	1(2.8%)	0(0.0%)	3(2.6%)	2(10.0%)	0(0.0%)	1(2.8%)	0(0.0%)
	糖尿病性腎症	80	16	31	33	10	80	16	31	33	10
		7(8.8%)	3(18.8%)	0(0.0%)	4(12.1%)	0(0.0%)	7(8.8%)	3(18.8%)	0(0.0%)	4(12.1%)	0(0.0%)
	腎硬化症	38	3	22	13	5	38	3	22	13	5
		2(5.3%)	1(33.3%)	0(0.0%)	1(7.7%)	0(0.0%)	2(5.3%)	1(33.3%)	0(0.0%)	1(7.7%)	0(0.0%)
	多発性嚢胞腎	19	4	13	2	1	19	4	13	2	1
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	その他	66	15	32	19	10	66	15	32	19	10
		6(9.1%)	2(13.3%)	1(3.1%)	3(15.8%)	0(0.0%)	6(9.1%)	2(13.3%)	1(3.1%)	3(15.8%)	0(0.0%)
透析期間別	<5 年	97	17	45	35	25	97	17	45	35	25
		9(9.3%)	4(23.5%)	0(0.0%)	5(14.3%)	0(0.0%)	9(9.3%)	4(23.5%)	0(0.0%)	5(14.3%)	0(0.0%)
	≥5 年 - <10 年	89	19	49	21	6	89	19	49	21	6
		5(5.6%)	3(15.8%)	1(2.0%)	1(4.8%)	0(0.0%)	5(5.6%)	3(15.8%)	1(2.0%)	1(4.8%)	0(0.0%)
	≥10 年 - <20 年	97	17	48	32	16	97	17	48	32	16
		3(3.1%)	1(5.9%)	0(0.0%)	2(6.3%)	0(0.0%)	3(3.1%)	1(5.9%)	0(0.0%)	2(6.3%)	0(0.0%)
	≥20 年	35	5	15	15	3	35	5	15	15	3
		1(2.9%)	0(0.0%)	0(0.0%)	1(6.7%)	0(0.0%)	1(2.9%)	0(0.0%)	0(0.0%)	1(6.7%)	0(0.0%)
血清 iPTH 濃度ベースライン値別	≤240 pg/mL	35	11	19	5	4	35	11	19	5	4
		2(5.7%)	1(9.1%)	0(0.0%)	1(20.0%)	0(0.0%)	2(5.7%)	1(9.1%)	0(0.0%)	1(20.0%)	0(0.0%)
	>240 pg/mL - <500 pg/mL	212	32	101	79	38	212	32	101	79	38
		15(7.1%)	7(21.9%)	1(1.0%)	7(8.9%)	0(0.0%)	15(7.1%)	7(21.9%)	1(1.0%)	7(8.9%)	0(0.0%)
	≥500 pg/mL	71	15	37	19	8	71	15	37	19	8
		1(1.4%)	0(0.0%)	0(0.0%)	1(5.3%)	0(0.0%)	1(1.4%)	0(0.0%)	0(0.0%)	1(5.3%)	0(0.0%)
血清補正 Ca 濃度ベースライン値別	<8.4 mg/dL	2	0	0	2	2	2	0	0	2	2
		0(0.0%)	0(-)	0(-)	0(0.0%)	0(0.0%)	0(0.0%)	0(-)	0(-)	0(0.0%)	0(0.0%)
	≥8.4 mg/dL - <9.0 mg/dL	75	14	24	37	15	75	14	24	37	15
		13(17.3%)	7(50.0%)	0(0.0%)	6(16.2%)	0(0.0%)	13(17.3%)	7(50.0%)	0(0.0%)	6(16.2%)	0(0.0%)
	≥9.0 mg/dL - ≤10.0 mg/dL	180	30	101	49	23	180	30	101	49	23
		5(2.8%)	1(3.3%)	1(1.0%)	3(6.1%)	0(0.0%)	5(2.8%)	1(3.3%)	1(1.0%)	3(6.1%)	0(0.0%)
	>10.0 mg/dL	61	14	32	15	10	61	14	32	15	10
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
血清 P 濃度ベースライン値別	<3.5 mg/dL	4 0(0.0%)	1 0(0.0%)	2 0(0.0%)	1 0(0.0%)	1 0(0.0%)	4 0(0.0%)	1 0(0.0%)	2 0(0.0%)	1 0(0.0%)	1 0(0.0%)
	≥3.5 mg/dL - ≤6.0 mg/dL	193 14(7.3%)	43 8(18.6%)	94 1(1.1%)	56 5(8.9%)	26 0(0.0%)	193 14(7.3%)	43 8(18.6%)	94 1(1.1%)	56 5(8.9%)	26 0(0.0%)
	>6.0 mg/dL	121 4(3.3%)	14 0(0.0%)	61 0(0.0%)	46 4(8.7%)	23 0(0.0%)	121 4(3.3%)	14 0(0.0%)	61 0(0.0%)	46 4(8.7%)	23 0(0.0%)

例数(割合(%))

表 2.7.4.7－58　内因性要因による部分集団解析　「骨代謝障害」に関連する有害事象

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
性別	男	241 0(0.0%)	43 0(0.0%)	121 0(0.0%)	77 0(0.0%)	39 0(0.0%)	241 0(0.0%)	43 0(0.0%)	121 0(0.0%)	77 0(0.0%)	39 0(0.0%)
	女	77 0(0.0%)	15 0(0.0%)	36 0(0.0%)	26 0(0.0%)	11 0(0.0%)	77 0(0.0%)	15 0(0.0%)	36 0(0.0%)	26 0(0.0%)	11 0(0.0%)
年齢別	<65 歳	172 0(0.0%)	33 0(0.0%)	91 0(0.0%)	48 0(0.0%)	20 0(0.0%)	172 0(0.0%)	33 0(0.0%)	91 0(0.0%)	48 0(0.0%)	20 0(0.0%)
	≥65 歳	146 0(0.0%)	25 0(0.0%)	66 0(0.0%)	55 0(0.0%)	30 0(0.0%)	146 0(0.0%)	25 0(0.0%)	66 0(0.0%)	55 0(0.0%)	30 0(0.0%)
原疾患別	慢性糸球体腎炎	115 0(0.0%)	20 0(0.0%)	59 0(0.0%)	36 0(0.0%)	24 0(0.0%)	115 0(0.0%)	20 0(0.0%)	59 0(0.0%)	36 0(0.0%)	24 0(0.0%)
	糖尿病性腎症	80 0(0.0%)	16 0(0.0%)	31 0(0.0%)	33 0(0.0%)	10 0(0.0%)	80 0(0.0%)	16 0(0.0%)	31 0(0.0%)	33 0(0.0%)	10 0(0.0%)
	腎硬化症	38 0(0.0%)	3 0(0.0%)	22 0(0.0%)	13 0(0.0%)	5 0(0.0%)	38 0(0.0%)	3 0(0.0%)	22 0(0.0%)	13 0(0.0%)	5 0(0.0%)
	多発性嚢胞腎	19 0(0.0%)	4 0(0.0%)	13 0(0.0%)	2 0(0.0%)	1 0(0.0%)	19 0(0.0%)	4 0(0.0%)	13 0(0.0%)	2 0(0.0%)	1 0(0.0%)
	その他	66 0(0.0%)	15 0(0.0%)	32 0(0.0%)	19 0(0.0%)	10 0(0.0%)	66 0(0.0%)	15 0(0.0%)	32 0(0.0%)	19 0(0.0%)	10 0(0.0%)

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
透析期間別	<5 年	97	17	45	35	25	97	17	45	35	25
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥5 年 - <10 年	89	19	49	21	6	89	19	49	21	6
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥10 年 - <20 年	97	17	48	32	16	97	17	48	32	16
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥20 年	35	5	15	15	3	35	5	15	15	3
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血清 iPTH 濃度 ベースライン値別	≤240 pg/mL	35	11	19	5	4	35	11	19	5	4
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	>240 pg/mL - <500 pg/mL	212	32	101	79	38	212	32	101	79	38
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥500 pg/mL	71	15	37	19	8	71	15	37	19	8
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血清補正 Ca 濃度 ベースライン値別	<8.4 mg/dL	2	0	0	2	2	2	0	0	2	2
		0(0.0%)	0(-)	0(-)	0(0.0%)	0(0.0%)	0(0.0%)	0(-)	0(-)	0(0.0%)	0(0.0%)
	≥8.4 mg/dL - <9.0 mg/dL	75	14	24	37	15	75	14	24	37	15
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥9.0 mg/dL - ≤10.0 mg/dL	180	30	101	49	23	180	30	101	49	23
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	>10.0 mg/dL	61	14	32	15	10	61	14	32	15	10
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血清 P 濃度 ベースライン値別	<3.5 mg/dL	4	1	2	1	1	4	1	2	1	1
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥3.5 mg/dL - ≤6.0 mg/dL	193	43	94	56	26	193	43	94	56	26
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	>6.0 mg/dL	121	14	61	46	23	121	14	61	46	23
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

例数(割合(%))

表 2.7.4.7－59　内因性要因による部分集団解析　「胃腸障害」に関連する有害事象

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
性別	男	241	43	121	77	39	241	43	121	77	39
		85(35.3%)	17(39.5%)	42(34.7%)	26(33.8%)	10(25.6%)	2(0.8%)	1(2.3%)	1(0.8%)	0(0.0%)	2(5.1%)
	女	77	15	36	26	11	77	15	36	26	11
		31(40.3%)	9(60.0%)	16(44.4%)	6(23.1%)	3(27.3%)	1(1.3%)	0(0.0%)	0(0.0%)	1(3.8%)	1(9.1%)
年齢別	<65 歳	172	33	91	48	20	172	33	91	48	20
		61(35.5%)	14(42.4%)	31(34.1%)	16(33.3%)	5(25.0%)	1(0.6%)	1(3.0%)	0(0.0%)	0(0.0%)	1(5.0%)
	≥65 歳	146	25	66	55	30	146	25	66	55	30
		55(37.7%)	12(48.0%)	27(40.9%)	16(29.1%)	8(26.7%)	2(1.4%)	0(0.0%)	1(1.5%)	1(1.8%)	2(6.7%)
原疾患別	慢性糸球体腎炎	115	20	59	36	24	115	20	59	36	24
		40(34.8%)	8(40.0%)	22(37.3%)	10(27.8%)	6(25.0%)	2(1.7%)	1(5.0%)	1(1.7%)	0(0.0%)	3(12.5%)
	糖尿病性腎症	80	16	31	33	10	80	16	31	33	10
		27(33.8%)	5(31.3%)	11(35.5%)	11(33.3%)	4(40.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	腎硬化症	38	3	22	13	5	38	3	22	13	5
		12(31.6%)	1(33.3%)	7(31.8%)	4(30.8%)	1(20.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	多発性嚢胞腎	19	4	13	2	1	19	4	13	2	1
		5(26.3%)	2(50.0%)	3(23.1%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	その他	66	15	32	19	10	66	15	32	19	10
		32(48.5%)	10(66.7%)	15(46.9%)	7(36.8%)	2(20.0%)	1(1.5%)	0(0.0%)	0(0.0%)	1(5.3%)	0(0.0%)
透析期間別	<5 年	97	17	45	35	25	97	17	45	35	25
		26(26.8%)	7(41.2%)	11(24.4%)	8(22.9%)	8(32.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(8.0%)
	≥5 年 - <10 年	89	19	49	21	6	89	19	49	21	6
		38(42.7%)	10(52.6%)	19(38.8%)	9(42.9%)	0(0.0%)	1(1.1%)	1(5.3%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥10 年 - <20 年	97	17	48	32	16	97	17	48	32	16
		38(39.2%)	9(52.9%)	21(43.8%)	8(25.0%)	4(25.0%)	1(1.0%)	0(0.0%)	0(0.0%)	1(3.1%)	1(6.3%)
	≥20 年	35	5	15	15	3	35	5	15	15	3
		14(40.0%)	0(0.0%)	7(46.7%)	7(46.7%)	1(33.3%)	1(2.9%)	0(0.0%)	1(6.7%)	0(0.0%)	0(0.0%)

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
血清 iPTH 濃度	≤240 pg/mL	35	11	19	5	4	35	11	19	5	4
ベースライン値別		13(37.1%)	6(54.5%)	6(31.6%)	1(20.0%)	2(50.0%)	1(2.9%)	1(9.1%)	0(0.0%)	0(0.0%)	1(25.0%)
	>240 pg/mL - <500 pg/mL	212	32	101	79	38	212	32	101	79	38
		76(35.8%)	12(37.5%)	39(38.6%)	25(31.6%)	8(21.1%)	2(0.9%)	0(0.0%)	1(1.0%)	1(1.3%)	2(5.3%)
	≥500 pg/mL	71	15	37	19	8	71	15	37	19	8
		27(38.0%)	8(53.3%)	13(35.1%)	6(31.6%)	3(37.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血清補正 Ca 濃度	<8.4 mg/dL	2	0	0	2	2	2	0	0	2	2
ベースライン値別		0(0.0%)	0(-)	0(-)	0(0.0%)	0(0.0%)	0(0.0%)	0(-)	0(-)	0(0.0%)	0(0.0%)
	≥8.4 mg/dL - <9.0 mg/dL	75	14	24	37	15	75	14	24	37	15
		25(33.3%)	6(42.9%)	13(54.2%)	6(16.2%)	4(26.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥9.0 mg/dL - ≤10.0 mg/dL	180	30	101	49	23	180	30	101	49	23
		71(39.4%)	14(46.7%)	37(36.6%)	20(40.8%)	7(30.4%)	2(1.1%)	1(3.3%)	1(1.0%)	0(0.0%)	3(13.0%)
	>10.0 mg/dL	61	14	32	15	10	61	14	32	15	10
		20(32.8%)	6(42.9%)	8(25.0%)	6(40.0%)	2(20.0%)	1(1.6%)	0(0.0%)	0(0.0%)	1(6.7%)	0(0.0%)
血清 P 濃度	<3.5 mg/dL	4	1	2	1	1	4	1	2	1	1
ベースライン値別		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(100.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥3.5 mg/dL - ≤6.0 mg/dL	193	43	94	56	26	193	43	94	56	26
		71(36.8%)	18(41.9%)	34(36.2%)	19(33.9%)	4(15.4%)	1(0.5%)	0(0.0%)	0(0.0%)	1(1.8%)	1(3.8%)
	>6.0 mg/dL	121	14	61	46	23	121	14	61	46	23
		45(37.2%)	8(57.1%)	24(39.3%)	13(28.3%)	8(34.8%)	2(1.7%)	1(7.1%)	1(1.6%)	0(0.0%)	2(8.7%)

例数(割合(%))

表 2.7.4.7－60　内因性要因による部分集団解析　「QT 延長」に関連する有害事象

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
性別	男	241	43	121	77	39	241	43	121	77	39
		5(2.1%)	2(4.7%)	2(1.7%)	1(1.3%)	0(0.0%)	3(1.2%)	1(2.3%)	2(1.7%)	0(0.0%)	0(0.0%)
	女	77	15	36	26	11	77	15	36	26	11
		1(1.3%)	1(6.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(1.3%)	1(6.7%)	0(0.0%)	0(0.0%)	0(0.0%)

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
年齢別	<65 歳	172	33	91	48	20	172	33	91	48	20
		3(1.7%)	1(3.0%)	2(2.2%)	0(0.0%)	0(0.0%)	3(1.7%)	1(3.0%)	2(2.2%)	0(0.0%)	0(0.0%)
	≥65 歳	146	25	66	55	30	146	25	66	55	30
		3(2.1%)	2(8.0%)	0(0.0%)	1(1.8%)	0(0.0%)	1(0.7%)	1(4.0%)	0(0.0%)	0(0.0%)	0(0.0%)
原疾患別	慢性糸球体腎炎	115	20	59	36	24	115	20	59	36	24
		4(3.5%)	2(10.0%)	1(1.7%)	1(2.8%)	0(0.0%)	2(1.7%)	1(5.0%)	1(1.7%)	0(0.0%)	0(0.0%)
	糖尿病性腎症	80	16	31	33	10	80	16	31	33	10
		1(1.3%)	0(0.0%)	1(3.2%)	0(0.0%)	0(0.0%)	1(1.3%)	0(0.0%)	1(3.2%)	0(0.0%)	0(0.0%)
	腎硬化症	38	3	22	13	5	38	3	22	13	5
		1(2.6%)	1(33.3%)	0(0.0%)	0(0.0%)	0(0.0%)	1(2.6%)	1(33.3%)	0(0.0%)	0(0.0%)	0(0.0%)
	多発性嚢胞腎	19	4	13	2	1	19	4	13	2	1
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	その他	66	15	32	19	10	66	15	32	19	10
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
透析期間別	<5 年	97	17	45	35	25	97	17	45	35	25
		1(1.0%)	1(5.9%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥5 年 - <10 年	89	19	49	21	6	89	19	49	21	6
		3(3.4%)	0(0.0%)	2(4.1%)	1(4.8%)	0(0.0%)	2(2.2%)	0(0.0%)	2(4.1%)	0(0.0%)	0(0.0%)
	≥10 年 - <20 年	97	17	48	32	16	97	17	48	32	16
		2(2.1%)	2(11.8%)	0(0.0%)	0(0.0%)	0(0.0%)	2(2.1%)	2(11.8%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥20 年	35	5	15	15	3	35	5	15	15	3
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血清 iPTH 濃度ベースライン値別	≤240 pg/mL	35	11	19	5	4	35	11	19	5	4
		2(5.7%)	1(9.1%)	1(5.3%)	0(0.0%)	0(0.0%)	1(2.9%)	0(0.0%)	1(5.3%)	0(0.0%)	0(0.0%)
	>240 pg/mL - <500 pg/mL	212	32	101	79	38	212	32	101	79	38
		3(1.4%)	1(3.1%)	1(1.0%)	1(1.3%)	0(0.0%)	2(0.9%)	1(3.1%)	1(1.0%)	0(0.0%)	0(0.0%)
	≥500 pg/mL	71	15	37	19	8	71	15	37	19	8
		1(1.4%)	1(6.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(1.4%)	1(6.7%)	0(0.0%)	0(0.0%)	0(0.0%)

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
血清補正 Ca 濃度ベースライン値別	<8.4 mg/dL	2	0	0	2	2	2	0	0	2	2
		0(0.0%)	0(-)	0(-)	0(0.0%)	0(0.0%)	0(0.0%)	0(-)	0(-)	0(0.0%)	0(0.0%)
	≥8.4 mg/dL - <9.0 mg/dL	75	14	24	37	15	75	14	24	37	15
		3(4.0%)	1(7.1%)	1(4.2%)	1(2.7%)	0(0.0%)	2(2.7%)	1(7.1%)	1(4.2%)	0(0.0%)	0(0.0%)
	≥9.0 mg/dL - ≤10.0 mg/dL	180	30	101	49	23	180	30	101	49	23
		2(1.1%)	1(3.3%)	1(1.0%)	0(0.0%)	0(0.0%)	1(0.6%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)
	>10.0 mg/dL	61	14	32	15	10	61	14	32	15	10
		1(1.6%)	1(7.1%)	0(0.0%)	0(0.0%)	0(0.0%)	1(1.6%)	1(7.1%)	0(0.0%)	0(0.0%)	0(0.0%)
血清 P 濃度ベースライン値別	<3.5 mg/dL	4	1	2	1	1	4	1	2	1	1
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥3.5 mg/dL - ≤6.0 mg/dL	193	43	94	56	26	193	43	94	56	26
		3(1.6%)	1(2.3%)	2(2.1%)	0(0.0%)	0(0.0%)	3(1.6%)	1(2.3%)	2(2.1%)	0(0.0%)	0(0.0%)
	>6.0 mg/dL	121	14	61	46	23	121	14	61	46	23
		3(2.5%)	2(14.3%)	0(0.0%)	1(2.2%)	0(0.0%)	1(0.8%)	1(7.1%)	0(0.0%)	0(0.0%)	0(0.0%)

例数(割合(%))

表 2.7.4.7−61　内因性要因による部分集団解析　「水晶体混濁」に関連する有害事象

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
性別	男	241	43	121	77	39	241	43	121	77	39
		5(2.1%)	0(0.0%)	3(2.5%)	2(2.6%)	0(0.0%)	2(0.8%)	0(0.0%)	2(1.7%)	0(0.0%)	0(0.0%)
	女	77	15	36	26	11	77	15	36	26	11
		3(3.9%)	1(6.7%)	1(2.8%)	1(3.8%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
年齢別	<65 歳	172	33	91	48	20	172	33	91	48	20
		3(1.7%)	0(0.0%)	2(2.2%)	1(2.1%)	0(0.0%)	1(0.6%)	0(0.0%)	1(1.1%)	0(0.0%)	0(0.0%)
	≥65 歳	146	25	66	55	30	146	25	66	55	30
		5(3.4%)	1(4.0%)	2(3.0%)	2(3.6%)	0(0.0%)	1(0.7%)	0(0.0%)	1(1.5%)	0(0.0%)	0(0.0%)

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
原疾患別	慢性糸球体腎炎	115	20	59	36	24	115	20	59	36	24
		4(3.5%)	0(0.0%)	2(3.4%)	2(5.6%)	0(0.0%)	1(0.9%)	0(0.0%)	1(1.7%)	0(0.0%)	0(0.0%)
	糖尿病性腎症	80	16	31	33	10	80	16	31	33	10
		1(1.3%)	0(0.0%)	0(0.0%)	1(3.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	腎硬化症	38	3	22	13	5	38	3	22	13	5
		2(5.3%)	1(33.3%)	1(4.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	多発性嚢胞腎	19	4	13	2	1	19	4	13	2	1
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	その他	66	15	32	19	10	66	15	32	19	10
		1(1.5%)	0(0.0%)	1(3.1%)	0(0.0%)	0(0.0%)	1(1.5%)	0(0.0%)	1(3.1%)	0(0.0%)	0(0.0%)
透析期間別	<5 年	97	17	45	35	25	97	17	45	35	25
		5(5.2%)	0(0.0%)	3(6.7%)	2(5.7%)	0(0.0%)	1(1.0%)	0(0.0%)	1(2.2%)	0(0.0%)	0(0.0%)
	≥5 年 - <10 年	89	19	49	21	6	89	19	49	21	6
		2(2.2%)	1(5.3%)	1(2.0%)	0(0.0%)	0(0.0%)	1(1.1%)	0(0.0%)	1(2.0%)	0(0.0%)	0(0.0%)
	≥10 年 - <20 年	97	17	48	32	16	97	17	48	32	16
		1(1.0%)	0(0.0%)	0(0.0%)	1(3.1%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥20 年	35	5	15	15	3	35	5	15	15	3
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血清 iPTH 濃度ベースライン値別	≤240 pg/mL	35	11	19	5	4	35	11	19	5	4
		2(5.7%)	0(0.0%)	2(10.5%)	0(0.0%)	0(0.0%)	1(2.9%)	0(0.0%)	1(5.3%)	0(0.0%)	0(0.0%)
	>240 pg/mL - <500 pg/mL	212	32	101	79	38	212	32	101	79	38
		6(2.8%)	1(3.1%)	2(2.0%)	3(3.8%)	0(0.0%)	1(0.5%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)
	≥500 pg/mL	71	15	37	19	8	71	15	37	19	8
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
血清補正 Ca 濃度ベースライン値別	<8.4 mg/dL	2	0	0	2	2	2	0	0	2	2
		0(0.0%)	0(-)	0(-)	0(0.0%)	0(0.0%)	0(0.0%)	0(-)	0(-)	0(0.0%)	0(0.0%)
	≥8.4 mg/dL - <9.0 mg/dL	75	14	24	37	15	75	14	24	37	15
		3(4.0%)	1(7.1%)	1(4.2%)	1(2.7%)	0(0.0%)	1(1.3%)	0(0.0%)	1(4.2%)	0(0.0%)	0(0.0%)
	≥9.0 mg/dL - ≤10.0 mg/dL	180	30	101	49	23	180	30	101	49	23
		5(2.8%)	0(0.0%)	3(3.0%)	2(4.1%)	0(0.0%)	1(0.6%)	0(0.0%)	1(1.0%)	0(0.0%)	0(0.0%)
	>10.0 mg/dL	61	14	32	15	10	61	14	32	15	10
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
血清 P 濃度ベースライン値別	<3.5 mg/dL	4	1	2	1	1	4	1	2	1	1
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	≥3.5 mg/dL - ≤6.0 mg/dL	193	43	94	56	26	193	43	94	56	26
		6(3.1%)	1(2.3%)	3(3.2%)	2(3.6%)	0(0.0%)	2(1.0%)	0(0.0%)	2(2.1%)	0(0.0%)	0(0.0%)
	>6.0 mg/dL	121	14	61	46	23	121	14	61	46	23
		2(1.7%)	0(0.0%)	1(1.6%)	1(2.2%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

例数(割合(%))

表 2.7.4.7－62　外因性要因による部分集団解析 有害事象全体

部分集団		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
透析方法	HD:血液透析	156	29	84	43	25	156	29	84	43	25
		141(90.4%)	27(93.1%)	74(88.1%)	40(93.0%)	18(72.0%)	19(12.2%)	6(20.7%)	7(8.3%)	6(14.0%)	1(4.0%)
	HDF:血液透析ろ過	162	29	73	60	25	162	29	73	60	25
		143(88.3%)	28(96.6%)	67(91.8%)	48(80.0%)	18(72.0%)	15(9.3%)	6(20.7%)	3(4.1%)	6(10.0%)	3(12.0%)
透析液 Ca 濃度	2.5 mEq/L	122	12	78	32	14	122	12	78	32	14
		111(91.0%)	11(91.7%)	72(92.3%)	28(87.5%)	10(71.4%)	10(8.2%)	4(33.3%)	2(2.6%)	4(12.5%)	1(7.1%)
	2.75 mEq/L	101	16	46	39	21	101	16	46	39	21
		87(86.1%)	16(100.0%)	39(84.8%)	32(82.1%)	17(81.0%)	10(9.9%)	3(18.8%)	3(6.5%)	4(10.3%)	2(9.5%)
	3.0 mEq/L	95	30	33	32	15	95	30	33	32	15
		86(90.5%)	28(93.3%)	30(90.9%)	28(87.5%)	9(60.0%)	14(14.7%)	5(16.7%)	5(15.2%)	4(12.5%)	1(6.7%)
活性型ビタミン D 製剤の有無	無	61	12	22	27	7	61	12	22	27	7
		55(90.2%)	11(91.7%)	19(86.4%)	25(92.6%)	5(71.4%)	8(13.1%)	3(25.0%)	1(4.5%)	4(14.8%)	1(14.3%)
	有	257	46	135	76	43	257	46	135	76	43
		229(89.1%)	44(95.7%)	122(90.4%)	63(82.9%)	31(72.1%)	26(10.1%)	9(19.6%)	9(6.7%)	8(10.5%)	3(7.0%)

例数（割合 %）

表 2.7.4.7－63　外因性要因による部分集団解析 死亡に至った有害事象

		有害事象					副作用				
			SK-1403 群			プラセボ群		SK-1403 群			プラセボ群
部分集団		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
透析方法	HD:血液透析	156	29	84	43	25	156	29	84	43	25
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	HDF:血液透析ろ過	162	29	73	60	25	162	29	73	60	25
		1(0.6%)	0(0.0%)	0(0.0%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
透析液 Ca 濃度	2.5 mEq/L	122	12	78	32	14	122	12	78	32	14
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	2.75 mEq/L	101	16	46	39	21	101	16	46	39	21
		1(1.0%)	0(0.0%)	0(0.0%)	1(2.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	3.0 mEq/L	95	30	33	32	15	95	30	33	32	15
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
活性型ビタミン D 製剤の有無	無	61	12	22	27	7	61	12	22	27	7
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	有	257	46	135	76	43	257	46	135	76	43
		1(0.4%)	0(0.0%)	0(0.0%)	1(1.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

例数（割合 %）

表 2.7.4.7－64　外因性要因による部分集団解析 その他の重篤な有害事象

		有害事象					副作用				
			SK-1403 群			プラセボ群		SK-1403 群			プラセボ群
部分集団		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
透析方法	HD:血液透析	156	29	84	43	25	156	29	84	43	25
		22(14.1%)	6(20.7%)	11(13.1%)	5(11.6%)	4(16.0%)	1(0.6%)	0(0.0%)	1(1.2%)	0(0.0%)	0(0.0%)
	HDF:血液透析ろ過	162	29	73	60	25	162	29	73	60	25
		23(14.2%)	4(13.8%)	13(17.8%)	6(10.0%)	4(16.0%)	2(1.2%)	1(3.4%)	1(1.4%)	0(0.0%)	1(4.0%)

透析液 Ca 濃度	2.5 mEq/L	122	12	78	32	14	122	12	78	32	14
		19(15.6%)	2(16.7%)	15(19.2%)	2(6.3%)	1(7.1%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(7.1%)
	2.75 mEq/L	101	16	46	39	21	101	16	46	39	21
		12(11.9%)	2(12.5%)	4(8.7%)	6(15.4%)	6(28.6%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	3.0 mEq/L	95	30	33	32	15	95	30	33	32	15
		14(14.7%)	6(20.0%)	5(15.2%)	3(9.4%)	1(6.7%)	3(3.2%)	1(3.3%)	2(6.1%)	0(0.0%)	0(0.0%)
活性型ビタミン D 製剤の有無	無	61	12	22	27	7	61	12	22	27	7
		10(16.4%)	2(16.7%)	3(13.6%)	5(18.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	有	257	46	135	76	43	257	46	135	76	43
		35(13.6%)	8(17.4%)	21(15.6%)	6(7.9%)	8(18.6%)	3(1.2%)	1(2.2%)	2(1.5%)	0(0.0%)	1(2.3%)

例数（割合 %）

表 2.7.4.7－65　外因性要因による部分集団解析 中止の理由となった有害事象

		有害事象					副作用				
			SK-1403 群			プラセボ群		SK-1403 群			プラセボ群
部分集団		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
透析方法	HD:血液透析	156	29	84	43	25	156	29	84	43	25
		1(0.6%)	0(0.0%)	1(1.2%)	0(0.0%)	1(4.0%)	1(0.6%)	0(0.0%)	1(1.2%)	0(0.0%)	0(0.0%)
	HDF:血液透析ろ過	162	29	73	60	25	162	29	73	60	25
		2(1.2%)	1(3.4%)	1(1.4%)	0(0.0%)	3(12.0%)	2(1.2%)	1(3.4%)	1(1.4%)	0(0.0%)	2(8.0%)
透析液 Ca 濃度	2.5 mEq/L	122	12	78	32	14	122	12	78	32	14
		1(0.8%)	0(0.0%)	1(1.3%)	0(0.0%)	0(0.0%)	1(0.8%)	0(0.0%)	1(1.3%)	0(0.0%)	0(0.0%)
	2.75 mEq/L	101	16	46	39	21	101	16	46	39	21
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	2(9.5%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(4.8%)
	3.0 mEq/L	95	30	33	32	15	95	30	33	32	15
		2(2.1%)	1(3.3%)	1(3.0%)	0(0.0%)	2(13.3%)	2(2.1%)	1(3.3%)	1(3.0%)	0(0.0%)	1(6.7%)
活性型ビタミン D 製剤の有無	無	61	12	22	27	7	61	12	22	27	7
		1(1.6%)	0(0.0%)	1(4.5%)	0(0.0%)	2(28.6%)	1(1.6%)	0(0.0%)	1(4.5%)	0(0.0%)	1(14.3%)
	有	257	46	135	76	43	257	46	135	76	43
		2(0.8%)	1(2.2%)	1(0.7%)	0(0.0%)	2(4.7%)	2(0.8%)	1(2.2%)	1(0.7%)	0(0.0%)	1(2.3%)

例数（割合 %）

表 2.7.4.7－66　外因性要因による部分集団解析 休薬の理由となった有害事象

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
部分集団		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
透析方法	HD:血液透析	156	29	84	43	25	156	29	84	43	25
		8(5.1%)	6(20.7%)	1(1.2%)	1(2.3%)	0(0.0%)	8(5.1%)	6(20.7%)	1(1.2%)	1(2.3%)	0(0.0%)
	HDF:血液透析ろ過	162	29	73	60	25	162	29	73	60	25
		6(3.7%)	1(3.4%)	2(2.7%)	3(5.0%)	0(0.0%)	5(3.1%)	1(3.4%)	1(1.4%)	3(5.0%)	0(0.0%)
透析液 Ca 濃度	2.5 mEq/L	122	12	78	32	14	122	12	78	32	14
		6(4.9%)	4(33.3%)	0(0.0%)	2(6.3%)	0(0.0%)	6(4.9%)	4(33.3%)	0(0.0%)	2(6.3%)	0(0.0%)
	2.75 mEq/L	101	16	46	39	21	101	16	46	39	21
		5(5.0%)	3(18.8%)	2(4.3%)	0(0.0%)	0(0.0%)	5(5.0%)	3(18.8%)	2(4.3%)	0(0.0%)	0(0.0%)
	3.0 mEq/L	95	30	33	32	15	95	30	33	32	15
		3(3.2%)	0(0.0%)	1(3.0%)	2(6.3%)	0(0.0%)	2(2.1%)	0(0.0%)	0(0.0%)	2(6.3%)	0(0.0%)
活性型ビタミン D 製剤の有無	無	61	12	22	27	7	61	12	22	27	7
		3(4.9%)	2(16.7%)	0(0.0%)	1(3.7%)	0(0.0%)	3(4.9%)	2(16.7%)	0(0.0%)	1(3.7%)	0(0.0%)
	有	257	46	135	76	43	257	46	135	76	43
		11(4.3%)	5(10.9%)	3(2.2%)	3(3.9%)	0(0.0%)	10(3.9%)	5(10.9%)	2(1.5%)	3(3.9%)	0(0.0%)

例数（割合 %）

表 2.7.4.7－67　外因性要因による部分集団解析 減量の理由となった有害事象

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
部分集団		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
透析方法	HD:血液透析	156	29	84	43	25	156	29	84	43	25
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	HDF:血液透析ろ過	162	29	73	60	25	162	29	73	60	25
		1(0.6%)	1(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.6%)	1(3.4%)	0(0.0%)	0(0.0%)	0(0.0%)

透析液 Ca 濃度	2.5 mEq/L	122	12	78	32	14	122	12	78	32	14
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	2.75 mEq/L	101	16	46	39	21	101	16	46	39	21
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	3.0 mEq/L	95	30	33	32	15	95	30	33	32	15
		1(1.1%)	1(3.3%)	0(0.0%)	0(0.0%)	0(0.0%)	1(1.1%)	1(3.3%)	0(0.0%)	0(0.0%)	0(0.0%)
活性型ビタミン D 製剤の有無	無	61	12	22	27	7	61	12	22	27	7
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	有	257	46	135	76	43	257	46	135	76	43
		1(0.4%)	1(2.2%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.4%)	1(2.2%)	0(0.0%)	0(0.0%)	0(0.0%)

例数（割合 %）

表 2.7.4.7－68　外因性要因による部分集団解析　「低カルシウム血症」に関連する有害事象

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
部分集団		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
透析方法	HD:血液透析	156	29	84	43	25	156	29	84	43	25
		12(7.7%)	6(20.7%)	1(1.2%)	5(11.6%)	0(0.0%)	12(7.7%)	6(20.7%)	1(1.2%)	5(11.6%)	0(0.0%)
	HDF:血液透析ろ過	162	29	73	60	25	162	29	73	60	25
		6(3.7%)	2(6.9%)	0(0.0%)	4(6.7%)	0(0.0%)	6(3.7%)	2(6.9%)	0(0.0%)	4(6.7%)	0(0.0%)
透析液 Ca 濃度	2.5 mEq/L	122	12	78	32	14	122	12	78	32	14
		7(5.7%)	4(33.3%)	0(0.0%)	3(9.4%)	0(0.0%)	7(5.7%)	4(33.3%)	0(0.0%)	3(9.4%)	0(0.0%)
	2.75 mEq/L	101	16	46	39	21	101	16	46	39	21
		5(5.0%)	3(18.8%)	0(0.0%)	2(5.1%)	0(0.0%)	5(5.0%)	3(18.8%)	0(0.0%)	2(5.1%)	0(0.0%)
	3.0 mEq/L	95	30	33	32	15	95	30	33	32	15
		6(6.3%)	1(3.3%)	1(3.0%)	4(12.5%)	0(0.0%)	6(6.3%)	1(3.3%)	1(3.0%)	4(12.5%)	0(0.0%)
活性型ビタミン D 製剤の有無	無	61	12	22	27	7	61	12	22	27	7
		6(9.8%)	3(25.0%)	0(0.0%)	3(11.1%)	0(0.0%)	6(9.8%)	3(25.0%)	0(0.0%)	3(11.1%)	0(0.0%)
	有	257	46	135	76	43	257	46	135	76	43
		12(4.7%)	5(10.9%)	1(0.7%)	6(7.9%)	0(0.0%)	12(4.7%)	5(10.9%)	1(0.7%)	6(7.9%)	0(0.0%)

例数（割合 %）

表 2.7.4.7－69　外因性要因による部分集団解析　「骨代謝障害」に関連する有害事象

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
部分集団		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
透析方法	HD:血液透析	156	29	84	43	25	156	29	84	43	25
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	HDF:血液透析ろ過	162	29	73	60	25	162	29	73	60	25
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
透析液 Ca 濃度	2.5 mEq/L	122	12	78	32	14	122	12	78	32	14
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	2.75 mEq/L	101	16	46	39	21	101	16	46	39	21
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	3.0 mEq/L	95	30	33	32	15	95	30	33	32	15
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
活性型ビタミン D 製剤の有無	無	61	12	22	27	7	61	12	22	27	7
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	有	257	46	135	76	43	257	46	135	76	43
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

例数（割合 %）

表 2.7.4.7－70　外因性要因による部分集団解析　「胃腸障害」に関連する有害事象

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
部分集団		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
透析方法	HD:血液透析	156	29	84	43	25	156	29	84	43	25
		52(33.3%)	11(37.9%)	30(35.7%)	11(25.6%)	8(32.0%)	1(0.6%)	0(0.0%)	1(1.2%)	0(0.0%)	1(4.0%)
	HDF:血液透析ろ過	162	29	73	60	25	162	29	73	60	25
		64(39.5%)	15(51.7%)	28(38.4%)	21(35.0%)	5(20.0%)	2(1.2%)	1(3.4%)	0(0.0%)	1(1.7%)	2(8.0%)

透析液 Ca 濃度	2.5 mEq/L	122	12	78	32	14	122	12	78	32	14
		43(35.2%)	5(41.7%)	29(37.2%)	9(28.1%)	5(35.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	2.75 mEq/L	101	16	46	39	21	101	16	46	39	21
		36(35.6%)	6(37.5%)	16(34.8%)	14(35.9%)	6(28.6%)	2(2.0%)	0(0.0%)	1(2.2%)	1(2.6%)	2(9.5%)
	3.0 mEq/L	95	30	33	32	15	95	30	33	32	15
		37(38.9%)	15(50.0%)	13(39.4%)	9(28.1%)	2(13.3%)	1(1.1%)	1(3.3%)	0(0.0%)	0(0.0%)	1(6.7%)
活性型ビタミン D 製剤の有無	無	61	12	22	27	7	61	12	22	27	7
		16(26.2%)	6(50.0%)	5(22.7%)	5(18.5%)	1(14.3%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	1(14.3%)
	有	257	46	135	76	43	257	46	135	76	43
		100(38.9%)	20(43.5%)	53(39.3%)	27(35.5%)	12(27.9%)	3(1.2%)	1(2.2%)	1(0.7%)	1(1.3%)	2(4.7%)

例数（割合 %）

表 2.7.4.7−71　外因性要因による部分集団解析　「QT 延長」に関連する有害事象

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
部分集団		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
透析方法	HD:血液透析	156	29	84	43	25	156	29	84	43	25
		3(1.9%)	2(6.9%)	1(1.2%)	0(0.0%)	0(0.0%)	2(1.3%)	1(3.4%)	1(1.2%)	0(0.0%)	0(0.0%)
	HDF:血液透析ろ過	162	29	73	60	25	162	29	73	60	25
		3(1.9%)	1(3.4%)	1(1.4%)	1(1.7%)	0(0.0%)	2(1.2%)	1(3.4%)	1(1.4%)	0(0.0%)	0(0.0%)
透析液 Ca 濃度	2.5 mEq/L	122	12	78	32	14	122	12	78	32	14
		2(1.6%)	2(16.7%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.8%)	1(8.3%)	0(0.0%)	0(0.0%)	0(0.0%)
	2.75 mEq/L	101	16	46	39	21	101	16	46	39	21
		1(1.0%)	0(0.0%)	1(2.2%)	0(0.0%)	0(0.0%)	1(1.0%)	0(0.0%)	1(2.2%)	0(0.0%)	0(0.0%)
	3.0 mEq/L	95	30	33	32	15	95	30	33	32	15
		3(3.2%)	1(3.3%)	1(3.0%)	1(3.1%)	0(0.0%)	2(2.1%)	1(3.3%)	1(3.0%)	0(0.0%)	0(0.0%)
活性型ビタミン D 製剤の有無	無	61	12	22	27	7	61	12	22	27	7
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	有	257	46	135	76	43	257	46	135	76	43
		6(2.3%)	3(6.5%)	2(1.5%)	1(1.3%)	0(0.0%)	4(1.6%)	2(4.3%)	2(1.5%)	0(0.0%)	0(0.0%)

例数（割合 %）

表 2.7.4.7－72　外因性要因による部分集団解析　「水晶体混濁」に関連する有害事象

		有害事象					副作用				
		SK-1403 群				プラセボ群	SK-1403 群				プラセボ群
部分集団		併合	AJ1002	AJ1003	AJ1004	AJ1004	併合	AJ1002	AJ1003	AJ1004	AJ1004
透析方法	HD:血液透析	156	29	84	43	25	156	29	84	43	25
		6(3.8%)	1(3.4%)	3(3.6%)	2(4.7%)	0(0.0%)	2(1.3%)	0(0.0%)	2(2.4%)	0(0.0%)	0(0.0%)
	HDF:血液透析ろ過	162	29	73	60	25	162	29	73	60	25
		2(1.2%)	0(0.0%)	1(1.4%)	1(1.7%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
透析液 Ca 濃度	2.5 mEq/L	122	12	78	32	14	122	12	78	32	14
		4(3.3%)	1(8.3%)	2(2.6%)	1(3.1%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	2.75 mEq/L	101	16	46	39	21	101	16	46	39	21
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	3.0 mEq/L	95	30	33	32	15	95	30	33	32	15
		4(4.2%)	0(0.0%)	2(6.1%)	2(6.3%)	0(0.0%)	2(2.1%)	0(0.0%)	2(6.1%)	0(0.0%)	0(0.0%)
活性型ビタミン D 製剤の有無	無	61	12	22	27	7	61	12	22	27	7
		0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	有	257	46	135	76	43	257	46	135	76	43
		8(3.1%)	1(2.2%)	4(3.0%)	3(3.9%)	0(0.0%)	2(0.8%)	0(0.0%)	2(1.5%)	0(0.0%)	0(0.0%)

例数（割合 %）

ウパシタ静注透析用 25μg シリンジ
ウパシタ静注透析用 50μg シリンジ
ウパシタ静注透析用 100μg シリンジ
ウパシタ静注透析用 150μg シリンジ
ウパシタ静注透析用 200μg シリンジ
ウパシタ静注透析用 250μg シリンジ
ウパシタ静注透析用 300μg シリンジ

第 2 部（モジュール 2）

2.7.5 参考文献

株式会社三和化学研究所

2.7.5　参考文献

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