SIMPLIFY-1 試験（GS-US-352-0101 試験）

治験の標題

A Phase 3, Randomized, Double-blind Active-controlled Study Evaluating Momelotinib vs. Ruxolitinib in Subjects with Primary Myelofibrosis (PMF) or Post-polycythemia Vera or Post-essential Thrombocythemia Myelofibrosis (Post-PV/ET MF)

報告書番号

FINAL CLINICAL STUDY REPORT

治験責任医師

多施設共同試験

実施医療機関

本試験にはオーストラリア、オーストリア、ベルギー、ブルガリア、カナダ、チェコ、デンマーク、フランス、ドイツ、ハンガリー、イスラエル、日本、オランダ、ポーランド、韓国、ルーマニア、シンガポール、スペイン、スウェーデン、台湾、英国、米国の合計 131 施設から 432 例の被験者が登録された。

公表文献

Mesa RA, Kiladjian JJ, Catalano J V., et al. Simplify-1: A phase III randomized trial of momelotinib versus ruxolitinib in janus kinase inhibitor–naïve patients with myelofibrosis. J Clin Oncol. 2017;35(34):3844–50.

治験期間

最初の被験者のスクリーニング日：2013 年 12 月 6 日
最後の被験者の最終来院日：2019 年 5 月 2 日

開発のフェーズ

第 III 相

目的

GS-US-352-0101（SIMPLIFY-1）試験はヤヌスキナーゼ（JAK）阻害剤による治療歴のない原発性骨髄線維症（PMF）、真性多血症から移行した骨髄線維症（Post PV-MF）又は本態性血小板血症から移行した骨髄線維症（Post ET-MF）の患者を対象として、モメロチニブとルキソリチニブの有効性及び安全性を二重盲検で比較するためにデザインされた。

主要目的：本試験の主要目的は 24 週時の脾臓縮小割合（SRR）に基づきモメロチニブとルキソリチニブの有効性を比較することであった。

副次目的：本試験の副次目的は以下のとおりであった。

- 24 週時の総症状スコア（TSS）改善に対するモメロチニブとルキソリチニブの効果を比較する。
- 24 週時までの赤血球輸血割合に対するモメロチニブとルキソリチニブの効果を比較する。
- 24 週時の赤血球輸血非依存割合に対するモメロチニブとルキソリチニブの効果を比較する。
- 24 週時の赤血球輸血依存割合に対するモメロチニブとルキソリチニブの効果を比較する。

治験方法

本試験は JAK 阻害剤による治療歴のない PMF、Post PV-MF 又は Post ET-MF の患者を対象としてモメロチニブのルキソリチニブに対する非劣性を評価する第 III 相、無作為化、二重盲検、実薬対照、多施設共同試験であった。

本試験の主要期間は最長 5 週間のスクリーニング期、24 週間の二重盲検無作為化期で構成された。被験者は二重盲検無作為化期で以下の 2 つの二重盲検投与群のいずれかに 1：1 の比率で無作為割付けされた。

- モメロチニブ 200 mg 錠 1 日 1 回及びルキソリチニブのプラセボ 1 日 2 回投与
- ルキソリチニブ 1 日 2 回及びモメロチニブのプラセボ 1 日 1 回投与。血小板数、クレアチニンクリアランス、トランスアミナーゼ値［アスパラギン酸アミノトランスフェラーゼ（AST）又はアラニンアミノトランスフェラーゼ（ALT）］に基づき、ルキソリチニブの投与量は 5 mg から 20 mg で 1 日 2 回投与であった。

無作為割付けは、輸血依存（あり又はなし）及び血小板数（100×10^9/L 未満、100×10^9/L 以上 200×10^9/L 以下又は 200×10^9/L 超）により層別化した。

二重盲検無作為化期の完了後、被験者は非盲検拡大治療期（最長 216 週間）にモメロチニブの投与を受けることができた。計画時点での試験参加の最長期間は、スクリーニング期、投与期間、投与後追跡調査期間及び生存調査期間を含めて約 5 年間であった。

スクリーニング後、被験者は modified MPN Symptom Assessment Form TSS（modified MPN-SAF TSS）version 2.0 を毎日入力するため、電子日誌（eDiary）を受け取った。被験者は 24 週間の試験参加中、modified MPN-SAF TSS を毎日入力した。定期的な治験来院時に患者報告に基づくアウトカム（PRO）評価、臨床評価、臨床検査及び疾患評価を実施した。

被験者が治験薬の投与を中止した場合、12 週間の投与後追跡調査を行い、その後は約 6 ヵ月ごとに最長 5 年間又は試験終了まで生存状況を追跡した。

被験者数（計画時及び解析時）

計画時には約 420 例を、2 つの投与群に 1：1 の比率で無作為割付けする予定であった。実際には、二重盲検無作為化期に 432 例を登録し、215 例はモメロチニブ群に、217 例はルキソリチニブ群に割り付けた。非盲検拡大治療期にはモメロチニブを投与された 171 例の被

験者が継続してモメロチニブを投与され（MMB to MMB 集団）、ルキソリチニブを投与された 197 例の被験者がモメロチニブに切り替えた（RUX to MMB 集団）。

診断及び主要な組入れ基準

被験者は本試験に適格となるためには、選択基準をすべて満たし、いずれの除外基準にも該当しないこととした。

選択基準：

1. 18 歳以上の者
2. 左肋骨縁の下方に 5 cm 以上の触知可能な脾腫を有する者
3. 世界保健機関（WHO）の基準に基づいた PMF、International Working Group for Myelofibrosis Research and Treatment（IWG-MRT）効果判定基準に基づいた Post PV-MF/Post ET-MF と確定診断された者
4. 治験責任医師の判断により骨髄線維症の治療を要する者
5. PMF の International Prognostic Scoring System（IPSS）の定義に基づき高リスク若しくは中間-2 リスクの者又は IPSS の定義に基づき中間-1 リスクであり、かつ症候性脾腫、肝腫大、貧血（ヘモグロビン 10.0 g/dL 未満）を伴う者及び／又は現在利用可能な治療法が無効である者
6. 治験薬初回投与前 14 日以内に得られた臨床検査値が以下の基準を満たす者
   - 7 日前から増殖因子を投与しない状態で、好中球絶対数（ANC）が 0.75×10^9/L 以上
   - 7 日前から血小板輸血又はトロンボポエチン模倣薬を投与しない状態で、血小板数が 50×10^9/L 以上［AST／血清グルタミン酸オキサロ酢酸トランスアミナーゼ（SGOT）又は ALT／血清グルタミン酸ピルビン酸トランスアミナーゼ（SGPT）が基準値上限（ULN）の 2 倍以上の場合は 100×10^9/L 以上］
   - 末梢血芽球数が 10%未満
   - AST 及び ALT が ULN の 3 倍以下（肝臓で髄外造血が生じていると治験責任医師が判断した場合又は治験薬初回投与前の 60 日以内に鉄キレート剤を開始した場合は、ULN の 5 倍以下）
   - クレアチニンクリアランス推定値が 45 mL/min 以上
   - 直接ビリルビン値が ULN の 2.0 倍以下
7. Eastern Cooperative Oncology Group（ECOG）パフォーマンスステータスが 0、1 又は 2 の者
8. 24 週間を超える余命が見込まれる者
9. 女性の場合、血清妊娠検査が陰性の者（手術によって不妊の女性又は閉経後 2 年を超えた女性でない場合）
10. 異性間性交を行う男性及び妊娠可能な女性の場合、治験実施計画書に規定した避妊法の使用に同意する者
11. 授乳中の女性の場合は、治験薬初回投与前に授乳を中断することに同意する者

12. 同意説明文書を理解し署名する意思がある者

除外基準：

1. 脾臓摘出歴のある者
2. 治験薬初回投与前の 3 ヵ月以内に脾臓に放射線照射を受けた者
3. 同種骨髄移植又は同種幹細胞移植の適応となる者
4. 治験実施計画書に規定のとおり、コントロール不良の併発疾患又は状態があり、治験要件の遵守が制限されると治療担当医師が判断する者
5. 脚ブロック以外の原因により補正 QT（QTc）間隔が 450 msec を超える者
6. 併発癌又は続発性癌の既往がある者。ただし、以下の場合を除く。適切な治療を施された限局性の皮膚の基底細胞癌若しくは扁平上皮癌、子宮頸部上皮内癌、表在性膀胱癌、転移巣が見つかっておらず、治療の必要がない若しくはホルモン療法のみを要し、無作為化前の 1 年以上にわたって前立腺特異抗原の検査値が正常な無症候性前立腺癌、適切な治療が施され現在は完全寛解の状態にあるステージ 1 若しくは 2 の癌、又は 5 年以上にわたって完全寛解の状態にあるその他の癌
7. ヒト免疫不全ウイルス（HIV）検査陽性の者
8. 慢性活動性若しくは急性の A、B、C 型肝炎ウイルス感染者（B 及び C 型肝炎の検査を要する）、又は B 若しくは C 型肝炎ウイルスのキャリア
9. JAK1 又は JAK2 阻害剤による治療歴のある者
10. 治験薬初回投与前の 1 週間以内に強力なチトクロム P450（CYP）3A4 阻害剤又は強力な CYP3A4 誘導剤、あるいは CYP3A4 と CYP2C9 のデュアル阻害剤を使用した者
11. 治験薬初回投与前の 4 週間以内に化学療法、免疫賦活療法、生物製剤療法、放射線療法又は他の治験治療を受けた者
12. 治験薬初回投与前の 14 日以内に鉄キレート剤の用量を変更した者
13. 過去の治療による非血液学的毒性が未回復で有害事象共通用語規準（CTCAE）グレード 1 超の者
14. CTCAE グレード 2 以上の末梢性ニューロパチーを有する者
15. 磁気共鳴画像（MRI）又はコンピュータ断層撮影（CT）スキャン検査を受ける意思がない又は受けられない者
16. 治験薬、その代謝物又は製剤添加剤に過敏症を有することが既知である者

被験薬、用量及び投与方法

モメロチニブは力価 100 mg、150 mg 及び 200 mg の錠剤であり、被験者自身が 1 日 1 回内服した。モメロチニブの実薬を内服した被験者はルキソリチニブのプラセボ錠を 1 日 2 回内服した。ルキソリチニブのプラセボ錠は有効成分を含まず、ルキソリチニブ錠の 3 通りの製剤と外観が同一になるよう 3 サイズの錠剤としてギリアド・サイエンシズ株式会社（ギリアド社）で製造された。

モメロチニブの開始用量は全被験者で 200 mg であった。モメロチニブの投与は治験実施計画書に規定したとおり治験薬と関連がある血小板減少症により中断する、及び／又は

150 mg 若しくは 100 mg の順に減量を可能としていた。ルキソリチニブのプラセボの開始用量はスクリーニング時の臨床検査値により決定した。

投与期間

被験者は二重盲検無作為化期で 24 週間、非盲検拡大治療期で更に最長 216 週間の投与を受けた。計画時点での試験参加の最長期間は、スクリーニング期、投与期間、投与後追跡調査期間及び生存調査期間を含め約 5 年間であった。

対照薬、用量及び投与方法

ルキソリチニブは力価 5 mg、15 mg 及び 20 mg の錠剤であり、被験者自身が 1 日 2 回内服した。ルキソリチニブの実薬を内服した被験者はモメロチニブのプラセボ錠を 1 日 1 回内服した。モメロチニブのプラセボ錠は有効成分を含まず、モメロチニブ錠と外観は同一であった。

ルキソリチニブの開始用量は治験実施計画書に詳述のとおり、スクリーニング時の臨床検査値により決定した。ルキソリチニブの投与は治験実施計画書の用量調節規定のとおり、治験薬と関連がある血小板減少症により中断及び／又は減量を可能としていた。

評価基準

<u>有効性</u>：

有効性評価はスクリーニング期、ベースライン、二重盲検無作為化期及び非盲検拡大治療期の治験来院、追跡調査来院で実施した。有効性評価には腹部 MRI 又は CT、MPN-SAF TSS v2、輸血記録、骨髄穿刺及び生検、治療効果及びその他の PRO が含まれた。

腹部 MRI は各実施医療機関の画像センターで実施し、脾臓容積の評価のため中央画像検査機関に送付した。被験者が MRI を受けることができない場合のみ、CT スキャンを実施した。可能な限り治験期間全体を通じて同一の画像検査方法を使用することとした。

modified MPN-SAF v2 は骨髄増殖性腫瘍（MPN）患者の症状負荷及び生活の質を評価するために開発された 8 項目の質問票である。被験者は過去 24 時間の次の症状を 0（症状なし）から 10（これ以上ないほど最悪）を用いて評価する［疲労、早期満腹感、腹部の不快感、寝汗、かゆみ（掻痒）、骨痛（関節痛や関節炎ではなく広範囲の骨痛）、左側の肋骨の内側の痛み、非活動性（TSS に含まれない）］。TSS は 0～70 までのスコアであり、非活動性の症状を含まず、経時的に MPN 関連症状の変化を評価した。質問票は eDiary デバイスで毎日入力することとした。

被験者はスクリーニング期間中と治験期間全体を通じて、日誌に輸血を記録した。日誌には、輸血の日付、種類（例：全血、血小板、濃縮血球）及び単位数を記載することとした。輸血及び、輸血時のヘモグロビン値又は血小板数は電子症例報告書（eCRF）に報告された。

各実施医療機関の血液病理医が骨髄穿刺及び生検の検体を評価し、骨髄線維症の重症度分類を行った。骨髄線維症の重症度分類では、レチクリン（例：銀染色）及びコラーゲン線維形成（例：トリクロム染色）も評価した。

治療効果は、MF の IWG-MRT／European Leukemia Net（EUMNET）効果判定基準（改訂版）を用いて判定した。この基準では、臨床検査（例：骨髄の組織検査、血液学的検査）、身体検査（例：脾腫）及び症状の評価に基づいて治療効果を分類した。

その他の PRO には、Patient Global Impression of Change（PGIC）、full MPN Symptom Assessment Form（full MPN-SAF）、Short Form Questionnaire-36 v2（SF-36v2）、European Quality of Life-5 Dimension（EQ-5D）questionnaire、ECOG パフォーマンスステータスの評価があった。

薬物動態：

モメロチニブ及びその主な代謝物 GS-644603（M21）の薬物動態（PK）を評価した。

すべての被験者でトラフ値用 PK 検体（前回のモメロチニブ投与から約 20～26 時間後）を二重盲検無作為化期の 2 週時及び 4 週時、非盲検拡大治療期の 4 週時に採取した。二重盲検無作為化期の 8 週時、12 週時、16 週時、20 週時及び 24 週時（可能な場合には投与前）にも sparse PK 検体を採取した。

Intensive PK 検体を採取する PK サブスタディは、指定した実施医療機関の 21 例を対象に二重盲検無作為化期の 2 週時の来院で実施した。検体は投与前、投与の 0.5、1、1.5、2、3、4、6、12 及び 24 時間後に採取した。

安全性：

安全性評価として、有害事象及び併用薬のモニタリング、臨床検査、バイタルサイン、心電図（ECG）及び身体検査を実施した。

統計手法

被験者の人口統計学的特性及び試験結果は、投与群及び関連する解析対象集団での評価ごとに記述し、要約した。記述的要約を作成し、連続変数については被験者数、平均値、標準偏差（StD）、中央値、第 1 四分位数（Q1）、第 3 四分位数（Q3）、最小値及び最大値を、カテゴリカル変数についてはカテゴリーの数及び割合を示した。評価は、評価日及び種類に基づき、二重盲検無作為化期又は非盲検拡大治療期に実施したものを分類した。二重盲検無作為化期の解析では、被験者を無作為割付けされた治療に従ってグループ化した。非盲検拡大治療期の解析では、モメロチニブを投与されたすべての被験者を二重盲検無作為化期の要約の治療割付けに基づいてグループ化し、二重盲検無作為化期にモメロチニブを投与され、非盲検拡大治療期にモメロチニブを継続投与された被験者は MMB to MMB 集団、二重盲検無作為化期にルキソリチニブを投与され、非盲検拡大治療期にモメロチニブに切り替えられた被験者は RUX to MMB 集団に含めた。二重盲検無作為化期にモメロチニブを投与されたが、非盲検拡大治療期に登録されなかった被験者は、Overall Exposed to MMB 集団に含めた。

有効性：

有効性評価項目の主要解析は、被験者の治験薬投与の有無に関係なく、無作為割付けされたすべての被験者からなる Intent-to-treat（ITT）解析対象集団に基づいて行った。治験薬は最初の無作為化に従って割り付けられた。

主要評価項目は 24 週時の SRR であり、MRI 又は CT の測定で、ベースラインと比較して 24 週時に 35%以上の脾臓容積の減少を達成した被験者の割合と定義した。モメロチニブの非劣性は、層別因子で調整する Cochran-Mantel-Haenszel（CMH）法を用いて、モメロチニブ群の 24 週時の SRR と、ルキソリチニブ群の 24 週時の SRR の 60%で比較し、両側有意水準 0.05 で評価した。非劣性が結論付けられた場合にルキソリチニブに対するモメロチニブの優越性も評価した。

主要有効性評価の結果の頑健性を評価するため、次の感度分析を実施した。Per-protocol 解析対象集団に基づく解析、層別因子で調整しない正確な方法及び CMH 法を用いた ITT 解析対象集団に基づく解析、Last Observation Carried Forward（LOCF）法及び固定マージン法［又は 95%信頼区間（CI）下限法］を用いたルキソリチニブに対するモメロチニブの非劣性解析（マージンは過去のデータに基づき 16%とした）。24 週時の SRR については、サブグループ解析も実施した。

24 週時の SRR に関する主要有効性仮説が両側有意水準 0.05 で棄却された場合、副次評価項目を以下の順で逐次検定し、第 1 種の過誤確率を制御した。帰無仮説が棄却されなかった場合、正式な逐次検定を中止し、残りの副次評価項目については名目上の有意水準のみを記載することにした。

1. ベースラインから 24 週時の TSS 改善割合。modified MPN-SAF TSS v2.0 日誌により測定した TSS が、ベースラインと比較して 24 週時に 50%以上低下した被験者の割合と定義した。
2. 24 週時の赤血球輸血非依存割合。これは、24 週時に輸血非依存であった被験者の割合と定義した。輸血非依存は、臨床的に明らかな出血を伴う被験者を除き、過去 12 週間に赤血球輸血を受けず、かつヘモグロビン値が 8 g/dL 以上と定義した。
3. 24 週時の赤血球輸血依存割合。これは、24 週時に輸血依存であった被験者の割合と定義した。輸血依存は、臨床的に明らかな出血を伴う被験者を除き、過去 8 週間に赤血球輸血を 4 単位以上受けた又はヘモグロビン値が 8 g/dL 未満と定義した。
4. 二重盲検無作為化期の赤血球輸血割合。二重盲検無作為化期における被験者の 1 ヵ月当たりの赤血球輸血単位の平均数で、臨床的に明らかな出血を伴わないものと定義した。

24 週時の SRR と同様の解析手法を用いて、24 週時の TSS 改善割合、輸血非依存割合、輸血依存割合を解析した。

赤血球輸血割合は、追跡調査期間をオフセットパラメータとした負の二項回帰モデルにより解析した。分散の頑健なサンドイッチ推定量を伴う比例平均モデル（Andersen-Gill モデル）を用いて、複数イベントまでの時間（反復輸血イベント）の解析を補助的解析として使用した。複数単位の輸血を考慮するため、同一の繰り返し時点を、同一ではないものとみな

した。主要解析はITT解析対象集団を対象に実施し、感度分析はPer-protocol解析対象集団を対象に実施した。サブグループ解析も実施した。

24週時のSRR、TSS改善割合及び輸血非依存割合を、以下の被験者カテゴリーごとに要約した。評価項目の達成なし、1つ以上の評価項目を達成、1つの評価項目のみ達成、2つの評価項目のみ達成及び3つの評価項目すべて達成。

事前に規定したサブグループ解析及び事後のサブグループ解析には以下を含めた。年齢（65歳未満又は65歳以上）、性別、人種（白人又はその他すべての人種）、ベースラインの脾臓容積（中央値未満又は中央値以上）、ベースラインのヘモグロビン値（8 g/dL未満又は8 g/dL以上）、IPSS予後分類（中間リスク又は高リスク）、MF（PMF、Post PV-MF又はPost ET-MF）、JAK2V617F変異（陽性又は陰性）、ベースラインの血小板数（100×10^9/L未満、100×10^9/L以上200×10^9/L以下、200×10^9/L超）、地理的地域、ベースラインの輸血非依存、ベースラインの非輸血非依存、ベースラインの輸血依存、ベースラインのTSS（10以上）、ベースラインのヘモグロビン値（10 g/dL未満、12 g/dL未満、12 g/dL以上）、ベースラインのTSSが10以上かつヘモグロビン値10 g/dL未満、ベースラインの血小板数（150×10^9/L未満、150×10^9/L以上300×10^9/L以下、300×10^9/L超）。

<u>薬物動態</u>：

モメロチニブとその主要な代謝物M21のPKパラメータは、標準的なノンコンパートメント法（WinNonlin®ソフトウェア）を用いて推定し、用量、投与時間、血漿中濃度及び実測値は、可能な限り投与時間に基づいて入力した。モメロチニブ及びM21のPKパラメータを一覧にし、記述統計量に要約した。

また、M21とモメロチニブの曝露量［最高血漿中濃度（Cmax）、0時間から最終定量可能時間までの血漿中濃度-時間曲線下面積（AUC）（AUClast）及び定常状態における投与間隔ごとのAUC（AUCtau）］のモル比も算出し、要約した。

<u>安全性</u>：

有害事象はICH国際医薬用語集（MedDRA）第22.0版を用いてコード化した。治験治療下で発現した以下の有害事象の概要を、投与群別に被験者数及び割合で簡潔に示した。有害事象、グレード3以上の有害事象、グレード3又は4の有害事象、治験薬と関連がある有害事象、グレード3以上の治験薬と関連がある有害事象、重篤な有害事象、治験薬と関連がある重篤な有害事象、治験薬の投与中止に至った有害事象、投与中断又は減量に至った有害事象、死亡に至った有害事象、注目すべき有害事象｛末梢性ニューロパチー［MedDRA標準検索式（SMQ）狭域］｝及び初回投与効果として定義される有害事象。有害事象の要約には、安全性解析対象集団に基づき、有害事象を発現した被験者数及び割合を器官別大分類（SOC）、基本語（PT）及び一般的な重症度（特に定義されていない場合）を投与群別に示した。臨床検査データは定量的及び定性的手法の両方を用いて解析し、要約した。

結果

本試験には合計 432 例の被験者が組み入れられ、二重盲検無作為化期にモメロチニブ群（215 例）又はルキソリチニブ群（217 例）のいずれかに無作為割付けされた。二重盲検無作為化期で、各投与群の 1 例が無作為割付けされたが、投与は受けなかった。したがって、モメロチニブ群では 214 例、ルキソリチニブ群では 216 例が投与を受けた。全体として、モメロチニブ群の 175 例（81.4%）及びルキソリチニブ群の 201 例（92.6%）が二重盲検無作為化期の投与を完了した。モメロチニブ群の 40 例（18.6%）及びルキソリチニブ群の 16 例（7.4%）が治験薬投与を早期に中止した。

合計 368 例が非盲検拡大治療期に移行した。このうち 171 例（79.5%）がモメロチニブを継続し（MMB to MMB 集団）、197 例（90.8%）がルキソリチニブからモメロチニブに切り替えた（RUX to MMB 集団）。治験依頼者は、被験者が 5 年間の追跡調査を完了する前に治験を終了した。治験終了時にモメロチニブを投与されていた被験者は、モメロチニブの投与を継続するために拡大アクセス試験（SRA-MMB-4365）へ移行することができた。

人口統計学的特性及びベースラインの疾患特性は投与群間で同程度であり、高いアンメットメディカルニーズを有する高リスクの MF 患者集団とも一致していた。二重盲検無作為化期では、ITT 解析対象集団のベースライン時の年齢の中央値は 66.0 歳であり、57.2%が 65 歳以上であった。全体では、被験者の 56.5%が男性、82.6%が白人であり、被験者の大部分（89.1%）はヒスパニック系又はラテン系ではなかった。被験者のおよそ半数（56.5%）が試験登録時に PMF と診断され、残りの被験者は Post ET-MF（20.8%）又は Post PV-MF（22.7%）と診断された。すべての被験者の MF 診断からの期間の中央値（範囲）は 1.7（0.0～28.0）年であった。

IPSS により、すべての被験者が高リスク（46.3%）、中間-2 リスク（33.1%）又は中間-1 リスク（20.6%）に分類され、低リスクに分類された被験者はいなかった。被験者の大半はベースラインの ECOG パフォーマンスステータスが 0（34.3%）又は 1（56.0%）、骨髄線維化評価のグレードが 3（57.3%）であった。ベースラインの脾臓容積の中央値（範囲）は 1915.6（206～9022）cm^3 であり、被験者の 63.2%で触知可能な 10 cm 以上の脾腫を有していた。脾臓容積及び脾臓サイズの中央値は、モメロチニブ群（それぞれ 2009.6 cm^3 及び 12.0 cm）でルキソリチニブ群（それぞれ 1910.8 cm^3 及び 11.0 cm）よりも大きかった。ベースラインの TSS の中央値は、モメロチニブ群で 17.4（範囲：0～53）、ルキソリチニブ群で 16.4（範囲：0～56）であった。

非盲検拡大治療期に移行した被験者の人口統計学的特性及びベースラインの疾患特性は、二重盲検無作為化期でのベースラインと概ね同様であった。

有効性の結果

脾臓縮小において、モメロチニブのルキソリチニブに対する非劣性が統計学的に示され、本試験の主要評価項目を達成した。副次評価項目である症状改善に関するモメロチニブの非劣性は示されなかった。多くの貧血の評価項目において、モメロチニブによる名目上有意な改善が示された。主な有効性の所見を以下に要約する。

脾臓の縮小：

脾臓縮小が認められた被験者の割合は、モメロチニブ群で 26.5%（215 例中 57 例）、ルキソリチニブ群で 29.5%（217 例中 64 例）であった。これらは臨床的に同程度の結果であり、層別 CMH 法による非劣性の割合の差（95% CI）は 0.09（0.02, 0.16）であった。両側 95% CI の下限が 0 を上回ったため、モメロチニブは主要評価項目であるルキソリチニブに対する非劣性を達成した。

モメロチニブの投与を継続した被験者及びルキソリチニブからモメロチニブに切り替えた被験者で、非盲検拡大治療期の 24 週以降、更なる脾臓縮小が認められた。非盲検拡大治療期の 48 週時に、MMB to MMB 集団（12 例）及び RUX to MMB 集団（22 例）で新たな脾臓縮小も認められた。

脾臓縮小は持続し、持続期間の中央値はモメロチニブ群で 156.3 週間（35.9 ヵ月）、ルキソリチニブ群で 83.0 週間（19.1 ヵ月）であった。安全性解析対象集団のすべての被験者の追跡調査期間の中央値は、モメロチニブ群で 35.4 ヵ月、ルキソリチニブ群で 35.2 ヵ月であった。

症状の改善：

modified MPN-SAF TSS がベースラインから 50%以上低下した被験者の割合は、ルキソリチニブ群（42.2%）と比較してモメロチニブ群（28.4%）で低かった。層別 CMH 法による非劣性の割合の差（95% CI）は 0.00（-0.08、0.08）であった。両側 95% CI の下限が 0 以下であったため、モメロチニブ群のルキソリチニブ群に対する非劣性は示されなかった。

すべての個々の症状スコアの中央値は、モメロチニブ群及びルキソリチニブ群の被験者でベースラインと比較して同程度に改善した。本試験での症状に関するベネフィット全体をより深く理解するため、個別項目の事後解析を実施した。カテゴリカルな健康状態の変化、カテゴリカルなレスポンダー割合、モデルに基づく改善度解析等、TSS を構成する 7 項目の単一項目ごとの解析により、これらの結果を確認した。

モメロチニブ群及びルキソリチニブ群の両方で認められた症状改善を考慮し、ITT 解析対象集団及び定義された症状を有する被験者サブセット（TSS が 10 以上）の両方について、経時的 MMRM 解析を用いて TSS による治療効果を検討した。本解析での、24 週時の 2 分変数を用いたランドマーク解析では最後の 4 週間のみではなく、24 週間の二重盲検無作為化期全体の PRO データをすべて使用した。モメロチニブ群とルキソリチニブ群間の 24 週時のベースラインからの変化量の最小二乗平均の差は、全集団の 70 ポイントスケールで 1.24 ポイントであった。その他の評価可能時点では、両群の差はより小さかった。症状を有する集団におけるモメロチニブ群とルキソリチニブ群間のベースラインからの変化量の平均値の差は、各来院時の 70 ポイントスケールで 1.26 ポイント以下であり、2 群間の臨床的な差がわずかであることが再度示された。

被験者がベネフィットを認識した TSS の最小の変化を事後的に算出し、この補助的な MMRM 解析に適用した。試験固有の被験者内で意味のある変化の閾値は 8 ポイントと判断された。モメロチニブを投与された被験者 175 例中 69 例（39%）及びルキソリチニブを投

与された被験者 190 例中 77 例（41%）で、ベースラインからの変化データが得られ、8 ポイント以上の改善が認められた。

貧血の改善：

モメロチニブは、activin A receptor type 1（ACVR1）阻害及びヘプシジン濃度上昇の抑制を介して炎症に起因する貧血に影響を及ぼすことにより、JAK 阻害剤による治療歴のない被験者で貧血の負担を軽減した。主な貧血改善所見を以下に要約する。

- モメロチニブ群及びルキソリチニブ群の輸血非依存割合を、24 週時のランドマーク解析（66.5%対 49.3%）及び 24 週時までの 12 週間のローリング解析（76.3%対 59.4%）で評価したところ、いずれにおいてもモメロチニブ群でルキソリチニブ群に対し、名目上の統計学的な有意差が認められた（$p<0.001$）。
- 24 週時の輸血非依存割合と同様に、24 週時の非赤血球輸血割合は、モメロチニブ群がルキソリチニブ群と比較して高かった（70.2%対 54.4%）。
- 非盲検拡大治療期の 24 週時（試験の 48 週時）では、非赤血球輸血割合は MMB to MMB 集団が 75.4%、RUX to MMB 集団が 66.5%であった。
- モメロチニブ群及びルキソリチニブ群のいずれにおいても、二重盲検無作為化期及び非盲検拡大治療期を合わせた輸血非依存の持続期間の中央値には到達しなかった。
- モメロチニブ群ではベースラインの血小板数が 50～150×10^9/L、150 超～300×10^9/L、300 超×10^9/L の各サブグループで輸血非依存割合が維持されたが、ルキソリチニブ群ではベースラインの血小板数が低い被験者における輸血非依存割合の顕著な減少が認められた。
- モメロチニブ群（30.2%）は、ルキソリチニブ群（40.1%）と比べて 24 週時の輸血依存の割合が低かった。この差は名目上統計学的に有意であった。
- 輸血を受けた被験者の割合、ゼロ過剰負の二項分布モデル及び初回、3 回目、5 回目の輸血までの期間に関する探索的事後解析は、いずれもルキソリチニブを投与された被験者と比較してモメロチニブを投与された被験者で輸血負荷が減少していることを示した。モメロチニブ投与中の輸血リスクのハザード比は、ルキソリチニブに対して 0.522 であった。
- モメロチニブを投与された被験者ではヘモグロビンの急速な増加が認められ、経時的に維持されたが、二重盲検無作為化期にルキソリチニブを投与された被験者ではヘモグロビンの有意な減少が認められた。非盲検拡大治療期にルキソリチニブからモメロチニブに切り替えた被験者では、ベースライン値あるいはそれ以上にヘモグロビンの平均値が持続的に上昇することが示された。
- ITT 解析対象集団及び輸血非依存集団において、モメロチニブは 24 週時にヘモグロビン増加を誘発した。ITT 解析対象集団の事後解析では、ヘモグロビンが 2 g/dL 以上増加した被験者の割合は、モメロチニブを投与された被験者では 16.7%であったのに対し、ルキソリチニブを投与された被験者では 6.0%であった。輸血非依存集団では、ヘモグロビンが 2 g/dL 以上増加した被験者の割合は、モメロチニブを

投与された被験者では 12.2%であったのに対し、ルキソリチニブを投与された被験者では 2.0%であった。

全生存期間：

全生存期間（OS）の Kaplan-Meier 推定値の中央値は、モメロチニブ群では未到達［95% CI：46.19、到達せず（NR）］であり、ルキソリチニブ群では 53.1 ヵ月（95% CI：48.72、NR）であった。ハザード比は 0.99 であった。この差は統計学的に有意ではなかった。

その他の有効性評価項目：

24 週時に、事前に規定した評価項目（脾臓縮小、症状改善又は輸血非依存）のうち 2 項目以上を達成した被験者の割合は、モメロチニブ群で 38.6%（83 例）、ルキソリチニブ群で 34.6%（75 例）であった。3 つの評価項目全てを達成した被験者の割合は、モメロチニブ群で 10.2%（22 例）、ルキソリチニブ群で 8.3%（18 例）であった。

薬物動態の結果

概して、モメロチニブ及び M21 の血漿中濃度は 2 週間以内に定常状態に達すると考えられ、血漿中濃度は 2 週時及び 24 週時で同程度であった。被験者のサブセットから算出された PK パラメータは、いずれの試験で算出されたパラメータも類似していた。

安全性の結果

本試験でモメロチニブを投与された MF 被験者 411 例（このうち 197 例は非盲検拡大治療期にルキソリチニブからモメロチニブへ切り替えた）の忍容性は良好であった。24 週間の二重盲検無作為化期において、モメロチニブはルキソリチニブと比較して良好な結果を示した。二重盲検無作為化期中のモメロチニブの忍容性は、ルキソリチニブの忍容性と概ね同程度であった。二重盲検無作為化期にモメロチニブを中止した被験者は、ルキソリチニブを中止した被験者よりも多かった。しかし、中止の大部分は低いグレード（グレード 1～3）の有害事象によるものであった。この不均衡は、治験実施計画書に詳述されているルキソリチニブの減量基準に起因するものであり、減量又は投与中断に至った被験者の割合は、ルキソリチニブに無作為割付けされた被験者で、モメロチニブに無作為割付けされた被験者と比較して 2 倍以上であった（56.0%対 26.2%）。24 週以降、モメロチニブの投与を継続した被験者では、新たな毒性所見又は進行性の毒性所見は認められなかった。非盲検拡大治療期にルキソリチニブからモメロチニブに切り替えた被験者でも、新たな安全性所見は認められなかった。

27 例が二重盲検無作為化期に有害事象によりモメロチニブを中止した。早期中止（1～24 週）割合の高さは、重症度が低く（グレード 1～3）、単一の SOC 又は PT 別の有害事象ではない有害事象の発現割合の高さに起因しており、早期のモメロチニブ中止の大部分を占めた。

モメロチニブを投与された被験者では、モメロチニブの用量強度が維持された。モメロチニブに無作為割付けされた被験者では、二重盲検無作為化期及び非盲検拡大治療期（0～48

週）のいずれにおいても、高い用量強度が維持された。一方、ルキソリチニブに無作為割付けされた被験者では、用量強度は低く、24 週間の二重盲検無作為化期終了まで 20～25 mg 1 日 2 回の最大用量を投与された被験者は 36.9%であった。非盲検拡大治療期（24～48 週）にルキソリチニブからモメロチニブに切り替えた被験者は、非盲検拡大治療期を通して高い用量強度を維持し、モメロチニブの 1 日平均用量は 174.6 mg（モメロチニブ最大用量の 87.3%）であった。

二重盲検無作為化期にモメロチニブ又はルキソリチニブに曝露した被験者で多く認められた有害事象のうち、一部例外はあったものの、ほとんどの有害事象の発現割合は 2 群間で類似していた。二重盲検無作為化期において、悪心、嘔吐、低血圧、潮紅及び末梢性ニューロパチーの発現割合はモメロチニブ群で高かったが、貧血、血小板減少症、高血圧及び骨痛の発現割合はルキソリチニブ群で高かった。24 週から 48 週までのモメロチニブの継続投与により、有害事象の発現は減少し、モメロチニブの忍容性は 24 週間を超えて継続投与した場合の方が良好であることが示された。ルキソリチニブからモメロチニブに切り替えた被験者での非盲検拡大治療期（24～48 週）のモメロチニブの安全性プロファイルは、JAK 阻害剤による治療歴のない被験者でのモメロチニブの安全性プロファイルがルキソリチニブによる治療歴のある被験者の安全性プロファイルと類似していることを示唆している。治験期間中のいずれかの時点でモメロチニブに曝露した被験者の有害事象プロファイルは、最初の 24 週間にモメロチニブを投与された被験者と類似しているが、発現割合がわずかに高かった。しかし、この集団の観察期間は二重盲検無作為化期よりもはるかに長かった。有害事象はモメロチニブの最初の投与期間中に発現し、その後、被験者がモメロチニブへの曝露を継続しても大幅に増加することはなかった。

グレード 3 又は 4 の有害事象は、二重盲検無作為化期にモメロチニブ群とルキソリチニブ群間で同程度の発現割合で報告されたが、例外として貧血はモメロチニブ群（6.1%）と比較して、ルキソリチニブ群で発現割合が高かった（22.7%）。しかし、非盲検拡大治療期にルキソリチニブ群の被験者がモメロチニブに移行した後、貧血の有害事象の発現は減少し、モメロチニブ投与期間を通してそれが維持された。グレード 3 又は 4 の有害事象の発現割合は、二重盲検無作為化期（0～24 週）に最初にモメロチニブに曝露した群と比較してモメロチニブを継続した群（24～48 週）で低かったことから、モメロチニブの継続投与によりグレード 3 又は 4 の有害事象の発現割合が上昇しないことが示唆された。グレード 3 又は 4 のその他の有害事象を発現した被験者の割合は、二重盲検無作為化期にモメロチニブに曝露した群と Overall Exposed to MMB 集団で類似していた。Overall Exposed to MMB 集団全体では、二重盲検無作為化期と比較してグレード 3 又は 4 の有害事象の発現割合がわずかに高かった。しかし、この集団の観察期間は二重盲検無作為化期よりもはるかに長かった。以上をまとめると、モメロチニブへの曝露を継続しても、グレードの高い有害事象が高頻度に発現することはないことが示唆された。

治験責任医師により治験薬と関連があると判断された有害事象は、モメロチニブ群とルキソリチニブ群間で類似しており、一部の治験薬と関連があると判断された有害事象は、モメロチニブ群又はルキソリチニブ群のいずれかで高い発現割合で認められた。2 群間で大幅に異なる割合（10%を上回る差）で治験薬と関連があると判断された有害事象は貧血のみであ

り、モメロチニブ群では 8.4%であったのに対し、ルキソリチニブ群では 30.1%であった。治験薬と関連があるグレード 3 又は 4 の有害事象は、二重盲検無作為化期ではモメロチニブ群とルキソリチニブ群で類似していたが、例外として貧血はルキソリチニブ群で高い発現割合であった（ルキソリチニブ群で 18.5%、モメロチニブ群で 3.3%）。治験薬と関連があると判定されたグレード 3 又は 4 の有害事象の発現割合は、二重盲検無作為化期（0～24 週）にモメロチニブに曝露した群よりも、モメロチニブを継続投与した群（24～48 週）の方が低かったことから、モメロチニブの継続投与により有害事象の発現割合が上昇しないことが示唆された。

二重盲検無作為化期では、末梢性ニューロパチー［末梢性ニューロパチー（狭域）］の事象が、モメロチニブ群でルキソリチニブ群より多く認められた［モメロチニブ群で 22 例（10.3%）、ルキソリチニブ群で 12 例（5.6%）］。二重盲検無作為化期では、ほぼすべての事象がグレード 1 又は 2 であり、ルキソリチニブ群ではグレード 3 の事象が 1 件認められた。二重盲検無作為化期中、末梢性ニューロパチーによりモメロチニブ又はルキソリチニブを中止した被験者はいなかったが、その後 9 例が中止した。更に、錯感覚のため 2 例がモメロチニブを中止した。Overall Exposed to MMB 集団では、69 例（16.8%）に末梢性ニューロパチーが認められた。ほとんどの事象は概してグレードが低く、6 例の被験者でグレード 3 の事象が認められた。Overall Exposed to MMB 集団では、22 例（5.4%）の被験者の末梢性ニューロパチーが試験終了時までに消失し、47 例（11.4%）の被験者の末梢性ニューロパチーは試験終了時までに消失しなかった。事象が未消失であった被験者の最大グレードは大半が軽度から中等度であったことから、ニューロパチーはモメロチニブ治療を継続しても低グレードで報告され、ほとんどの事象はモメロチニブへの曝露を継続しても重症度は上昇しないことが示唆された。

本試験では、重大な日和見感染は認められなかった。帯状疱疹等の日和見感染ではなく再活性化によると考えられる感染症は、二重盲検無作為化期にモメロチニブ群（1.9%）とルキソリチニブ群（1.3%）で同程度の発現割合で報告され、Overall Exposed to MMB 集団（1.7%）では顕著に高い値ではなかった。これは背景疾患での発現割合を反映した可能性がある。

血液及びリンパ系障害の SOC として報告された有害事象を、モメロチニブ群の二重盲検無作為化期（0～24 週）と Overall Exposed to MMB 集団で比較したところ、臨床的に意義のある差は認められず、蓄積性の血液毒性がないことが示唆された。血小板、好中球及びヘモグロビンでの重要な差、血小板減少症によるルキソリチニブの投与中断又は減量の高い割合、並びに二重盲検無作為化期でのルキソリチニブ群の血小板減少症及び貧血の有害事象の増加は、モメロチニブによる骨髄抑制作用がルキソリチニブよりも低いことを示唆している。24 週後にモメロチニブに切り替えたルキソリチニブ群の被験者では、より重大な骨髄抑制作用は速やかに消失すると考えられる。

ベースラインの血小板数が 150×10^9/L 未満であった血小板減少症の被験者の有害事象プロファイルは、モメロチニブ群とルキソリチニブ群で類似していた。血小板減少症は、モメロチニブ群（14.9%）と比較してルキソリチニブ群（38.2%）で多く認められ、両群で治験薬の投与中止に至った有害事象として最も高頻度であった。

二重盲検無作為化期の死亡に至った有害事象では、ルキソリチニブ群とモメロチニブ群で意義のある差は認められなかった。非盲検拡大治療期（24 週以降）では、モメロチニブを継続した被験者 18 例（10.5%）及びルキソリチニブからモメロチニブに切り替えた被験者 17 例（8.6%）が有害事象により死亡に至った。Overall Exposed to MMB 集団では、心停止、心不全、肺炎により各 3 例が死亡したが、3 例超の死亡に至った個別の有害事象は報告されなかった。死亡に至った有害事象のうち、治験薬と関連があると報告されたものはなかった。全体での死因は、MF 患者の既知の主な死因と一致していた。

結論

本試験の目的は、JAK 阻害剤による治療歴のない PMF、Post PV-MF 又は Post ET-MF を有する患者を対象に、モメロチニブの有効性及び安全性をルキソリチニブと比較し評価することであった。本試験の目的は、SRR 及び TSS 改善割合について、モメロチニブのルキソリチニブに対する非劣性を、赤血球輸血関連評価項目での優越性と共に示すことであった。

本試験は、SRR に臨床的に意義があり、非劣性であることを示す主要目的を達成した。しかし、TSS 改善割合の主な解析手法では、TSS に関する主な副次目的を達成しなかった。症状改善割合と個別の項目解析等の他のベネフィット指標との相違を理解するために実施した事後解析により、臨床的に同程度の症状に関するベネフィットが示された。

ベースラインの症状スコアによる層別化を実施しなかったことを含む、試験デザインの多くの特徴により、モメロチニブ群の被験者でベースラインの症状スコアの平均値及び中央値が高くなった。そのため、モメロチニブ群では 50%の改善の定義を満たすためには、TSS のより大きな変化が必要となり、意図的ではない不利がモメロチニブ群に生じた。症状負荷が低く（TSS が 10 未満等）、治療による症状負荷の変化が臨床的に重要ではない被験者を組み入れたことも、症状改善の解釈を複雑にした。

本試験では、JAK 阻害剤の承認申請を目的とした試験として初めて疲労を組み込んだ 7 項目の TSS 指標を用いたため、6 項目の TSS 指標を用いたルキソリチニブの COMFORT-1 試験に基づいて統計学的有意性に関する非劣性マージンを設定したことも症状改善の解釈を複雑にした。

以上をまとめると、JAK 阻害剤による治療歴のない集団全体でのドメイン及び個々の項目レベルの事後解析から、モメロチニブの一貫した臨床的に意義のある症状改善割合はルキソリチニブと同程度であることが示唆された。ただし、事前に規定した 24 週時の TSS 改善割合は、モメロチニブでルキソリチニブよりも低かった。この違いは、モメロチニブ群でルキソリチニブ群と比較して中止した被験者数が多いこと又はベースライン時に TSS による層別化を実施しなかったことに起因する可能性がある。欠測の被験者は、MMRM 及び個々の項目による事後解析に含めなかった。更に、症状を有する被験者（ベースライン時に TSS が 10 以上の被験者）のみを対象としたサブセット解析では、モメロチニブ群及びルキソリチニブ群の TSS 変化量及び変化割合が類似していた。

事前に規定した解析及び事後解析のデータから、輸血非依存割合の増加、輸血依存の減少、輸血量の減少、ヘモグロビンの増加等、モメロチニブは頑健で臨床的に意義のある一貫した貧血に対するベネフィットをもたらすという解釈が裏付けられる。貧血及び輸血依存の

予後に対する重要性、並びに輸血による急性及び慢性の医学的リスク、医療費、時間及び不便さといった患者負担に対し、モメロチニブは、ルキソリチニブと同程度の脾臓縮小及びほぼ同程度の症状改善をもたらすと同時に、MF 被験者の重大かつ臨床的に意義のあるアンメットニーズに応える可能性がある。

二重盲検無作為化期及び非盲検拡大治療期を合わせた OS の Kaplan-Meier 推定値の中央値は、モメロチニブを投与された被験者では頑健なベネフィット（MMB to MMB 集団は中央値に到達せず、RUX to MMB 集団は 53.1 ヵ月）を示した。これらの結果は、COMFORT-1 試験[Verstovsek 2012]及び COMFORT-1 試験の長期併合生存期間の探索的解析[Verstovsek 2017]で示された、JAK 阻害剤による治療歴のない被験者においてプラセボと比較した場合のルキソリチニブの OS 中央値の 51 週間及びハザード比 0.50（95% CI：0.25, 0.98、p＝0.04）という報告と比べて良好であった。JAK 阻害剤による治療歴のない被験者でのこれらのデータは、モメロチニブが生存に良好な治療効果をもたらすことを強く裏付けている。

JAK1 及び JAK2 に加え ACVR1 を阻害するモメロチニブの特徴は、脾腫及び／又は全身症状をコントロールする可能性と共に、貧血に対し大きなベネフィットをもたらすと考えられる。MF での貧血及び輸血依存の予後に対する重要性並びに本試験で 24 週時の輸血非依存が生存上の利点と関連する可能性があることが示唆されたことから、24 週までに輸血非依存を達成又は維持するという治療目標は、JAK 阻害剤による治療歴のない被験者の治療決定において重要な決定因子となる可能性がある。本試験で得られたデータは、貧血の程度にかかわらず、モメロチニブを投与された貧血の被験者（ヘモグロビン 12 g/dL 未満）では、ルキソリチニブを投与された被験者と比較して、24 週時の輸血非依存割合が実質的に高いことを示唆する。また、ベースラインの血小板数又はベースラインの輸血状況に関係なく、JAK 阻害剤による治療歴のない被験者の輸血非依存の達成又は維持において、モメロチニブはルキソリチニブと比較して有効であった。

ITT 解析対象集団の解析から得られた結論に加えて、サブセット解析からモメロチニブ及びルキソリチニブの相対的ベネフィットに関する考察が得られる。両剤とも JAK1 及び JAK2 を阻害するが、モメロチニブは ACVR1 を強力に阻害し、鉄貯蔵のホメオスタシスを回復させることにより、上記のような貧血改善効果を発揮する。モメロチニブとルキソリチニブは血液学的安全性プロファイルも明らかに異なる。例えば、血小板数の中央値はモメロチニブで維持され、ルキソリチニブでは減少しており、これは 24 週間の二重盲検無作為化期で認められた用量強度の差を説明している可能性がある。

全体として、ITT 解析対象集団の解析及び血小板サブセット解析から得られたデータは、貧血の被験者では維持又は輸血非依存の可能性が高まり、血小板減少症の被験者では脾臓及び貧血の転帰が良好で、症状のベネフィットが類似していた。したがって、あらゆるレベルの貧血患者及び／又は血小板数が低値の患者は、ルキソリチニブと比較してモメロチニブ投与で最適なベネフィットを得られる可能性を示唆している。PMF、Post PV-MF 及び Post ET-MF の被験者では、モメロチニブの投与は安全で忍容性が良好であった。有害事象プロファイルはモメロチニブを投与した被験者のサブセット間で類似しており、血小板減少性であった被験者（血小板数 150×10^9/L 未満）と血小板減少性ではなかった被験者（血小板数 150×10^9/L 以上）との間に顕著な差は認められなかった。ヘモグロビン 10 g/dL 未満の被験

者とヘモグロビン 10 g/dL 以上の被験者との間にも顕著な差は認められなかった。RUX to MMB 集団では、新たな毒性所見又は進行性の毒性所見は認められなかった。モメロチニブの忍容性は投与継続時及び 48 週時において良好であり、24 週時と比較して有害事象の発現割合は低かった。新たな安全性シグナルは認められず、PMF、Post PV-MF 及び Post ET-MF 患者におけるモメロチニブ投与の安全性及び忍容性に関する強力なエビデンスが得られた。

モメロチニブの生物学的プロファイル、低い骨髄抑制作用、良好な血液学的忍容性により、85%を上回る被験者でモメロチニブの持続的な高い用量強度での投与が維持された。良好な血液学的安全性プロファイル及びモメロチニブの貧血へのベネフィットにより、持続的な臨床効果に寄与する、あるいはそれを可能にする用量強度の維持が促進されたと考えられる。事後解析では、モメロチニブを投与された被験者の大多数が最大の用量でこの治療を受けられたことが示された。特記することとして、二重盲検無作為化期でのルキソリチニブの用量強度は、投与開始時にモメロチニブよりも低く、24 週間の投与期間中に更に低下した。

概して、本試験では、モメロチニブが脾腫を軽減し、症状を改善させるとともに、輸血非依存性を高め、生存に良好な治療的影響を及ぼすことが示唆された。更に、登録時の予後集団にかかわらず、良好な転帰が示された。既存のデータ全体から、以降の第 III 相試験でモメロチニブに対する総合的に良好なベネフィット・リスクが確立される可能性が示唆された。

報告書の日付

2021 年 3 月

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表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
有害事象発現例数 ANY EVENT	198 (92.5%)	206 (95.4%)	404 (94.0%)	134 (78.4%)	177 (89.8%)	311 (84.5%)
胃腸障害 Gastrointestinal disorders	103 (48.1%)	98 (45.4%)	201 (46.7%)	39 (22.8%)	80 (40.6%)	119 (32.3%)
下痢 Diarrhoea	39 (18.2%)	43 (19.9%)	82 (19.1%)	18 (10.5%)	28 (14.2%)	46 (12.5%)
腹痛 Abdominal pain	22 (10.3%)	25 (11.6%)	47 (10.9%)	5 (2.9%)	15 (7.6%)	20 (5.4%)
悪心 Nausea	34 (15.9%)	8 (3.7%)	42 (9.8%)	6 (3.5%)	28 (14.2%)	34 (9.2%)
便秘 Constipation	21 (9.8%)	15 (6.9%)	36 (8.4%)	6 (3.5%)	9 (4.6%)	15 (4.1%)
嘔吐 Vomiting	20 (9.3%)	8 (3.7%)	28 (6.5%)	6 (3.5%)	8 (4.1%)	14 (3.8%)
上腹部痛 Abdominal pain upper	10 (4.7%)	10 (4.6%)	20 (4.7%)	3 (1.8%)	4 (2.0%)	7 (1.9%)
腹部膨満 Abdominal distension	7 (3.3%)	7 (3.2%)	14 (3.3%)	1 (0.6%)	4 (2.0%)	5 (1.4%)
消化不良 Dyspepsia	3 (1.4%)	9 (4.2%)	12 (2.8%)	3 (1.8%)	6 (3.0%)	9 (2.4%)
腹部不快感 Abdominal discomfort	8 (3.7%)	3 (1.4%)	11 (2.6%)	1 (0.6%)	2 (1.0%)	3 (0.8%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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胃食道逆流性疾患 Gastrooesophageal reflux disease	6 (2.8%)	3 (1.4%)	9 (2.1%)	1 (0.6%)	7 (3.6%)	8 (2.2%)
鼓腸 Flatulence	3 (1.4%)	6 (2.8%)	9 (2.1%)	0	1 (0.5%)	1 (0.3%)
口内乾燥 Dry mouth	6 (2.8%)	2 (0.9%)	8 (1.9%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
歯痛 Toothache	3 (1.4%)	2 (0.9%)	5 (1.2%)	0	2 (1.0%)	2 (0.5%)
口腔内潰瘍形成 Mouth ulceration	1 (0.5%)	4 (1.9%)	5 (1.2%)	0	0	0
痔核 Haemorrhoids	2 (0.9%)	1 (0.5%)	3 (0.7%)	0	3 (1.5%)	3 (0.8%)
歯肉出血 Gingival bleeding	1 (0.5%)	2 (0.9%)	3 (0.7%)	0	1 (0.5%)	1 (0.3%)
鼠径ヘルニア Inguinal hernia	2 (0.9%)	1 (0.5%)	3 (0.7%)	1 (0.6%)	0	1 (0.3%)
口内炎 Stomatitis	0	3 (1.4%)	3 (0.7%)	0	1 (0.5%)	1 (0.3%)
小腸炎 Enteritis	2 (0.9%)	1 (0.5%)	3 (0.7%)	0	0	0
腹水 Ascites	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	2 (1.0%)	3 (0.8%)

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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
直腸出血 Rectal haemorrhage	2 (0.9%)	0	2 (0.5%)	0	2 (1.0%)	2 (0.5%)
口唇炎 Cheilitis	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
アフタ性潰瘍 Aphthous ulcer	0	2 (0.9%)	2 (0.5%)	0	0	0
腸炎 Enterocolitis	0	2 (0.9%)	2 (0.5%)	0	0	0
肛門周囲痛 Proctalgia	2 (0.9%)	0	2 (0.5%)	0	0	0
胃炎 Gastritis	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
食道静脈瘤 Varices oesophageal	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
嚥下障害 Dysphagia	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
レッチング Retching	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
小腸閉塞 Small intestinal obstruction	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
下腹部痛 Abdominal pain lower	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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Population: Safety Analysis Set
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	有害事象（因果関係を問わない）					
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System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
肛門出血 Anal haemorrhage	0	1 (0.5%)	1 (0.2%)	0	0	0
憩室穿孔 Diverticular perforation	0	1 (0.5%)	1 (0.2%)	0	0	0
びらん性食道炎 Erosive oesophagitis	0	1 (0.5%)	1 (0.2%)	0	0	0
変色便 Faeces discoloured	0	1 (0.5%)	1 (0.2%)	0	0	0
軟便 Faeces soft	1 (0.5%)	0	1 (0.2%)	0	0	0
胃ポリープ Gastric polyps	1 (0.5%)	0	1 (0.2%)	0	0	0
胃潰瘍 Gastric ulcer	1 (0.5%)	0	1 (0.2%)	0	0	0
血便排泄 Haematochezia	1 (0.5%)	0	1 (0.2%)	0	0	0
痔出血 Haemorrhoidal haemorrhage	1 (0.5%)	0	1 (0.2%)	0	0	0
イレウス Ileus	0	1 (0.5%)	1 (0.2%)	0	0	0
口唇痛 Lip pain	1 (0.5%)	0	1 (0.2%)	0	0	0

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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
メレナ Melaena	0	1 (0.5%)	1 (0.2%)	0	0	0
腸間膜静脈血栓症 Mesenteric vein thrombosis	1 (0.5%)	0	1 (0.2%)	0	0	0
嚥下痛 Odynophagia	1 (0.5%)	0	1 (0.2%)	0	0	0
食道痛 Oesophageal pain	0	1 (0.5%)	1 (0.2%)	0	0	0
食道炎 Oesophagitis	1 (0.5%)	0	1 (0.2%)	0	0	0
消化性潰瘍 Peptic ulcer	1 (0.5%)	0	1 (0.2%)	0	0	0
腹膜出血 Peritoneal haemorrhage	0	1 (0.5%)	1 (0.2%)	0	0	0
亜イレウス Subileus	0	1 (0.5%)	1 (0.2%)	0	0	0
舌紅斑 Tongue erythema	1 (0.5%)	0	1 (0.2%)	0	0	0
肛門失禁 Anal incontinence	0	0	0	0	2 (1.0%)	2 (0.5%)
口角口唇炎 Angular cheilitis	0	0	0	2 (1.2%)	0	2 (0.5%)

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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
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心窩部不快感 Epigastric discomfort	0	0	0	0	2 (1.0%)	2 (0.5%)
口腔内痛 Oral pain	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
腹部硬直 Abdominal rigidity	0	0	0	0	1 (0.5%)	1 (0.3%)
便意切迫 Defaecation urgency	0	0	0	0	1 (0.5%)	1 (0.3%)
齲歯 Dental caries	0	0	0	0	1 (0.5%)	1 (0.3%)
出血性十二指腸潰瘍 Duodenal ulcer haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)
食中毒 Food poisoning	0	0	0	1 (0.6%)	0	1 (0.3%)
胃出血 Gastric haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)
出血性胃潰瘍 Gastric ulcer haemorrhage	0	0	0	1 (0.6%)	0	1 (0.3%)
びらん性胃炎 Gastritis erosive	0	0	0	0	1 (0.5%)	1 (0.3%)
胃腸出血 Gastrointestinal haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
消化器痛 Gastrointestinal pain	0	0	0	1 (0.6%)	0	1 (0.3%)
胃腸音異常 Gastrointestinal sounds abnormal	0	0	0	1 (0.6%)	0	1 (0.3%)
裂孔ヘルニア Hiatus hernia	0	0	0	1 (0.6%)	0	1 (0.3%)
口の感覚鈍麻 Hypoaesthesia oral	0	0	0	0	1 (0.5%)	1 (0.3%)
下部消化管出血 Lower gastrointestinal haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)
口腔内出血 Mouth haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)
食道静脈瘤出血 Oesophageal varices haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)
口腔粘膜血腫 Oral mucosa haematoma	0	0	0	1 (0.6%)	0	1 (0.3%)
歯周病 Periodontal disease	0	0	0	0	1 (0.5%)	1 (0.3%)
咳嗽後嘔吐 Post-tussive vomiting	0	0	0	0	1 (0.5%)	1 (0.3%)
小腸出血 Small intestinal haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)

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	有害事象（因果関係を問わない）					
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血液およびリンパ系障害 Blood and lymphatic system disorders	75 (35.0%)	122 (56.5%)	197 (45.8%)	34 (19.9%)	57 (28.9%)	91 (24.7%)
貧血 Anaemia	31 (14.5%)	81 (37.5%)	112 (26.0%)	14 (8.2%)	21 (10.7%)	35 (9.5%)
血小板減少症 Thrombocytopenia	40 (18.7%)	63 (29.2%)	103 (24.0%)	16 (9.4%)	28 (14.2%)	44 (12.0%)
好中球減少症 Neutropenia	9 (4.2%)	14 (6.5%)	23 (5.3%)	5 (2.9%)	4 (2.0%)	9 (2.4%)
白血球減少症 Leukopenia	5 (2.3%)	4 (1.9%)	9 (2.1%)	3 (1.8%)	4 (2.0%)	7 (1.9%)
血小板増加症 Thrombocytosis	5 (2.3%)	2 (0.9%)	7 (1.6%)	0	4 (2.0%)	4 (1.1%)
白血球増加症 Leukocytosis	4 (1.9%)	0	4 (0.9%)	1 (0.6%)	3 (1.5%)	4 (1.1%)
発熱性好中球減少症 Febrile neutropenia	1 (0.5%)	2 (0.9%)	3 (0.7%)	2 (1.2%)	0	2 (0.5%)
リンパ球減少症 Lymphopenia	2 (0.9%)	1 (0.5%)	3 (0.7%)	0	2 (1.0%)	2 (0.5%)
脾腫 Splenomegaly	1 (0.5%)	0	1 (0.2%)	2 (1.2%)	1 (0.5%)	3 (0.8%)
内出血発生の増加傾向 Increased tendency to bruise	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)

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凝血異常 Coagulopathy	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
赤血球増加症 Polycythaemia	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
脾臓梗塞 Splenic infarction	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
失血性貧血 Blood loss anaemia	0	1 (0.5%)	1 (0.2%)	0	0	0
低プロトロンビン血症 Hypoprothrombinaemia	1 (0.5%)	0	1 (0.2%)	0	0	0
リンパ節石灰化 Lymph node calcification	1 (0.5%)	0	1 (0.2%)	0	0	0
リンパ節症 Lymphadenopathy	1 (0.5%)	0	1 (0.2%)	0	0	0
リンパ球増加症 Lymphocytosis	1 (0.5%)	0	1 (0.2%)	0	0	0
微小血管症性溶血性貧血 Microangiopathic haemolytic anaemia	1 (0.5%)	0	1 (0.2%)	0	0	0
脾血腫 Splenic haematoma	0	0	0	0	2 (1.0%)	2 (0.5%)
過粘稠度症候群 Hyperviscosity syndrome	0	0	0	1 (0.6%)	0	1 (0.3%)

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肥満細胞症 Mastocytosis	0	0	0	1 (0.6%)	0	1 (0.3%)
好中球増加症 Neutrophilia	0	0	0	0	1 (0.5%)	1 (0.3%)
特発性血腫 Spontaneous haematoma	0	0	0	0	1 (0.5%)	1 (0.3%)
感染症および寄生虫症 Infections and infestations	77 (36.0%)	92 (42.6%)	169 (39.3%)	51 (29.8%)	70 (35.5%)	121 (32.9%)
上気道感染 Upper respiratory tract infection	12 (5.6%)	14 (6.5%)	26 (6.0%)	8 (4.7%)	12 (6.1%)	20 (5.4%)
上咽頭炎 Nasopharyngitis	9 (4.2%)	16 (7.4%)	25 (5.8%)	5 (2.9%)	8 (4.1%)	13 (3.5%)
尿路感染 Urinary tract infection	10 (4.7%)	11 (5.1%)	21 (4.9%)	8 (4.7%)	11 (5.6%)	19 (5.2%)
帯状疱疹 Herpes zoster	4 (1.9%)	9 (4.2%)	13 (3.0%)	4 (2.3%)	0	4 (1.1%)
肺炎 Pneumonia	5 (2.3%)	6 (2.8%)	11 (2.6%)	5 (2.9%)	7 (3.6%)	12 (3.3%)
気道感染 Respiratory tract infection	3 (1.4%)	8 (3.7%)	11 (2.6%)	2 (1.2%)	4 (2.0%)	6 (1.6%)
口腔ヘルペス Oral herpes	3 (1.4%)	8 (3.7%)	11 (2.6%)	2 (1.2%)	3 (1.5%)	5 (1.4%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
気管支炎 Bronchitis	4 (1.9%)	5 (2.3%)	9 (2.1%)	3 (1.8%)	11 (5.6%)	14 (3.8%)
膀胱炎 Cystitis	7 (3.3%)	0	7 (1.6%)	4 (2.3%)	3 (1.5%)	7 (1.9%)
インフルエンザ Influenza	1 (0.5%)	6 (2.8%)	7 (1.6%)	1 (0.6%)	4 (2.0%)	5 (1.4%)
鼻炎 Rhinitis	2 (0.9%)	4 (1.9%)	6 (1.4%)	0	1 (0.5%)	1 (0.3%)
胃腸炎 Gastroenteritis	3 (1.4%)	2 (0.9%)	5 (1.2%)	1 (0.6%)	4 (2.0%)	5 (1.4%)
皮膚感染 Skin infection	4 (1.9%)	1 (0.5%)	5 (1.2%)	1 (0.6%)	0	1 (0.3%)
下気道感染 Lower respiratory tract infection	3 (1.4%)	1 (0.5%)	4 (0.9%)	2 (1.2%)	3 (1.5%)	5 (1.4%)
敗血症 Sepsis	3 (1.4%)	1 (0.5%)	4 (0.9%)	2 (1.2%)	0	2 (0.5%)
副鼻腔炎 Sinusitis	0	3 (1.4%)	3 (0.7%)	0	4 (2.0%)	4 (1.1%)
蜂巣炎 Cellulitis	3 (1.4%)	0	3 (0.7%)	2 (1.2%)	0	2 (0.5%)
ウイルス感染 Viral infection	1 (0.5%)	2 (0.9%)	3 (0.7%)	1 (0.6%)	1 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
術後創感染 Postoperative wound infection	1 (0.5%)	2 (0.9%)	3 (0.7%)	1 (0.6%)	0	1 (0.3%)
結膜炎 Conjunctivitis	0	3 (1.4%)	3 (0.7%)	0	0	0
癜風 Tinea versicolour	3 (1.4%)	0	3 (0.7%)	0	0	0
皮膚真菌感染 Fungal skin infection	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
消化管感染 Gastrointestinal infection	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
限局性感染 Localised infection	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
口腔カンジダ症 Oral candidiasis	2 (0.9%)	0	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
毛包炎 Folliculitis	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
歯肉炎 Gingivitis	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
感染 Infection	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
歯周炎 Periodontitis	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
咽頭炎 Pharyngitis	0	2 (0.9%)	2 (0.5%)	0	0	0
気管気管支炎 Tracheobronchitis	0	2 (0.9%)	2 (0.5%)	0	0	0
膣感染 Vaginal infection	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
陰部ヘルペス Genital herpes	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
クロストリジウム・ディフィシレ大腸炎 Clostridium difficile colitis	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
大腸菌性尿路感染 Escherichia urinary tract infection	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
真菌感染 Fungal infection	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
肺感染 Lung infection	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
外耳炎 Otitis externa	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
赤痢菌感染 Shigella infection	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
肛門膿瘍 Anal abscess	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
憩室炎 Diverticulitis	1 (0.5%)	0	1 (0.2%)	0	0	0
大腸菌性敗血症 Escherichia sepsis	1 (0.5%)	0	1 (0.2%)	0	0	0
真菌性食道炎 Fungal oesophagitis	0	1 (0.5%)	1 (0.2%)	0	0	0
せつ Furuncle	0	1 (0.5%)	1 (0.2%)	0	0	0
ウイルス性消化管感染 Gastrointestinal viral infection	0	1 (0.5%)	1 (0.2%)	0	0	0
麦粒腫 Hordeolum	0	1 (0.5%)	1 (0.2%)	0	0	0
膿痂疹 Impetigo	0	1 (0.5%)	1 (0.2%)	0	0	0
喉頭炎 Laryngitis	1 (0.5%)	0	1 (0.2%)	0	0	0
口唇感染 Lip infection	1 (0.5%)	0	1 (0.2%)	0	0	0
ライム病 Lyme disease	1 (0.5%)	0	1 (0.2%)	0	0	0
爪真菌症 Onychomycosis	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
爪囲炎 Paronychia	0	1 (0.5%)	1 (0.2%)	0	0	0
腹膜炎 Peritonitis	0	1 (0.5%)	1 (0.2%)	0	0	0
細菌性肺炎 Pneumonia bacterial	1 (0.5%)	0	1 (0.2%)	0	0	0
処置後感染 Post procedural infection	1 (0.5%)	0	1 (0.2%)	0	0	0
肺敗血症 Pulmonary sepsis	0	1 (0.5%)	1 (0.2%)	0	0	0
腎盂膀胱炎 Pyelocystitis	1 (0.5%)	0	1 (0.2%)	0	0	0
腎盂腎炎 Pyelonephritis	1 (0.5%)	0	1 (0.2%)	0	0	0
陰嚢膿瘍 Scrotal abscess	1 (0.5%)	0	1 (0.2%)	0	0	0
皮膚細菌感染 Skin bacterial infection	1 (0.5%)	0	1 (0.2%)	0	0	0
ブドウ球菌感染 Staphylococcal infection	1 (0.5%)	0	1 (0.2%)	0	0	0
レンサ球菌性敗血症 Streptococcal sepsis	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
気管炎 Tracheitis	0	1 (0.5%)	1 (0.2%)	0	0	0
ウイルス性上気道感染 Viral upper respiratory tract infection	0	1 (0.5%)	1 (0.2%)	0	0	0
外陰部腟カンジダ症 Vulvovaginal candidiasis	0	1 (0.5%)	1 (0.2%)	0	0	0
外陰腟真菌感染 Vulvovaginal mycotic infection	0	1 (0.5%)	1 (0.2%)	0	0	0
創傷感染 Wound infection	0	1 (0.5%)	1 (0.2%)	0	0	0
クロストリジウム・ディフィシレ感染 Clostridium difficile infection	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
耳感染 Ear infection	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
単純ヘルペス Herpes simplex	0	0	0	0	2 (1.0%)	2 (0.5%)
中耳炎 Otitis media	0	0	0	2 (1.2%)	0	2 (0.5%)
扁桃炎 Tonsillitis	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
ボレリア感染 Borrelia infection	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
丹毒 Erysipelas	0	0	0	0	1 (0.5%)	1 (0.3%)
壊疽 Gangrene	0	0	0	1 (0.6%)	0	1 (0.3%)
サルモネラ菌性胃腸炎 Gastroenteritis salmonella	0	0	0	0	1 (0.5%)	1 (0.3%)
消化器カンジダ症 Gastrointestinal candidiasis	0	0	0	0	1 (0.5%)	1 (0.3%)
ヘルペス性皮膚炎 Herpes dermatitis	0	0	0	0	1 (0.5%)	1 (0.3%)
感染性皮膚潰瘍 Infected skin ulcer	0	0	0	1 (0.6%)	0	1 (0.3%)
迷路炎 Labyrinthitis	0	0	0	1 (0.6%)	0	1 (0.3%)
鼻ヘルペス Nasal herpes	0	0	0	1 (0.6%)	0	1 (0.3%)
百日咳 Pertussis	0	0	0	0	1 (0.5%)	1 (0.3%)
ピコルナウイルス感染 Picornavirus infection	0	0	0	1 (0.6%)	0	1 (0.3%)
歯膿瘍 Tooth abscess	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
水痘帯状疱疹ウイルス感染 Varicella zoster virus infection	0	0	0	0	1 (0.5%)	1 (0.3%)
ウイルス性ぶどう膜炎 Viral uveitis	0	0	0	0	1 (0.5%)	1 (0.3%)
神経系障害 Nervous system disorders	93 (43.5%)	76 (35.2%)	169 (39.3%)	35 (20.5%)	52 (26.4%)	87 (23.6%)
頭痛 Headache	38 (17.8%)	43 (19.9%)	81 (18.8%)	4 (2.3%)	13 (6.6%)	17 (4.6%)
浮動性めまい Dizziness	34 (15.9%)	25 (11.6%)	59 (13.7%)	11 (6.4%)	13 (6.6%)	24 (6.5%)
末梢性感覚ニューロパチー Peripheral sensory neuropathy	20 (9.3%)	12 (5.6%)	32 (7.4%)	7 (4.1%)	15 (7.6%)	22 (6.0%)
錯感覚 Paraesthesia	15 (7.0%)	7 (3.2%)	22 (5.1%)	5 (2.9%)	6 (3.0%)	11 (3.0%)
失神寸前の状態 Presyncope	6 (2.8%)	0	6 (1.4%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
嗜眠 Lethargy	2 (0.9%)	3 (1.4%)	5 (1.2%)	3 (1.8%)	1 (0.5%)	4 (1.1%)
感覚鈍麻 Hypoaesthesia	2 (0.9%)	2 (0.9%)	4 (0.9%)	4 (2.3%)	2 (1.0%)	6 (1.6%)
振戦 Tremor	3 (1.4%)	1 (0.5%)	4 (0.9%)	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
記憶障害 Memory impairment	2 (0.9%)	2 (0.9%)	4 (0.9%)	0	0	0
坐骨神経痛 Sciatica	0	3 (1.4%)	3 (0.7%)	1 (0.6%)	4 (2.0%)	5 (1.4%)
失神 Syncope	3 (1.4%)	0	3 (0.7%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
味覚障害 Taste disorder	2 (0.9%)	1 (0.5%)	3 (0.7%)	0	0	0
平衡障害 Balance disorder	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
健忘 Amnesia	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
片頭痛 Migraine	0	2 (0.9%)	2 (0.5%)	0	0	0
味覚異常 Dysgeusia	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
一過性脳虚血発作 Transient ischaemic attack	0	1 (0.5%)	1 (0.2%)	0	2 (1.0%)	2 (0.5%)
異常感覚 Dysaesthesia	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
前頭側頭型認知症 Frontotemporal dementia	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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	有害事象（因果関係を問わない）					
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System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
神経痛 Neuralgia	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
末梢性ニューロパチー Neuropathy peripheral	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
傾眠 Somnolence	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
失語症 Aphasia	0	1 (0.5%)	1 (0.2%)	0	0	0
手根管症候群 Carpal tunnel syndrome	0	1 (0.5%)	1 (0.2%)	0	0	0
脳虚血 Cerebral ischaemia	1 (0.5%)	0	1 (0.2%)	0	0	0
頚髄神経根障害 Cervical radiculopathy	0	1 (0.5%)	1 (0.2%)	0	0	0
頚腕症候群 Cervicobrachial syndrome	1 (0.5%)	0	1 (0.2%)	0	0	0
昏睡 Coma	0	1 (0.5%)	1 (0.2%)	0	0	0
注意力障害 Disturbance in attention	1 (0.5%)	0	1 (0.2%)	0	0	0
体位性めまい Dizziness postural	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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	有害事象（因果関係を問わない）					
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System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
脳症 Encephalopathy	0	1 (0.5%)	1 (0.2%)	0	0	0
蟻走感 Formication	1 (0.5%)	0	1 (0.2%)	0	0	0
前兆を伴う片頭痛 Migraine with aura	1 (0.5%)	0	1 (0.2%)	0	0	0
神経系障害 Nervous system disorder	1 (0.5%)	0	1 (0.2%)	0	0	0
末梢性運動ニューロパチー Peripheral motor neuropathy	1 (0.5%)	0	1 (0.2%)	0	0	0
ヘルペス後神経痛 Post herpetic neuralgia	0	1 (0.5%)	1 (0.2%)	0	0	0
血管性脳症 Vascular encephalopathy	0	1 (0.5%)	1 (0.2%)	0	0	0
脳血管発作 Cerebrovascular accident	0	0	0	2 (1.2%)	0	2 (0.5%)
味覚消失 Ageusia	0	0	0	0	1 (0.5%)	1 (0.3%)
運動失調 Ataxia	0	0	0	0	1 (0.5%)	1 (0.3%)
脳微小血管症 Cerebral microangiopathy	0	0	0	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
脱髄 Demyelination	0	0	0	0	1 (0.5%)	1 (0.3%)
意識消失 Loss of consciousness	0	0	0	0	1 (0.5%)	1 (0.3%)
末梢性感覚運動ニューロパチー Peripheral sensorimotor neuropathy	0	0	0	1 (0.6%)	0	1 (0.3%)
副鼻腔炎に伴う頭痛 Sinus headache	0	0	0	0	1 (0.5%)	1 (0.3%)
くも膜下出血 Subarachnoid haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)
声帯麻痺 Vocal cord paralysis	0	0	0	1 (0.6%)	0	1 (0.3%)
一般・全身障害および投与部位の状態 General disorders and administration site conditions	80 (37.4%)	83 (38.4%)	163 (37.9%)	42 (24.6%)	58 (29.4%)	100 (27.2%)
疲労 Fatigue	31 (14.5%)	26 (12.0%)	57 (13.3%)	11 (6.4%)	26 (13.2%)	37 (10.1%)
発熱 Pyrexia	14 (6.5%)	17 (7.9%)	31 (7.2%)	7 (4.1%)	5 (2.5%)	12 (3.3%)
無力症 Asthenia	12 (5.6%)	16 (7.4%)	28 (6.5%)	6 (3.5%)	6 (3.0%)	12 (3.3%)
末梢性浮腫 Oedema peripheral	10 (4.7%)	14 (6.5%)	24 (5.6%)	8 (4.7%)	3 (1.5%)	11 (3.0%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
胸痛 Chest pain	7 (3.3%)	5 (2.3%)	12 (2.8%)	2 (1.2%)	6 (3.0%)	8 (2.2%)
インフルエンザ様疾患 Influenza like illness	4 (1.9%)	8 (3.7%)	12 (2.8%)	2 (1.2%)	5 (2.5%)	7 (1.9%)
倦怠感 Malaise	4 (1.9%)	4 (1.9%)	8 (1.9%)	0	2 (1.0%)	2 (0.5%)
悪寒 Chills	1 (0.5%)	5 (2.3%)	6 (1.4%)	0	2 (1.0%)	2 (0.5%)
末梢腫脹 Peripheral swelling	4 (1.9%)	1 (0.5%)	5 (1.2%)	3 (1.8%)	0	3 (0.8%)
早期満腹 Early satiety	2 (0.9%)	2 (0.9%)	4 (0.9%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
疼痛 Pain	2 (0.9%)	2 (0.9%)	4 (0.9%)	0	1 (0.5%)	1 (0.3%)
浮腫 Oedema	1 (0.5%)	2 (0.9%)	3 (0.7%)	0	2 (1.0%)	2 (0.5%)
胸部不快感 Chest discomfort	1 (0.5%)	2 (0.9%)	3 (0.7%)	0	1 (0.5%)	1 (0.3%)
非心臓性胸痛 Non-cardiac chest pain	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
乾燥症 Xerosis	0	2 (0.9%)	2 (0.5%)	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
顔面痛 Facial pain	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
重力性浮腫 Gravitational oedema	2 (0.9%)	0	2 (0.5%)	0	0	0
炎症 Inflammation	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
粘膜の炎症 Mucosal inflammation	2 (0.9%)	0	2 (0.5%)	0	0	0
死亡 Death	1 (0.5%)	0	1 (0.2%)	0	2 (1.0%)	2 (0.5%)
全身健康状態悪化 General physical health deterioration	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
全身性浮腫 Generalised oedema	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
カテーテル留置部位出血 Catheter site haemorrhage	0	1 (0.5%)	1 (0.2%)	0	0	0
捻髪音 Crepitations	1 (0.5%)	0	1 (0.2%)	0	0	0
異常感 Feeling abnormal	0	1 (0.5%)	1 (0.2%)	0	0	0
冷感 Feeling cold	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
歩行障害 Gait disturbance	1 (0.5%)	0	1 (0.2%)	0	0	0
硬結 Induration	1 (0.5%)	0	1 (0.2%)	0	0	0
粘膜出血 Mucosal haemorrhage	0	1 (0.5%)	1 (0.2%)	0	0	0
突然死 Sudden death	1 (0.5%)	0	1 (0.2%)	0	0	0
腫脹 Swelling	0	1 (0.5%)	1 (0.2%)	0	0	0
熱感 Feeling hot	0	0	0	1 (0.6%)	2 (1.0%)	3 (0.8%)
カテーテル留置部位疼痛 Catheter site pain	0	0	0	0	1 (0.5%)	1 (0.3%)
不快感 Discomfort	0	0	0	0	1 (0.5%)	1 (0.3%)
薬剤離脱症候群 Drug withdrawal syndrome	0	0	0	0	1 (0.5%)	1 (0.3%)
高熱 Hyperthermia	0	0	0	1 (0.6%)	0	1 (0.3%)
治癒不良 Impaired healing	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
注射部位出血 Injection site haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)
口渇 Thirst	0	0	0	0	1 (0.5%)	1 (0.3%)
呼吸器、胸郭および縦隔障害 Respiratory, thoracic and mediastinal disorders	61 (28.5%)	67 (31.0%)	128 (29.8%)	31 (18.1%)	43 (21.8%)	74 (20.1%)
呼吸困難 Dyspnoea	19 (8.9%)	17 (7.9%)	36 (8.4%)	3 (1.8%)	9 (4.6%)	12 (3.3%)
咳嗽 Cough	18 (8.4%)	17 (7.9%)	35 (8.1%)	12 (7.0%)	22 (11.2%)	34 (9.2%)
鼻出血 Epistaxis	9 (4.2%)	15 (6.9%)	24 (5.6%)	7 (4.1%)	7 (3.6%)	14 (3.8%)
労作性呼吸困難 Dyspnoea exertional	7 (3.3%)	7 (3.2%)	14 (3.3%)	0	2 (1.0%)	2 (0.5%)
口腔咽頭痛 Oropharyngeal pain	2 (0.9%)	9 (4.2%)	11 (2.6%)	2 (1.2%)	1 (0.5%)	3 (0.8%)
鼻漏 Rhinorrhoea	3 (1.4%)	3 (1.4%)	6 (1.4%)	2 (1.2%)	0	2 (0.5%)
湿性咳嗽 Productive cough	4 (1.9%)	1 (0.5%)	5 (1.2%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
低酸素症 Hypoxia	2 (0.9%)	1 (0.5%)	3 (0.7%)	1 (0.6%)	2 (1.0%)	3 (0.8%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
慢性閉塞性肺疾患 Chronic obstructive pulmonary disease	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
発声障害 Dysphonia	2 (0.9%)	0	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
しゃっくり Hiccups	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
カタル Catarrh	0	2 (0.9%)	2 (0.5%)	0	0	0
ラ音 Rales	2 (0.9%)	0	2 (0.5%)	0	0	0
呼吸不全 Respiratory failure	1 (0.5%)	0	1 (0.2%)	0	2 (1.0%)	2 (0.5%)
喀血 Haemoptysis	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
鼻閉 Nasal congestion	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
肺水腫 Pulmonary oedema	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
上気道咳症候群 Upper-airway cough syndrome	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
急性呼吸不全 Acute respiratory failure	0	1 (0.5%)	1 (0.2%)	0	0	0

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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
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咽喉乾燥 Dry throat	1 (0.5%)	0	1 (0.2%)	0	0	0
発作性夜間呼吸困難 Dyspnoea paroxysmal nocturnal	1 (0.5%)	0	1 (0.2%)	0	0	0
肺浸潤 Lung infiltration	0	1 (0.5%)	1 (0.2%)	0	0	0
呼吸時疼痛 Painful respiration	1 (0.5%)	0	1 (0.2%)	0	0	0
咽頭潰瘍 Pharyngeal ulceration	1 (0.5%)	0	1 (0.2%)	0	0	0
胸膜痛 Pleuritic pain	0	1 (0.5%)	1 (0.2%)	0	0	0
誤嚥性肺炎 Pneumonia aspiration	1 (0.5%)	0	1 (0.2%)	0	0	0
肺線維症 Pulmonary fibrosis	1 (0.5%)	0	1 (0.2%)	0	0	0
肺肉芽腫 Pulmonary granuloma	1 (0.5%)	0	1 (0.2%)	0	0	0
肺出血 Pulmonary haemorrhage	0	1 (0.5%)	1 (0.2%)	0	0	0
肺高血圧症 Pulmonary hypertension	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
逆流性喉頭炎 Reflux laryngitis	1 (0.5%)	0	1 (0.2%)	0	0	0
睡眠時無呼吸症候群 Sleep apnoea syndrome	0	1 (0.5%)	1 (0.2%)	0	0	0
痰貯留 Sputum retention	0	1 (0.5%)	1 (0.2%)	0	0	0
咽喉刺激感 Throat irritation	0	1 (0.5%)	1 (0.2%)	0	0	0
咽喉絞扼感 Throat tightness	1 (0.5%)	0	1 (0.2%)	0	0	0
胸水 Pleural effusion	0	0	0	0	3 (1.5%)	3 (0.8%)
喘息 Asthma	0	0	0	0	2 (1.0%)	2 (0.5%)
肺塞栓症 Pulmonary embolism	0	0	0	2 (1.2%)	0	2 (0.5%)
気管支拡張症 Bronchiectasis	0	0	0	0	1 (0.5%)	1 (0.3%)
慢性気管支炎 Bronchitis chronic	0	0	0	1 (0.6%)	0	1 (0.3%)
肺気腫 Emphysema	0	0	0	1 (0.6%)	0	1 (0.3%)

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喉頭の炎症 Laryngeal inflammation	0	0	0	0	1 (0.5%)	1 (0.3%)
肺硬化 Lung consolidation	0	0	0	0	1 (0.5%)	1 (0.3%)
肺障害 Lung disorder	0	0	0	0	1 (0.5%)	1 (0.3%)
起坐呼吸 Orthopnoea	0	0	0	0	1 (0.5%)	1 (0.3%)
胸膜炎 Pleurisy	0	0	0	0	1 (0.5%)	1 (0.3%)
肺腫瘤 Pulmonary mass	0	0	0	1 (0.6%)	0	1 (0.3%)
副鼻腔痛 Sinus pain	0	0	0	1 (0.6%)	0	1 (0.3%)
喘鳴 Wheezing	0	0	0	1 (0.6%)	0	1 (0.3%)
筋骨格系および結合組織障害 Musculoskeletal and connective tissue disorders	58 (27.1%)	67 (31.0%)	125 (29.1%)	25 (14.6%)	48 (24.4%)	73 (19.8%)
四肢痛 Pain in extremity	14 (6.5%)	18 (8.3%)	32 (7.4%)	6 (3.5%)	12 (6.1%)	18 (4.9%)
関節痛 Arthralgia	15 (7.0%)	10 (4.6%)	25 (5.8%)	4 (2.3%)	5 (2.5%)	9 (2.4%)

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背部痛 Back pain	10 (4.7%)	10 (4.6%)	20 (4.7%)	3 (1.8%)	12 (6.1%)	15 (4.1%)
筋痙縮 Muscle spasms	8 (3.7%)	11 (5.1%)	19 (4.4%)	0	4 (2.0%)	4 (1.1%)
骨痛 Bone pain	3 (1.4%)	15 (6.9%)	18 (4.2%)	3 (1.8%)	7 (3.6%)	10 (2.7%)
筋骨格痛 Musculoskeletal pain	8 (3.7%)	3 (1.4%)	11 (2.6%)	3 (1.8%)	3 (1.5%)	6 (1.6%)
筋肉痛 Myalgia	5 (2.3%)	6 (2.8%)	11 (2.6%)	1 (0.6%)	4 (2.0%)	5 (1.4%)
筋力低下 Muscular weakness	2 (0.9%)	4 (1.9%)	6 (1.4%)	2 (1.2%)	1 (0.5%)	3 (0.8%)
鼠径部痛 Groin pain	2 (0.9%)	2 (0.9%)	4 (0.9%)	0	1 (0.5%)	1 (0.3%)
筋骨格系胸痛 Musculoskeletal chest pain	1 (0.5%)	3 (1.4%)	4 (0.9%)	1 (0.6%)	0	1 (0.3%)
関節炎 Arthritis	1 (0.5%)	3 (1.4%)	4 (0.9%)	0	0	0
脊椎痛 Spinal pain	3 (1.4%)	0	3 (0.7%)	0	2 (1.0%)	2 (0.5%)
側腹部痛 Flank pain	2 (0.9%)	1 (0.5%)	3 (0.7%)	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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筋肉疲労 Muscle fatigue	0	2 (0.9%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
顎痛 Pain in jaw	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
変形性関節症 Osteoarthritis	0	2 (0.9%)	2 (0.5%)	0	0	0
腱炎 Tendonitis	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
滑液包炎 Bursitis	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
筋骨格硬直 Musculoskeletal stiffness	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
滑液貯留 Bursal fluid accumulation	1 (0.5%)	0	1 (0.2%)	0	0	0
足変形 Foot deformity	1 (0.5%)	0	1 (0.2%)	0	0	0
痛風性関節炎 Gouty arthritis	1 (0.5%)	0	1 (0.2%)	0	0	0
骨減少症 Osteopenia	1 (0.5%)	0	1 (0.2%)	0	0	0
シェーグレン症候群 Sjogren's syndrome	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
変形性脊椎症 Spinal osteoarthritis	1 (0.5%)	0	1 (0.2%)	0	0	0
開口障害 Trismus	0	1 (0.5%)	1 (0.2%)	0	0	0
頚部痛 Neck pain	0	0	0	0	2 (1.0%)	2 (0.5%)
反応性関節炎 Arthritis reactive	0	0	0	1 (0.6%)	0	1 (0.3%)
骨病変 Bone lesion	0	0	0	0	1 (0.5%)	1 (0.3%)
胸壁血腫 Chest wall haematoma	0	0	0	1 (0.6%)	0	1 (0.3%)
筋膜炎 Fasciitis	0	0	0	0	1 (0.5%)	1 (0.3%)
関節滲出液 Joint effusion	0	0	0	0	1 (0.5%)	1 (0.3%)
四肢不快感 Limb discomfort	0	0	0	0	1 (0.5%)	1 (0.3%)
骨溶解 Osteolysis	0	0	0	0	1 (0.5%)	1 (0.3%)
骨硬化症 Osteosclerosis	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
関節周囲炎 Periarthritis	0	0	0	0	1 (0.5%)	1 (0.3%)
腱痛 Tendon pain	0	0	0	1 (0.6%)	0	1 (0.3%)
皮膚および皮下組織障害 Skin and subcutaneous tissue disorders	51 (23.8%)	46 (21.3%)	97 (22.6%)	33 (19.3%)	50 (25.4%)	83 (22.6%)
そう痒症 Pruritus	10 (4.7%)	11 (5.1%)	21 (4.9%)	6 (3.5%)	17 (8.6%)	23 (6.3%)
寝汗 Night sweats	8 (3.7%)	9 (4.2%)	17 (4.0%)	7 (4.1%)	11 (5.6%)	18 (4.9%)
発疹 Rash	9 (4.2%)	5 (2.3%)	14 (3.3%)	4 (2.3%)	10 (5.1%)	14 (3.8%)
紅斑 Erythema	7 (3.3%)	0	7 (1.6%)	3 (1.8%)	1 (0.5%)	4 (1.1%)
斑状出血 Ecchymosis	4 (1.9%)	3 (1.4%)	7 (1.6%)	1 (0.6%)	0	1 (0.3%)
脱毛症 Alopecia	3 (1.4%)	2 (0.9%)	5 (1.2%)	1 (0.6%)	0	1 (0.3%)
皮膚潰瘍 Skin ulcer	2 (0.9%)	3 (1.4%)	5 (1.2%)	1 (0.6%)	0	1 (0.3%)
斑状丘疹状皮疹 Rash maculo-papular	3 (1.4%)	1 (0.5%)	4 (0.9%)	1 (0.6%)	2 (1.0%)	3 (0.8%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
点状出血 Petechiae	3 (1.4%)	1 (0.5%)	4 (0.9%)	0	2 (1.0%)	2 (0.5%)
多汗症 Hyperhidrosis	0	3 (1.4%)	3 (0.7%)	2 (1.2%)	7 (3.6%)	9 (2.4%)
皮膚病変 Skin lesion	2 (0.9%)	1 (0.5%)	3 (0.7%)	1 (0.6%)	0	1 (0.3%)
皮膚乾燥 Dry skin	2 (0.9%)	1 (0.5%)	3 (0.7%)	0	0	0
紅斑性皮疹 Rash erythematous	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
接触皮膚炎 Dermatitis contact	2 (0.9%)	0	2 (0.5%)	0	0	0
湿疹 Eczema	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
過角化 Hyperkeratosis	2 (0.9%)	0	2 (0.5%)	0	0	0
皮膚疼痛 Pain of skin	0	2 (0.9%)	2 (0.5%)	0	0	0
皮膚出血 Skin haemorrhage	2 (0.9%)	0	2 (0.5%)	0	0	0
毛細血管拡張症 Telangiectasia	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
全身性そう痒症 Pruritus generalised	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	3 (1.5%)	4 (1.1%)
光線角化症 Actinic keratosis	0	1 (0.5%)	1 (0.2%)	3 (1.8%)	0	3 (0.8%)
アレルギー性皮膚炎 Dermatitis allergic	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
全身性皮疹 Rash generalised	1 (0.5%)	0	1 (0.2%)	0	2 (1.0%)	2 (0.5%)
斑状皮疹 Rash macular	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
丘疹性皮疹 Rash papular	0	1 (0.5%)	1 (0.2%)	0	2 (1.0%)	2 (0.5%)
薬疹 Drug eruption	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
嵌入爪 Ingrowing nail	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
乾癬 Psoriasis	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
紫斑 Purpura	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
水原性そう痒症 Aquagenic pruritus	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
水疱 Blister	1 (0.5%)	0	1 (0.2%)	0	0	0
血性水疱 Blood blister	1 (0.5%)	0	1 (0.2%)	0	0	0
紅色症 Erythrosis	1 (0.5%)	0	1 (0.2%)	0	0	0
間擦疹 Intertrigo	0	1 (0.5%)	1 (0.2%)	0	0	0
手掌・足底発赤知覚不全症候群 Palmar-plantar erythrodysaesthesia syndrome	0	1 (0.5%)	1 (0.2%)	0	0	0
口囲皮膚炎 Perioral dermatitis	0	1 (0.5%)	1 (0.2%)	0	0	0
毛孔性皮疹 Rash follicular	1 (0.5%)	0	1 (0.2%)	0	0	0
そう痒性皮疹 Rash pruritic	0	1 (0.5%)	1 (0.2%)	0	0	0
脂腺過形成 Sebaceous hyperplasia	0	1 (0.5%)	1 (0.2%)	0	0	0
中毒性皮疹 Toxic skin eruption	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
冷汗 Cold sweat	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
皮膚嚢腫 Dermal cyst	0	0	0	1 (0.6%)	0	1 (0.3%)
全身性剥脱性皮膚炎 Dermatitis exfoliative generalised	0	0	0	0	1 (0.5%)	1 (0.3%)
皮膚症 Dermatosis	0	0	0	1 (0.6%)	0	1 (0.3%)
酒さ Rosacea	0	0	0	1 (0.6%)	0	1 (0.3%)
皮膚剥脱 Skin exfoliation	0	0	0	1 (0.6%)	0	1 (0.3%)
皮膚脆弱性 Skin fragility	0	0	0	1 (0.6%)	0	1 (0.3%)
顔面腫脹 Swelling face	0	0	0	0	1 (0.5%)	1 (0.3%)
蕁麻疹 Urticaria	0	0	0	0	1 (0.5%)	1 (0.3%)
代謝および栄養障害 Metabolism and nutrition disorders	48 (22.4%)	43 (19.9%)	91 (21.2%)	29 (17.0%)	45 (22.8%)	74 (20.1%)
食欲減退 Decreased appetite	11 (5.1%)	13 (6.0%)	24 (5.6%)	7 (4.1%)	11 (5.6%)	18 (4.9%)
ビタミンＢ１欠乏 Vitamin B1 deficiency	7 (3.3%)	12 (5.6%)	19 (4.4%)	5 (2.9%)	8 (4.1%)	13 (3.5%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
高尿酸血症 Hyperuricaemia	10 (4.7%)	7 (3.2%)	17 (4.0%)	5 (2.9%)	7 (3.6%)	12 (3.3%)
高カリウム血症 Hyperkalaemia	7 (3.3%)	5 (2.3%)	12 (2.8%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
低カリウム血症 Hypokalaemia	4 (1.9%)	4 (1.9%)	8 (1.9%)	0	5 (2.5%)	5 (1.4%)
低マグネシウム血症 Hypomagnesaemia	6 (2.8%)	1 (0.5%)	7 (1.6%)	0	1 (0.5%)	1 (0.3%)
低カルシウム血症 Hypocalcaemia	3 (1.4%)	3 (1.4%)	6 (1.4%)	1 (0.6%)	4 (2.0%)	5 (1.4%)
脱水 Dehydration	2 (0.9%)	2 (0.9%)	4 (0.9%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
ビタミンD欠乏 Vitamin D deficiency	3 (1.4%)	1 (0.5%)	4 (0.9%)	0	1 (0.5%)	1 (0.3%)
痛風 Gout	3 (1.4%)	0	3 (0.7%)	2 (1.2%)	0	2 (0.5%)
糖尿病 Diabetes mellitus	0	2 (0.9%)	2 (0.5%)	2 (1.2%)	4 (2.0%)	6 (1.6%)
低ナトリウム血症 Hyponatraemia	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	3 (1.5%)	4 (1.1%)
低血糖 Hypoglycaemia	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	2 (1.0%)	3 (0.8%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
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高血糖 Hyperglycaemia	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	2 (1.0%)	2 (0.5%)
ビタミンB群欠乏 Vitamin B complex deficiency	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
鉄欠乏 Iron deficiency	2 (0.9%)	0	2 (0.5%)	0	0	0
鉄過剰 Iron overload	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
体液貯留 Fluid retention	0	1 (0.5%)	1 (0.2%)	2 (1.2%)	1 (0.5%)	3 (0.8%)
高カルシウム血症 Hypercalcaemia	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
高マグネシウム血症 Hypermagnesaemia	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
低アルブミン血症 Hypoalbuminaemia	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
低リン酸血症 Hypophosphataemia	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
葉酸欠乏 Folate deficiency	0	1 (0.5%)	1 (0.2%)	0	0	0
ヘモジデリン沈着症 Haemosiderosis	1 (0.5%)	0	1 (0.2%)	0	0	0

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血液量増加症 Hypervolaemia	0	1 (0.5%)	1 (0.2%)	0	0	0
栄養障害 Malnutrition	1 (0.5%)	0	1 (0.2%)	0	0	0
多飲症 Polydipsia	0	1 (0.5%)	1 (0.2%)	0	0	0
腫瘍崩壊症候群 Tumour lysis syndrome	0	1 (0.5%)	1 (0.2%)	0	0	0
ビタミンK欠乏 Vitamin K deficiency	1 (0.5%)	0	1 (0.2%)	0	0	0
高トリグリセリド血症 Hypertriglyceridaemia	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
異常体重減少 Abnormal loss of weight	0	0	0	0	1 (0.5%)	1 (0.3%)
電解質失調 Electrolyte imbalance	0	0	0	0	1 (0.5%)	1 (0.3%)
高コレステロール血症 Hypercholesterolaemia	0	0	0	0	1 (0.5%)	1 (0.3%)
高フェリチン血症 Hyperferritinaemia	0	0	0	1 (0.6%)	0	1 (0.3%)
ビタミンＢ６欠乏 Vitamin B6 deficiency	0	0	0	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
血管障害 Vascular disorders	49 (22.9%)	29 (13.4%)	78 (18.1%)	19 (11.1%)	32 (16.2%)	51 (13.9%)
高血圧 Hypertension	9 (4.2%)	20 (9.3%)	29 (6.7%)	7 (4.1%)	13 (6.6%)	20 (5.4%)
低血圧 Hypotension	19 (8.9%)	1 (0.5%)	20 (4.7%)	3 (1.8%)	7 (3.6%)	10 (2.7%)
潮紅 Flushing	13 (6.1%)	1 (0.5%)	14 (3.3%)	1 (0.6%)	3 (1.5%)	4 (1.1%)
血腫 Haematoma	6 (2.8%)	3 (1.4%)	9 (2.1%)	4 (2.3%)	2 (1.0%)	6 (1.6%)
ほてり Hot flush	3 (1.4%)	4 (1.9%)	7 (1.6%)	1 (0.6%)	3 (1.5%)	4 (1.1%)
静脈炎 Phlebitis	2 (0.9%)	0	2 (0.5%)	0	0	0
出血 Haemorrhage	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
起立性低血圧 Orthostatic hypotension	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
末梢動脈閉塞性疾患 Peripheral arterial occlusive disease	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
表在性血栓性静脈炎 Thrombophlebitis superficial	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)

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四肢静脈血栓症 Venous thrombosis limb	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
大動脈硬化症 Aortic arteriosclerosis	1 (0.5%)	0	1 (0.2%)	0	0	0
大動脈解離 Aortic dissection	1 (0.5%)	0	1 (0.2%)	0	0	0
大動脈血栓症 Aortic thrombosis	1 (0.5%)	0	1 (0.2%)	0	0	0
本態性高血圧症 Essential hypertension	1 (0.5%)	0	1 (0.2%)	0	0	0
高血圧クリーゼ Hypertensive crisis	0	1 (0.5%)	1 (0.2%)	0	0	0
末梢冷感 Peripheral coldness	1 (0.5%)	0	1 (0.2%)	0	0	0
末梢性虚血 Peripheral ischaemia	0	1 (0.5%)	1 (0.2%)	0	0	0
末梢静脈疾患 Peripheral venous disease	0	1 (0.5%)	1 (0.2%)	0	0	0
静脈穿刺不良 Poor venous access	1 (0.5%)	0	1 (0.2%)	0	0	0
血栓性静脈炎 Thrombophlebitis	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
大動脈狭窄 Aortic stenosis	0	0	0	0	1 (0.5%)	1 (0.3%)
動脈硬化症 Arteriosclerosis	0	0	0	0	1 (0.5%)	1 (0.3%)
末梢循環不良 Poor peripheral circulation	0	0	0	0	1 (0.5%)	1 (0.3%)
静脈瘤 Varicose vein	0	0	0	0	1 (0.5%)	1 (0.3%)
血管拡張 Vasodilatation	0	0	0	1 (0.6%)	0	1 (0.3%)
臨床検査 Investigations	40 (18.7%)	37 (17.1%)	77 (17.9%)	25 (14.6%)	30 (15.2%)	55 (14.9%)
アラニンアミノトランスフェラーゼ増加 Alanine aminotransferase increased	10 (4.7%)	10 (4.6%)	20 (4.7%)	2 (1.2%)	7 (3.6%)	9 (2.4%)
γ－グルタミルトランスフェラーゼ増加 Gamma-glutamyltransferase increased	6 (2.8%)	7 (3.2%)	13 (3.0%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
アスパラギン酸アミノトランスフェラーゼ増加 Aspartate aminotransferase increased	7 (3.3%)	5 (2.3%)	12 (2.8%)	1 (0.6%)	6 (3.0%)	7 (1.9%)
血中クレアチニン増加 Blood creatinine increased	9 (4.2%)	2 (0.9%)	11 (2.6%)	4 (2.3%)	7 (3.6%)	11 (3.0%)
血中アルカリホスファターゼ増加 Blood alkaline phosphatase increased	3 (1.4%)	5 (2.3%)	8 (1.9%)	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
体重減少 Weight decreased	6 (2.8%)	1 (0.5%)	7 (1.6%)	6 (3.5%)	3 (1.5%)	9 (2.4%)
体重増加 Weight increased	2 (0.9%)	5 (2.3%)	7 (1.6%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
血中ビリルビン増加 Blood bilirubin increased	2 (0.9%)	4 (1.9%)	6 (1.4%)	4 (2.3%)	3 (1.5%)	7 (1.9%)
心電図ＱＴ延長 Electrocardiogram QT prolonged	1 (0.5%)	4 (1.9%)	5 (1.2%)	0	0	0
活性化部分トロンボプラスチン時間延長 Activated partial thromboplastin time prolonged	1 (0.5%)	2 (0.9%)	3 (0.7%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
心雑音 Cardiac murmur	2 (0.9%)	1 (0.5%)	3 (0.7%)	0	0	0
腎クレアチニン・クリアランス減少 Creatinine renal clearance decreased	2 (0.9%)	0	2 (0.5%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
総蛋白増加 Protein total increased	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
リパーゼ増加 Lipase increased	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
トランスアミナーゼ上昇 Transaminases increased	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
国際標準比増加 International normalised ratio increased	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
血中鉄減少 Blood iron decreased	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
ヘマトクリット増加 Haematocrit increased	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
出血時間延長 Bleeding time prolonged	0	1 (0.5%)	1 (0.2%)	0	0	0
血中重炭酸塩減少 Blood bicarbonate decreased	1 (0.5%)	0	1 (0.2%)	0	0	0
血中クレアチンホスホキナーゼ増加 Blood creatine phosphokinase increased	0	1 (0.5%)	1 (0.2%)	0	0	0
血中乳酸増加 Blood lactic acid increased	1 (0.5%)	0	1 (0.2%)	0	0	0
体温上昇 Body temperature increased	0	1 (0.5%)	1 (0.2%)	0	0	0
心電図ＳＴ部分下降 Electrocardiogram ST segment depression	1 (0.5%)	0	1 (0.2%)	0	0	0
心電図異常 Electrocardiogram abnormal	1 (0.5%)	0	1 (0.2%)	0	0	0
ヘモグロビン増加 Haemoglobin increased	0	1 (0.5%)	1 (0.2%)	0	0	0
ヘプシジン減少 Hepcidin decreased	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
リンパ節触知 Lymph node palpable	1 (0.5%)	0	1 (0.2%)	0	0	0
好中球数増加 Neutrophil count increased	1 (0.5%)	0	1 (0.2%)	0	0	0
脈拍欠損 Pulse absent	0	1 (0.5%)	1 (0.2%)	0	0	0
血中乳酸脱水素酵素増加 Blood lactate dehydrogenase increased	0	0	0	1 (0.6%)	2 (1.0%)	3 (0.8%)
プロトロンビン時間延長 Prothrombin time prolonged	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
抗リン脂質抗体陽性 Antiphospholipid antibodies positive	0	0	0	1 (0.6%)	0	1 (0.3%)
血中葉酸減少 Blood folate decreased	0	0	0	1 (0.6%)	0	1 (0.3%)
血中尿素増加 Blood urea increased	0	0	0	1 (0.6%)	0	1 (0.3%)
胸部X線異常 Chest X-ray abnormal	0	0	0	0	1 (0.5%)	1 (0.3%)
骨盤コンピュータ断層撮影異常 Computerised tomogram pelvis abnormal	0	0	0	0	1 (0.5%)	1 (0.3%)
肝酵素上昇 Hepatic enzyme increased	0	0	0	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
肝機能検査異常 Liver function test abnormal	0	0	0	1 (0.6%)	0	1 (0.3%)
平均赤血球容積減少 Mean cell volume decreased	0	0	0	0	1 (0.5%)	1 (0.3%)
血清フェリチン増加 Serum ferritin increased	0	0	0	0	1 (0.5%)	1 (0.3%)
傷害、中毒および処置合併症 Injury, poisoning and procedural complications	26 (12.1%)	29 (13.4%)	55 (12.8%)	14 (8.2%)	16 (8.1%)	30 (8.2%)
挫傷 Contusion	16 (7.5%)	10 (4.6%)	26 (6.0%)	4 (2.3%)	4 (2.0%)	8 (2.2%)
転倒 Fall	6 (2.8%)	4 (1.9%)	10 (2.3%)	5 (2.9%)	5 (2.5%)	10 (2.7%)
皮膚擦過傷 Skin abrasion	1 (0.5%)	3 (1.4%)	4 (0.9%)	0	2 (1.0%)	2 (0.5%)
皮膚裂傷 Skin laceration	2 (0.9%)	2 (0.9%)	4 (0.9%)	0	2 (1.0%)	2 (0.5%)
四肢損傷 Limb injury	2 (0.9%)	1 (0.5%)	3 (0.7%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
処置による疼痛 Procedural pain	1 (0.5%)	2 (0.9%)	3 (0.7%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
処置後出血 Post procedural haemorrhage	0	2 (0.9%)	2 (0.5%)	2 (1.2%)	1 (0.5%)	3 (0.8%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
創傷 Wound	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
靱帯捻挫 Ligament sprain	0	2 (0.9%)	2 (0.5%)	0	0	0
眼窩周囲血腫 Periorbital haematoma	2 (0.9%)	0	2 (0.5%)	0	0	0
頭部損傷 Head injury	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
過量投与 Overdose	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
膝蓋骨骨折 Patella fracture	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
腱断裂 Tendon rupture	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
腹部損傷 Abdominal injury	0	1 (0.5%)	1 (0.2%)	0	0	0
節足動物咬傷 Arthropod bite	1 (0.5%)	0	1 (0.2%)	0	0	0
眼挫傷 Eye contusion	0	1 (0.5%)	1 (0.2%)	0	0	0
大腿骨骨折 Femur fracture	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
手骨折 Hand fracture	0	1 (0.5%)	1 (0.2%)	0	0	0
低圧症 Hypobarism	0	1 (0.5%)	1 (0.2%)	0	0	0
靱帯断裂 Ligament rupture	0	1 (0.5%)	1 (0.2%)	0	0	0
四肢圧挫損傷 Limb crushing injury	1 (0.5%)	0	1 (0.2%)	0	0	0
口腔内損傷 Mouth injury	0	1 (0.5%)	1 (0.2%)	0	0	0
処置後合併症 Post procedural complication	1 (0.5%)	0	1 (0.2%)	0	0	0
処置後挫傷 Post procedural contusion	1 (0.5%)	0	1 (0.2%)	0	0	0
術後譫妄 Postoperative delirium	1 (0.5%)	0	1 (0.2%)	0	0	0
肋骨骨折 Rib fracture	0	1 (0.5%)	1 (0.2%)	0	0	0
引っかき傷 Scratch	1 (0.5%)	0	1 (0.2%)	0	0	0
漿液腫 Seroma	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
脊椎圧迫骨折 Spinal compression fracture	1 (0.5%)	0	1 (0.2%)	0	0	0
輸血反応 Transfusion reaction	0	1 (0.5%)	1 (0.2%)	0	0	0
輸血関連合併症 Transfusion related complication	0	1 (0.5%)	1 (0.2%)	0	0	0
外傷性血腫 Traumatic haematoma	1 (0.5%)	0	1 (0.2%)	0	0	0
創合併症 Wound complication	1 (0.5%)	0	1 (0.2%)	0	0	0
足骨折 Foot fracture	0	0	0	0	2 (1.0%)	2 (0.5%)
吻合部狭窄 Anastomotic stenosis	0	0	0	1 (0.6%)	0	1 (0.3%)
顔面骨骨折 Facial bones fracture	0	0	0	0	1 (0.5%)	1 (0.3%)
筋損傷 Muscle injury	0	0	0	1 (0.6%)	0	1 (0.3%)
処置による悪心 Procedural nausea	0	0	0	0	1 (0.5%)	1 (0.3%)
骨格損傷 Skeletal injury	0	0	0	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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外傷性血胸 Traumatic haemothorax	0	0	0	0	1 (0.5%)	1 (0.3%)
腎および尿路障害 Renal and urinary disorders	24 (11.2%)	19 (8.8%)	43 (10.0%)	13 (7.6%)	19 (9.6%)	32 (8.7%)
腎不全 Renal failure	3 (1.4%)	4 (1.9%)	7 (1.6%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
排尿困難 Dysuria	3 (1.4%)	3 (1.4%)	6 (1.4%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
頻尿 Pollakiuria	3 (1.4%)	2 (0.9%)	5 (1.2%)	1 (0.6%)	3 (1.5%)	4 (1.1%)
急性腎障害 Acute kidney injury	3 (1.4%)	1 (0.5%)	4 (0.9%)	2 (1.2%)	4 (2.0%)	6 (1.6%)
血尿 Haematuria	3 (1.4%)	1 (0.5%)	4 (0.9%)	0	2 (1.0%)	2 (0.5%)
腎結石症 Nephrolithiasis	2 (0.9%)	2 (0.9%)	4 (0.9%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
腎仙痛 Renal colic	0	4 (1.9%)	4 (0.9%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
慢性腎臓病 Chronic kidney disease	2 (0.9%)	1 (0.5%)	3 (0.7%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
腎機能障害 Renal impairment	2 (0.9%)	0	2 (0.5%)	2 (1.2%)	2 (1.0%)	4 (1.1%)

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夜間頻尿 Nocturia	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
尿失禁 Urinary incontinence	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	2 (1.0%)	2 (0.5%)
着色尿 Chromaturia	2 (0.9%)	0	2 (0.5%)	0	0	0
多尿 Polyuria	2 (0.9%)	0	2 (0.5%)	0	0	0
蛋白尿 Proteinuria	1 (0.5%)	0	1 (0.2%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
白血球尿 Leukocyturia	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
出血性膀胱炎 Cystitis haemorrhagic	0	1 (0.5%)	1 (0.2%)	0	0	0
中毒性ネフロパシー Nephropathy toxic	0	1 (0.5%)	1 (0.2%)	0	0	0
腎動脈狭窄症 Renal artery stenosis	0	1 (0.5%)	1 (0.2%)	0	0	0
膀胱ポリープ Urinary bladder polyp	1 (0.5%)	0	1 (0.2%)	0	0	0
尿閉 Urinary retention	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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	有害事象（因果関係を問わない）					
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尿路痛 Urinary tract pain	1 (0.5%)	0	1 (0.2%)	0	0	0
尿管結石症 Ureterolithiasis	0	0	0	1 (0.6%)	0	1 (0.3%)
眼障害 Eye disorders	24 (11.2%)	17 (7.9%)	41 (9.5%)	18 (10.5%)	17 (8.6%)	35 (9.5%)
霧視 Vision blurred	5 (2.3%)	3 (1.4%)	8 (1.9%)	2 (1.2%)	1 (0.5%)	3 (0.8%)
皮質白内障 Cataract cortical	3 (1.4%)	3 (1.4%)	6 (1.4%)	2 (1.2%)	4 (2.0%)	6 (1.6%)
核性白内障 Cataract nuclear	4 (1.9%)	1 (0.5%)	5 (1.2%)	4 (2.3%)	5 (2.5%)	9 (2.4%)
ドライアイ Dry eye	0	3 (1.4%)	3 (0.7%)	0	3 (1.5%)	3 (0.8%)
視力低下 Visual acuity reduced	1 (0.5%)	2 (0.9%)	3 (0.7%)	0	2 (1.0%)	2 (0.5%)
嚢下白内障 Cataract subcapsular	1 (0.5%)	1 (0.5%)	2 (0.5%)	3 (1.8%)	0	3 (0.8%)
眼痛 Eye pain	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
流涙増加 Lacrimation increased	2 (0.9%)	0	2 (0.5%)	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
視力障害 Visual impairment	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
白内障 Cataract	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
角膜炎 Keratitis	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
複視 Diplopia	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
眼出血 Eye haemorrhage	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
眼刺激 Eye irritation	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
眼瞼浮腫 Eyelid oedema	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
黄斑変性 Macular degeneration	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
網膜出血 Retinal haemorrhage	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
結膜上皮侵入 Conjunctivalisation	0	1 (0.5%)	1 (0.2%)	0	0	0
眼球浮腫 Eye oedema	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
眼部腫脹 Eye swelling	1 (0.5%)	0	1 (0.2%)	0	0	0
星状硝子体症 Hyalosis asteroid	1 (0.5%)	0	1 (0.2%)	0	0	0
眼窩浮腫 Orbital oedema	1 (0.5%)	0	1 (0.2%)	0	0	0
眼窩周囲浮腫 Periorbital oedema	1 (0.5%)	0	1 (0.2%)	0	0	0
光視症 Photopsia	1 (0.5%)	0	1 (0.2%)	0	0	0
眼瞼腫脹 Swelling of eyelid	1 (0.5%)	0	1 (0.2%)	0	0	0
硝子体浮遊物 Vitreous floaters	1 (0.5%)	0	1 (0.2%)	0	0	0
結膜出血 Conjunctival haemorrhage	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
糖尿病網膜症 Diabetic retinopathy	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
眼充血 Ocular hyperaemia	0	0	0	0	2 (1.0%)	2 (0.5%)
眼瞼炎 Blepharitis	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
眼瞼下垂 Eyelid ptosis	0	0	0	1 (0.6%)	0	1 (0.3%)
緑内障 Glaucoma	0	0	0	1 (0.6%)	0	1 (0.3%)
睫毛の成長 Growth of eyelashes	0	0	0	0	1 (0.5%)	1 (0.3%)
マイボーム腺機能不全 Meibomian gland dysfunction	0	0	0	0	1 (0.5%)	1 (0.3%)
網膜瘢痕 Retinal scar	0	0	0	1 (0.6%)	0	1 (0.3%)
硝子体変性 Vitreous degeneration	0	0	0	1 (0.6%)	0	1 (0.3%)
精神障害 Psychiatric disorders	20 (9.3%)	17 (7.9%)	37 (8.6%)	13 (7.6%)	15 (7.6%)	28 (7.6%)
不安 Anxiety	7 (3.3%)	6 (2.8%)	13 (3.0%)	3 (1.8%)	1 (0.5%)	4 (1.1%)
不眠症 Insomnia	4 (1.9%)	6 (2.8%)	10 (2.3%)	5 (2.9%)	6 (3.0%)	11 (3.0%)
うつ病 Depression	6 (2.8%)	3 (1.4%)	9 (2.1%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
錯乱状態 Confusional state	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	1 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
精神状態変化 Mental status changes	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
神経過敏 Nervousness	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
激越 Agitation	1 (0.5%)	0	1 (0.2%)	0	0	0
不安障害 Anxiety disorder	0	1 (0.5%)	1 (0.2%)	0	0	0
精神緩慢 Bradyphrenia	0	1 (0.5%)	1 (0.2%)	0	0	0
幻覚 Hallucination	1 (0.5%)	0	1 (0.2%)	0	0	0
初期不眠症 Initial insomnia	0	1 (0.5%)	1 (0.2%)	0	0	0
悪夢 Nightmare	0	1 (0.5%)	1 (0.2%)	0	0	0
リビドー減退 Libido decreased	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
感情障害 Affective disorder	0	0	0	0	1 (0.5%)	1 (0.3%)
抑うつ気分 Depressed mood	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
失見当識 Disorientation	0	0	0	1 (0.6%)	0	1 (0.3%)
睡眠障害 Sleep disorder	0	0	0	0	1 (0.5%)	1 (0.3%)
自殺念慮 Suicidal ideation	0	0	0	1 (0.6%)	0	1 (0.3%)
心臓障害 Cardiac disorders	20 (9.3%)	15 (6.9%)	35 (8.1%)	7 (4.1%)	11 (5.6%)	18 (4.9%)
心房細動 Atrial fibrillation	8 (3.7%)	2 (0.9%)	10 (2.3%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
狭心症 Angina pectoris	4 (1.9%)	1 (0.5%)	5 (1.2%)	0	2 (1.0%)	2 (0.5%)
心不全 Cardiac failure	2 (0.9%)	3 (1.4%)	5 (1.2%)	0	2 (1.0%)	2 (0.5%)
動悸 Palpitations	2 (0.9%)	3 (1.4%)	5 (1.2%)	0	2 (1.0%)	2 (0.5%)
頻脈 Tachycardia	2 (0.9%)	2 (0.9%)	4 (0.9%)	1 (0.6%)	0	1 (0.3%)
急性心筋梗塞 Acute myocardial infarction	3 (1.4%)	0	3 (0.7%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
うっ血性心不全 Cardiac failure congestive	1 (0.5%)	2 (0.9%)	3 (0.7%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
急性心不全 Cardiac failure acute	0	2 (0.9%)	2 (0.5%)	0	0	0
心拡大 Cardiomegaly	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
左室不全 Left ventricular failure	0	2 (0.9%)	2 (0.5%)	0	0	0
心房粗動 Atrial flutter	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
洞性徐脈 Sinus bradycardia	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
不安定狭心症 Angina unstable	1 (0.5%)	0	1 (0.2%)	0	0	0
完全房室ブロック Atrioventricular block complete	1 (0.5%)	0	1 (0.2%)	0	0	0
徐脈 Bradycardia	0	1 (0.5%)	1 (0.2%)	0	0	0
期外収縮 Extrasystoles	1 (0.5%)	0	1 (0.2%)	0	0	0
高血圧性心疾患 Hypertensive heart disease	0	1 (0.5%)	1 (0.2%)	0	0	0
左室機能不全 Left ventricular dysfunction	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
僧帽弁閉鎖不全症 Mitral valve incompetence	0	1 (0.5%)	1 (0.2%)	0	0	0
心嚢液貯留 Pericardial effusion	1 (0.5%)	0	1 (0.2%)	0	0	0
上室性頻脈 Supraventricular tachycardia	1 (0.5%)	0	1 (0.2%)	0	0	0
三尖弁閉鎖不全症 Tricuspid valve incompetence	1 (0.5%)	0	1 (0.2%)	0	0	0
第一度房室ブロック Atrioventricular block first degree	0	0	0	1 (0.6%)	0	1 (0.3%)
心停止 Cardiac arrest	0	0	0	0	1 (0.5%)	1 (0.3%)
慢性心不全 Cardiac failure chronic	0	0	0	0	1 (0.5%)	1 (0.3%)
心臓弁膜疾患 Cardiac valve disease	0	0	0	0	1 (0.5%)	1 (0.3%)
拡張機能障害 Diastolic dysfunction	0	0	0	0	1 (0.5%)	1 (0.3%)
心筋虚血 Myocardial ischaemia	0	0	0	1 (0.6%)	0	1 (0.3%)
耳および迷路障害 Ear and labyrinth disorders	13 (6.1%)	13 (6.0%)	26 (6.0%)	7 (4.1%)	7 (3.6%)	14 (3.8%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
回転性めまい Vertigo	8 (3.7%)	7 (3.2%)	15 (3.5%)	3 (1.8%)	5 (2.5%)	8 (2.2%)
耳鳴 Tinnitus	2 (0.9%)	2 (0.9%)	4 (0.9%)	0	0	0
耳痛 Ear pain	1 (0.5%)	2 (0.9%)	3 (0.7%)	0	0	0
耳不快感 Ear discomfort	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
聴力低下 Hypoacusis	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
耳閉 Ear congestion	0	1 (0.5%)	1 (0.2%)	0	0	0
難聴 Deafness	0	0	0	1 (0.6%)	0	1 (0.3%)
耳出血 Ear haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)
乗物酔い Motion sickness	0	0	0	1 (0.6%)	0	1 (0.3%)
突発性難聴 Sudden hearing loss	0	0	0	1 (0.6%)	0	1 (0.3%)
鼓膜穿孔 Tympanic membrane perforation	0	0	0	1 (0.6%)	0	1 (0.3%)

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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） Neoplasms benign, malignant and unspecified (incl cysts and polyps)	11 (5.1%)	14 (6.5%)	25 (5.8%)	10 (5.8%)	14 (7.1%)	24 (6.5%)
皮膚有棘細胞癌 Squamous cell carcinoma of skin	3 (1.4%)	4 (1.9%)	7 (1.6%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
基底細胞癌 Basal cell carcinoma	2 (0.9%)	3 (1.4%)	5 (1.2%)	3 (1.8%)	2 (1.0%)	5 (1.4%)
急性骨髄性白血病 Acute myeloid leukaemia	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	2 (1.0%)	2 (0.5%)
膵管内乳頭粘液性腫瘍 Intraductal papillary mucinous neoplasm	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
骨髄線維症 Myelofibrosis	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
悪性黒色腫 Malignant melanoma	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
メラノサイト性母斑 Melanocytic naevus	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
膀胱移行上皮癌 Bladder transitional cell carcinoma	1 (0.5%)	0	1 (0.2%)	0	0	0
再発マントル細胞リンパ腫 Mantle cell lymphoma recurrent	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
鼻の良性新生物 Nasal neoplasm benign	0	1 (0.5%)	1 (0.2%)	0	0	0
食道扁平上皮癌 Oesophageal squamous cell carcinoma	1 (0.5%)	0	1 (0.2%)	0	0	0
卵巣明細胞癌 Ovarian clear cell carcinoma	1 (0.5%)	0	1 (0.2%)	0	0	0
再発前立腺癌 Prostate cancer recurrent	0	1 (0.5%)	1 (0.2%)	0	0	0
脾臓辺縁帯リンパ腫 Splenic marginal zone lymphoma	1 (0.5%)	0	1 (0.2%)	0	0	0
急性骨髄性白血病への転化 Transformation to acute myeloid leukaemia	0	1 (0.5%)	1 (0.2%)	0	0	0
子宮癌 Uterine cancer	1 (0.5%)	0	1 (0.2%)	0	0	0
脂漏性角化症 Seborrhoeic keratosis	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
子宮平滑筋腫 Uterine leiomyoma	0	0	0	0	2 (1.0%)	2 (0.5%)
乳腺線維腺腫 Fibroadenoma of breast	0	0	0	1 (0.6%)	0	1 (0.3%)
骨血管腫 Haemangioma of bone	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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白赤芽球症 Leukoerythroblastosis	0	0	0	1 (0.6%)	0	1 (0.3%)
遠隔転移を伴う扁平上皮癌 Metastatic squamous cell carcinoma	0	0	0	0	1 (0.5%)	1 (0.3%)
前立腺癌 Prostate cancer	0	0	0	0	1 (0.5%)	1 (0.3%)
直腸癌 Rectal cancer	0	0	0	1 (0.6%)	0	1 (0.3%)
鼻副鼻腔乳頭腫 Sinonasal papilloma	0	0	0	0	1 (0.5%)	1 (0.3%)
生殖系および乳房障害 Reproductive system and breast disorders	5 (2.3%)	7 (3.2%)	12 (2.8%)	2 (1.2%)	4 (2.0%)	6 (1.6%)
良性前立腺肥大症 Benign prostatic hyperplasia	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
腟出血 Vaginal haemorrhage	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
腟分泌物 Vaginal discharge	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
月経過多 Menorrhagia	0	1 (0.5%)	1 (0.2%)	0	0	0
会陰痛 Perineal pain	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
陰嚢浮腫 Scrotal oedema	0	1 (0.5%)	1 (0.2%)	0	0	0
自発陰茎勃起 Spontaneous penile erection	0	1 (0.5%)	1 (0.2%)	0	0	0
腟ポリープ Vaginal polyp	0	1 (0.5%)	1 (0.2%)	0	0	0
外陰腟の炎症 Vulvovaginal inflammation	1 (0.5%)	0	1 (0.2%)	0	0	0
外陰腟痛 Vulvovaginal pain	1 (0.5%)	0	1 (0.2%)	0	0	0
精巣上体嚢胞 Epididymal cyst	0	0	0	1 (0.6%)	0	1 (0.3%)
子宮頚部びらん Uterine cervical erosion	0	0	0	0	1 (0.5%)	1 (0.3%)
腟脱 Vaginal prolapse	0	0	0	1 (0.6%)	0	1 (0.3%)
肝胆道系障害 Hepatobiliary disorders	1 (0.5%)	5 (2.3%)	6 (1.4%)	2 (1.2%)	5 (2.5%)	7 (1.9%)
胆道仙痛 Biliary colic	0	2 (0.9%)	2 (0.5%)	0	0	0
胆石症 Cholelithiasis	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
肝機能異常 Hepatic function abnormal	0	1 (0.5%)	1 (0.2%)	0	0	0
肝細胞損傷 Hepatocellular injury	0	1 (0.5%)	1 (0.2%)	0	0	0
過形成性胆嚢症 Hyperplastic cholecystopathy	1 (0.5%)	0	1 (0.2%)	0	0	0
黄疸眼 Ocular icterus	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
急性胆嚢炎 Cholecystitis acute	0	0	0	0	1 (0.5%)	1 (0.3%)
胆汁うっ滞 Cholestasis	0	0	0	1 (0.6%)	0	1 (0.3%)
肝硬変 Hepatic cirrhosis	0	0	0	0	1 (0.5%)	1 (0.3%)
肝不全 Hepatic failure	0	0	0	0	1 (0.5%)	1 (0.3%)
門脈圧亢進症 Portal hypertension	0	0	0	0	1 (0.5%)	1 (0.3%)
先天性、家族性および遺伝性障害 Congenital, familial and genetic disorders	0	3 (1.4%)	3 (0.7%)	0	0	0
ジルベール症候群 Gilbert's syndrome	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（因果関係を問わない）					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
陰嚢水瘤 Hydrocele	0	1 (0.5%)	1 (0.2%)	0	0	0
包茎 Phimosis	0	1 (0.5%)	1 (0.2%)	0	0	0
内分泌障害 Endocrine disorders	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
低アルドステロン症 Hypoaldosteronism	1 (0.5%)	0	1 (0.2%)	0	0	0
甲状腺機能低下症 Hypothyroidism	1 (0.5%)	0	1 (0.2%)	0	0	0
甲状腺腫瘤 Thyroid mass	0	0	0	1 (0.6%)	0	1 (0.3%)
外科および内科処置 Surgical and medical procedures	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
抜歯 Tooth extraction	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
有害事象発現例数 ANY EVENT	138 (64.5%)	143 (66.2%)	281 (65.3%)	67 (39.2%)	111 (56.3%)	178 (48.4%)
胃腸障害 Gastrointestinal disorders	48 (22.4%)	33 (15.3%)	81 (18.8%)	5 (2.9%)	34 (17.3%)	39 (10.6%)
下痢 Diarrhoea	17 (7.9%)	19 (8.8%)	36 (8.4%)	1 (0.6%)	12 (6.1%)	13 (3.5%)
腹痛 Abdominal pain	7 (3.3%)	4 (1.9%)	11 (2.6%)	2 (1.2%)	4 (2.0%)	6 (1.6%)
悪心 Nausea	23 (10.7%)	2 (0.9%)	25 (5.8%)	1 (0.6%)	18 (9.1%)	19 (5.2%)
便秘 Constipation	2 (0.9%)	3 (1.4%)	5 (1.2%)	0	0	0
嘔吐 Vomiting	6 (2.8%)	2 (0.9%)	8 (1.9%)	0	4 (2.0%)	4 (1.1%)
上腹部痛 Abdominal pain upper	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
腹部膨満 Abdominal distension	3 (1.4%)	1 (0.5%)	4 (0.9%)	0	0	0
消化不良 Dyspepsia	1 (0.5%)	4 (1.9%)	5 (1.2%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
腹部不快感 Abdominal discomfort	2 (0.9%)	1 (0.5%)	3 (0.7%)	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
胃食道逆流性疾患 Gastrooesophageal reflux disease	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
鼓腸 Flatulence	1 (0.5%)	3 (1.4%)	4 (0.9%)	0	1 (0.5%)	1 (0.3%)
口内乾燥 Dry mouth	2 (0.9%)	0	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
歯痛 Toothache	0	0	0	0	0	0
口腔内潰瘍形成 Mouth ulceration	0	1 (0.5%)	1 (0.2%)	0	0	0
痔核 Haemorrhoids	0	0	0	0	0	0
歯肉出血 Gingival bleeding	0	0	0	0	1 (0.5%)	1 (0.3%)
鼠径ヘルニア Inguinal hernia	0	0	0	0	0	0
口内炎 Stomatitis	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
小腸炎 Enteritis	0	0	0	0	0	0
腹水 Ascites	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
直腸出血 Rectal haemorrhage	1 (0.5%)	0	1 (0.2%)	0	0	0
口唇炎 Cheilitis	0	1 (0.5%)	1 (0.2%)	0	0	0
アフタ性潰瘍 Aphthous ulcer	0	0	0	0	0	0
腸炎 Enterocolitis	0	0	0	0	0	0
肛門周囲痛 Proctalgia	0	0	0	0	0	0
胃炎 Gastritis	0	0	0	0	0	0
食道静脈瘤 Varices oesophageal	0	0	0	0	0	0
嚥下障害 Dysphagia	0	0	0	0	0	0
レッチング Retching	0	0	0	0	1 (0.5%)	1 (0.3%)
小腸閉塞 Small intestinal obstruction	0	0	0	0	0	0
下腹部痛 Abdominal pain lower	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
肛門出血 Anal haemorrhage	0	0	0	0	0	0
憩室穿孔 Diverticular perforation	0	0	0	0	0	0
びらん性食道炎 Erosive oesophagitis	0	0	0	0	0	0
変色便 Faeces discoloured	0	0	0	0	0	0
軟便 Faeces soft	0	0	0	0	0	0
胃ポリープ Gastric polyps	0	0	0	0	0	0
胃潰瘍 Gastric ulcer	0	0	0	0	0	0
血便排泄 Haematochezia	1 (0.5%)	0	1 (0.2%)	0	0	0
痔出血 Haemorrhoidal haemorrhage	0	0	0	0	0	0
イレウス Ileus	0	0	0	0	0	0
口唇痛 Lip pain	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
メレナ Melaena	0	0	0	0	0	0
腸間膜静脈血栓症 Mesenteric vein thrombosis	0	0	0	0	0	0
嚥下痛 Odynophagia	0	0	0	0	0	0
食道痛 Oesophageal pain	0	1 (0.5%)	1 (0.2%)	0	0	0
食道炎 Oesophagitis	0	0	0	0	0	0
消化性潰瘍 Peptic ulcer	0	0	0	0	0	0
腹膜出血 Peritoneal haemorrhage	0	0	0	0	0	0
亜イレウス Subileus	0	0	0	0	0	0
舌紅斑 Tongue erythema	0	0	0	0	0	0
肛門失禁 Anal incontinence	0	0	0	0	1 (0.5%)	1 (0.3%)
口角口唇炎 Angular cheilitis	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
心窩部不快感 Epigastric discomfort	0	0	0	0	1 (0.5%)	1 (0.3%)
口腔内痛 Oral pain	0	0	0	0	0	0
腹部硬直 Abdominal rigidity	0	0	0	0	0	0
便意切迫 Defaecation urgency	0	0	0	0	1 (0.5%)	1 (0.3%)
齲歯 Dental caries	0	0	0	0	0	0
出血性十二指腸潰瘍 Duodenal ulcer haemorrhage	0	0	0	0	0	0
食中毒 Food poisoning	0	0	0	0	0	0
胃出血 Gastric haemorrhage	0	0	0	0	0	0
出血性胃潰瘍 Gastric ulcer haemorrhage	0	0	0	0	0	0
びらん性胃炎 Gastritis erosive	0	0	0	0	1 (0.5%)	1 (0.3%)
胃腸出血 Gastrointestinal haemorrhage	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
消化器痛 Gastrointestinal pain	0	0	0	0	0	0
胃腸音異常 Gastrointestinal sounds abnormal	0	0	0	0	0	0
裂孔ヘルニア Hiatus hernia	0	0	0	0	0	0
口の感覚鈍麻 Hypoaesthesia oral	0	0	0	0	1 (0.5%)	1 (0.3%)
下部消化管出血 Lower gastrointestinal haemorrhage	0	0	0	0	0	0
口腔内出血 Mouth haemorrhage	0	0	0	0	0	0
食道静脈瘤出血 Oesophageal varices haemorrhage	0	0	0	0	0	0
口腔粘膜血腫 Oral mucosa haematoma	0	0	0	0	0	0
歯周病 Periodontal disease	0	0	0	0	0	0
咳嗽後嘔吐 Post-tussive vomiting	0	0	0	0	1 (0.5%)	1 (0.3%)
小腸出血 Small intestinal haemorrhage	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
血液およびリンパ系障害 Blood and lymphatic system disorders	51 (23.8%)	104 (48.1%)	155 (36.0%)	24 (14.0%)	38 (19.3%)	62 (16.8%)
貧血 Anaemia	18 (8.4%)	65 (30.1%)	83 (19.3%)	10 (5.8%)	10 (5.1%)	20 (5.4%)
血小板減少症 Thrombocytopenia	34 (15.9%)	55 (25.5%)	89 (20.7%)	13 (7.6%)	25 (12.7%)	38 (10.3%)
好中球減少症 Neutropenia	8 (3.7%)	12 (5.6%)	20 (4.7%)	5 (2.9%)	3 (1.5%)	8 (2.2%)
白血球減少症 Leukopenia	5 (2.3%)	4 (1.9%)	9 (2.1%)	3 (1.8%)	4 (2.0%)	7 (1.9%)
血小板増加症 Thrombocytosis	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
白血球増加症 Leukocytosis	3 (1.4%)	0	3 (0.7%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
発熱性好中球減少症 Febrile neutropenia	0	1 (0.5%)	1 (0.2%)	2 (1.2%)	0	2 (0.5%)
リンパ球減少症 Lymphopenia	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	2 (1.0%)	2 (0.5%)
脾腫 Splenomegaly	0	0	0	0	0	0
内出血発生の増加傾向 Increased tendency to bruise	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
凝血異常 Coagulopathy	0	0	0	0	0	0
赤血球増加症 Polycythaemia	0	0	0	0	1 (0.5%)	1 (0.3%)
脾臓梗塞 Splenic infarction	0	0	0	0	0	0
失血性貧血 Blood loss anaemia	0	0	0	0	0	0
低プロトロンビン血症 Hypoprothrombinaemia	0	0	0	0	0	0
リンパ節石灰化 Lymph node calcification	0	0	0	0	0	0
リンパ節症 Lymphadenopathy	0	0	0	0	0	0
リンパ球増加症 Lymphocytosis	1 (0.5%)	0	1 (0.2%)	0	0	0
微小血管症性溶血性貧血 Microangiopathic haemolytic anaemia	0	0	0	0	0	0
脾血腫 Splenic haematoma	0	0	0	0	0	0
過粘稠度症候群 Hyperviscosity syndrome	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
肥満細胞症 Mastocytosis	0	0	0	0	0	0
好中球増加症 Neutrophilia	0	0	0	0	1 (0.5%)	1 (0.3%)
特発性血腫 Spontaneous haematoma	0	0	0	0	0	0
感染症および寄生虫症 Infections and infestations	5 (2.3%)	15 (6.9%)	20 (4.7%)	11 (6.4%)	11 (5.6%)	22 (6.0%)
上気道感染 Upper respiratory tract infection	0	1 (0.5%)	1 (0.2%)	2 (1.2%)	1 (0.5%)	3 (0.8%)
上咽頭炎 Nasopharyngitis	0	2 (0.9%)	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
尿路感染 Urinary tract infection	1 (0.5%)	3 (1.4%)	4 (0.9%)	2 (1.2%)	3 (1.5%)	5 (1.4%)
帯状疱疹 Herpes zoster	3 (1.4%)	3 (1.4%)	6 (1.4%)	2 (1.2%)	0	2 (0.5%)
肺炎 Pneumonia	1 (0.5%)	0	1 (0.2%)	2 (1.2%)	3 (1.5%)	5 (1.4%)
気道感染 Respiratory tract infection	0	1 (0.5%)	1 (0.2%)	0	0	0
口腔ヘルペス Oral herpes	0	3 (1.4%)	3 (0.7%)	1 (0.6%)	2 (1.0%)	3 (0.8%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
気管支炎 Bronchitis	0	0	0	0	1 (0.5%)	1 (0.3%)
膀胱炎 Cystitis	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
インフルエンザ Influenza	0	0	0	0	0	0
鼻炎 Rhinitis	0	0	0	0	0	0
胃腸炎 Gastroenteritis	0	0	0	0	1 (0.5%)	1 (0.3%)
皮膚感染 Skin infection	1 (0.5%)	0	1 (0.2%)	0	0	0
下気道感染 Lower respiratory tract infection	0	0	0	1 (0.6%)	0	1 (0.3%)
敗血症 Sepsis	0	0	0	0	0	0
副鼻腔炎 Sinusitis	0	0	0	0	0	0
蜂巣炎 Cellulitis	0	0	0	0	0	0
ウイルス感染 Viral infection	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
術後創感染 Postoperative wound infection	0	0	0	0	0	0
結膜炎 Conjunctivitis	0	0	0	0	0	0
癜風 Tinea versicolour	0	0	0	0	0	0
皮膚真菌感染 Fungal skin infection	0	0	0	0	0	0
消化管感染 Gastrointestinal infection	0	0	0	0	0	0
限局性感染 Localised infection	0	0	0	0	0	0
口腔カンジダ症 Oral candidiasis	0	0	0	0	0	0
毛包炎 Folliculitis	0	0	0	0	0	0
歯肉炎 Gingivitis	0	0	0	0	0	0
感染 Infection	0	0	0	0	0	0
歯周炎 Periodontitis	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
咽頭炎 Pharyngitis	0	0	0	0	0	0
気管気管支炎 Tracheobronchitis	0	0	0	0	0	0
腟感染 Vaginal infection	0	0	0	0	0	0
陰部ヘルペス Genital herpes	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
クロストリジウム・ディフィシレ大腸炎 Clostridium difficile colitis	0	0	0	0	0	0
大腸菌性尿路感染 Escherichia urinary tract infection	0	0	0	0	0	0
真菌感染 Fungal infection	0	0	0	0	0	0
肺感染 Lung infection	0	0	0	0	0	0
外耳炎 Otitis externa	0	0	0	0	0	0
赤痢菌感染 Shigella infection	0	0	0	0	0	0
肛門膿瘍 Anal abscess	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
憩室炎 Diverticulitis	0	0	0	0	0	0
大腸菌性敗血症 Escherichia sepsis	0	0	0	0	0	0
真菌性食道炎 Fungal oesophagitis	0	1 (0.5%)	1 (0.2%)	0	0	0
せつ Furuncle	0	0	0	0	0	0
ウイルス性消化管感染 Gastrointestinal viral infection	0	0	0	0	0	0
麦粒腫 Hordeolum	0	1 (0.5%)	1 (0.2%)	0	0	0
膿痂疹 Impetigo	0	1 (0.5%)	1 (0.2%)	0	0	0
喉頭炎 Laryngitis	0	0	0	0	0	0
口唇感染 Lip infection	0	0	0	0	0	0
ライム病 Lyme disease	0	0	0	0	0	0
爪真菌症 Onychomycosis	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
爪囲炎 Paronychia	0	0	0	0	0	0
腹膜炎 Peritonitis	0	0	0	0	0	0
細菌性肺炎 Pneumonia bacterial	0	0	0	0	0	0
処置後感染 Post procedural infection	0	0	0	0	0	0
肺敗血症 Pulmonary sepsis	0	0	0	0	0	0
腎盂膀胱炎 Pyelocystitis	0	0	0	0	0	0
腎盂腎炎 Pyelonephritis	0	0	0	0	0	0
陰嚢膿瘍 Scrotal abscess	0	0	0	0	0	0
皮膚細菌感染 Skin bacterial infection	0	0	0	0	0	0
ブドウ球菌感染 Staphylococcal infection	0	0	0	0	0	0
レンサ球菌性敗血症 Streptococcal sepsis	0	0	0	0	0	0

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Population: Safety Analysis Set
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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
気管炎 Tracheitis	0	0	0	0	0	0
ウイルス性上気道感染 Viral upper respiratory tract infection	0	0	0	0	0	0
外陰部腟カンジダ症 Vulvovaginal candidiasis	0	0	0	0	0	0
外陰腟真菌感染 Vulvovaginal mycotic infection	0	0	0	0	0	0
創傷感染 Wound infection	0	0	0	0	0	0
クロストリジウム・ディフィシレ感染 Clostridium difficile infection	0	0	0	0	0	0
耳感染 Ear infection	0	0	0	0	0	0
単純ヘルペス Herpes simplex	0	0	0	0	1 (0.5%)	1 (0.3%)
中耳炎 Otitis media	0	0	0	0	0	0
扁桃炎 Tonsillitis	0	0	0	0	0	0
ボレリア感染 Borrelia infection	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
丹毒 Erysipelas	0	0	0	0	0	0
壊疽 Gangrene	0	0	0	1 (0.6%)	0	1 (0.3%)
サルモネラ菌性胃腸炎 Gastroenteritis salmonella	0	0	0	0	0	0
消化器カンジダ症 Gastrointestinal candidiasis	0	0	0	0	0	0
ヘルペス性皮膚炎 Herpes dermatitis	0	0	0	0	0	0
感染性皮膚潰瘍 Infected skin ulcer	0	0	0	0	0	0
迷路炎 Labyrinthitis	0	0	0	0	0	0
鼻ヘルペス Nasal herpes	0	0	0	0	0	0
百日咳 Pertussis	0	0	0	0	0	0
ピコルナウイルス感染 Picornavirus infection	0	0	0	0	0	0
歯膿瘍 Tooth abscess	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
水痘帯状疱疹ウイルス感染 Varicella zoster virus infection	0	0	0	0	1 (0.5%)	1 (0.3%)
ウイルス性ぶどう膜炎 Viral uveitis	0	0	0	0	0	0
神経系障害 Nervous system disorders	65 (30.4%)	30 (13.9%)	95 (22.1%)	14 (8.2%)	35 (17.8%)	49 (13.3%)
頭痛 Headache	26 (12.1%)	17 (7.9%)	43 (10.0%)	0	7 (3.6%)	7 (1.9%)
浮動性めまい Dizziness	24 (11.2%)	9 (4.2%)	33 (7.7%)	3 (1.8%)	9 (4.6%)	12 (3.3%)
末梢性感覚ニューロパチー Peripheral sensory neuropathy	16 (7.5%)	5 (2.3%)	21 (4.9%)	4 (2.3%)	12 (6.1%)	16 (4.3%)
錯感覚 Paraesthesia	13 (6.1%)	4 (1.9%)	17 (4.0%)	2 (1.2%)	4 (2.0%)	6 (1.6%)
失神寸前の状態 Presyncope	2 (0.9%)	0	2 (0.5%)	0	0	0
嗜眠 Lethargy	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
感覚鈍麻 Hypoaesthesia	1 (0.5%)	1 (0.5%)	2 (0.5%)	2 (1.2%)	1 (0.5%)	3 (0.8%)
振戦 Tremor	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
記憶障害 Memory impairment	1 (0.5%)	2 (0.9%)	3 (0.7%)	0	0	0
坐骨神経痛 Sciatica	0	0	0	0	0	0
失神 Syncope	1 (0.5%)	0	1 (0.2%)	0	2 (1.0%)	2 (0.5%)
味覚障害 Taste disorder	2 (0.9%)	1 (0.5%)	3 (0.7%)	0	0	0
平衡障害 Balance disorder	2 (0.9%)	0	2 (0.5%)	0	0	0
健忘 Amnesia	0	0	0	0	0	0
片頭痛 Migraine	0	0	0	0	0	0
味覚異常 Dysgeusia	0	0	0	0	1 (0.5%)	1 (0.3%)
一過性脳虚血発作 Transient ischaemic attack	0	0	0	0	0	0
異常感覚 Dysaesthesia	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
前頭側頭型認知症 Frontotemporal dementia	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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神経痛 Neuralgia	0	0	0	0	1 (0.5%)	1 (0.3%)
末梢性ニューロパチー Neuropathy peripheral	0	0	0	1 (0.6%)	0	1 (0.3%)
傾眠 Somnolence	0	0	0	0	1 (0.5%)	1 (0.3%)
失語症 Aphasia	0	1 (0.5%)	1 (0.2%)	0	0	0
手根管症候群 Carpal tunnel syndrome	0	0	0	0	0	0
脳虚血 Cerebral ischaemia	0	0	0	0	0	0
頚髄神経根障害 Cervical radiculopathy	0	0	0	0	0	0
頚腕症候群 Cervicobrachial syndrome	0	0	0	0	0	0
昏睡 Coma	0	0	0	0	0	0
注意力障害 Disturbance in attention	0	0	0	0	0	0
体位性めまい Dizziness postural	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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脳症 Encephalopathy	0	0	0	0	0	0
蟻走感 Formication	0	0	0	0	0	0
前兆を伴う片頭痛 Migraine with aura	0	0	0	0	0	0
神経系障害 Nervous system disorder	1 (0.5%)	0	1 (0.2%)	0	0	0
末梢性運動ニューロパチー Peripheral motor neuropathy	1 (0.5%)	0	1 (0.2%)	0	0	0
ヘルペス後神経痛 Post herpetic neuralgia	0	0	0	0	0	0
血管性脳症 Vascular encephalopathy	0	0	0	0	0	0
脳血管発作 Cerebrovascular accident	0	0	0	0	0	0
味覚消失 Ageusia	0	0	0	0	1 (0.5%)	1 (0.3%)
運動失調 Ataxia	0	0	0	0	0	0
脳微小血管症 Cerebral microangiopathy	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
脱髄 Demyelination	0	0	0	0	1 (0.5%)	1 (0.3%)
意識消失 Loss of consciousness	0	0	0	0	0	0
末梢性感覚運動ニューロパチー Peripheral sensorimotor neuropathy	0	0	0	1 (0.6%)	0	1 (0.3%)
副鼻腔炎に伴う頭痛 Sinus headache	0	0	0	0	0	0
くも膜下出血 Subarachnoid haemorrhage	0	0	0	0	0	0
声帯麻痺 Vocal cord paralysis	0	0	0	0	0	0
一般・全身障害および投与部位の状態 General disorders and administration site conditions	27 (12.6%)	22 (10.2%)	49 (11.4%)	9 (5.3%)	23 (11.7%)	32 (8.7%)
疲労 Fatigue	14 (6.5%)	7 (3.2%)	21 (4.9%)	2 (1.2%)	12 (6.1%)	14 (3.8%)
発熱 Pyrexia	3 (1.4%)	2 (0.9%)	5 (1.2%)	2 (1.2%)	1 (0.5%)	3 (0.8%)
無力症 Asthenia	4 (1.9%)	3 (1.4%)	7 (1.6%)	3 (1.8%)	3 (1.5%)	6 (1.6%)
末梢性浮腫 Oedema peripheral	0	2 (0.9%)	2 (0.5%)	2 (1.2%)	1 (0.5%)	3 (0.8%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
胸痛 Chest pain	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
インフルエンザ様疾患 Influenza like illness	0	1 (0.5%)	1 (0.2%)	0	2 (1.0%)	2 (0.5%)
倦怠感 Malaise	2 (0.9%)	1 (0.5%)	3 (0.7%)	0	1 (0.5%)	1 (0.3%)
悪寒 Chills	0	0	0	0	1 (0.5%)	1 (0.3%)
末梢腫脹 Peripheral swelling	0	1 (0.5%)	1 (0.2%)	0	0	0
早期満腹 Early satiety	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
疼痛 Pain	0	1 (0.5%)	1 (0.2%)	0	0	0
浮腫 Oedema	0	0	0	0	0	0
胸部不快感 Chest discomfort	1 (0.5%)	2 (0.9%)	3 (0.7%)	0	1 (0.5%)	1 (0.3%)
非心臓性胸痛 Non-cardiac chest pain	0	0	0	0	0	0
乾燥症 Xerosis	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
顔面痛 Facial pain	0	0	0	0	0	0
重力性浮腫 Gravitational oedema	2 (0.9%)	0	2 (0.5%)	0	0	0
炎症 Inflammation	1 (0.5%)	0	1 (0.2%)	0	0	0
粘膜の炎症 Mucosal inflammation	1 (0.5%)	0	1 (0.2%)	0	0	0
死亡 Death	0	0	0	0	0	0
全身健康状態悪化 General physical health deterioration	0	0	0	0	0	0
全身性浮腫 Generalised oedema	0	0	0	0	0	0
カテーテル留置部位出血 Catheter site haemorrhage	0	1 (0.5%)	1 (0.2%)	0	0	0
捻髪音 Crepitations	0	0	0	0	0	0
異常感 Feeling abnormal	0	0	0	0	0	0
冷感 Feeling cold	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
歩行障害 Gait disturbance	1 (0.5%)	0	1 (0.2%)	0	0	0
硬結 Induration	0	0	0	0	0	0
粘膜出血 Mucosal haemorrhage	0	0	0	0	0	0
突然死 Sudden death	0	0	0	0	0	0
腫脹 Swelling	0	0	0	0	0	0
熱感 Feeling hot	0	0	0	1 (0.6%)	2 (1.0%)	3 (0.8%)
カテーテル留置部位疼痛 Catheter site pain	0	0	0	0	0	0
不快感 Discomfort	0	0	0	0	1 (0.5%)	1 (0.3%)
薬剤離脱症候群 Drug withdrawal syndrome	0	0	0	0	0	0
高熱 Hyperthermia	0	0	0	0	0	0
治癒不良 Impaired healing	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
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System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
注射部位出血 Injection site haemorrhage	0	0	0	0	0	0
口渇 Thirst	0	0	0	0	0	0
呼吸器、胸郭および縦隔障害 Respiratory, thoracic and mediastinal disorders	11 (5.1%)	11 (5.1%)	22 (5.1%)	8 (4.7%)	8 (4.1%)	16 (4.3%)
呼吸困難 Dyspnoea	4 (1.9%)	3 (1.4%)	7 (1.6%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
咳嗽 Cough	4 (1.9%)	1 (0.5%)	5 (1.2%)	4 (2.3%)	5 (2.5%)	9 (2.4%)
鼻出血 Epistaxis	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
労作性呼吸困難 Dyspnoea exertional	2 (0.9%)	2 (0.9%)	4 (0.9%)	0	0	0
口腔咽頭痛 Oropharyngeal pain	0	3 (1.4%)	3 (0.7%)	1 (0.6%)	0	1 (0.3%)
鼻漏 Rhinorrhoea	0	0	0	0	0	0
湿性咳嗽 Productive cough	0	0	0	0	0	0
低酸素症 Hypoxia	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
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System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
慢性閉塞性肺疾患 Chronic obstructive pulmonary disease	0	0	0	0	1 (0.5%)	1 (0.3%)
発声障害 Dysphonia	0	0	0	0	0	0
しゃっくり Hiccups	0	0	0	0	0	0
カタル Catarrh	0	0	0	0	0	0
ラ音 Rales	1 (0.5%)	0	1 (0.2%)	0	0	0
呼吸不全 Respiratory failure	0	0	0	0	0	0
喀血 Haemoptysis	0	0	0	0	0	0
鼻閉 Nasal congestion	0	0	0	0	0	0
肺水腫 Pulmonary oedema	0	0	0	0	0	0
上気道咳症候群 Upper-airway cough syndrome	0	0	0	0	0	0
急性呼吸不全 Acute respiratory failure	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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	治験薬との因果関係がある有害事象					
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System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
咽喉乾燥 Dry throat	0	0	0	0	0	0
発作性夜間呼吸困難 Dyspnoea paroxysmal nocturnal	0	0	0	0	0	0
肺浸潤 Lung infiltration	0	0	0	0	0	0
呼吸時疼痛 Painful respiration	0	0	0	0	0	0
咽頭潰瘍 Pharyngeal ulceration	0	0	0	0	0	0
胸膜痛 Pleuritic pain	0	0	0	0	0	0
誤嚥性肺炎 Pneumonia aspiration	0	0	0	0	0	0
肺線維症 Pulmonary fibrosis	0	0	0	0	0	0
肺肉芽腫 Pulmonary granuloma	0	0	0	0	0	0
肺出血 Pulmonary haemorrhage	0	0	0	0	0	0
肺高血圧症 Pulmonary hypertension	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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	治験薬との因果関係がある有害事象					
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System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
逆流性喉頭炎 Reflux laryngitis	0	0	0	0	0	0
睡眠時無呼吸症候群 Sleep apnoea syndrome	0	0	0	0	0	0
痰貯留 Sputum retention	0	1 (0.5%)	1 (0.2%)	0	0	0
咽喉刺激感 Throat irritation	0	0	0	0	0	0
咽喉絞扼感 Throat tightness	0	0	0	0	0	0
胸水 Pleural effusion	0	0	0	0	1 (0.5%)	1 (0.3%)
喘息 Asthma	0	0	0	0	0	0
肺塞栓症 Pulmonary embolism	0	0	0	1 (0.6%)	0	1 (0.3%)
気管支拡張症 Bronchiectasis	0	0	0	0	0	0
慢性気管支炎 Bronchitis chronic	0	0	0	0	0	0
肺気腫 Emphysema	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
喉頭の炎症 Laryngeal inflammation	0	0	0	0	0	0
肺硬化 Lung consolidation	0	0	0	0	0	0
肺障害 Lung disorder	0	0	0	0	0	0
起坐呼吸 Orthopnoea	0	0	0	0	0	0
胸膜炎 Pleurisy	0	0	0	0	0	0
肺腫瘤 Pulmonary mass	0	0	0	0	0	0
副鼻腔痛 Sinus pain	0	0	0	1 (0.6%)	0	1 (0.3%)
喘鳴 Wheezing	0	0	0	0	0	0
筋骨格系および結合組織障害 Musculoskeletal and connective tissue disorders	15 (7.0%)	19 (8.8%)	34 (7.9%)	3 (1.8%)	13 (6.6%)	16 (4.3%)
四肢痛 Pain in extremity	3 (1.4%)	6 (2.8%)	9 (2.1%)	0	4 (2.0%)	4 (1.1%)
関節痛 Arthralgia	4 (1.9%)	3 (1.4%)	7 (1.6%)	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
背部痛 Back pain	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
筋痙縮 Muscle spasms	4 (1.9%)	5 (2.3%)	9 (2.1%)	0	2 (1.0%)	2 (0.5%)
骨痛 Bone pain	0	3 (1.4%)	3 (0.7%)	1 (0.6%)	4 (2.0%)	5 (1.4%)
筋骨格痛 Musculoskeletal pain	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
筋肉痛 Myalgia	2 (0.9%)	2 (0.9%)	4 (0.9%)	0	3 (1.5%)	3 (0.8%)
筋力低下 Muscular weakness	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
鼠径部痛 Groin pain	0	0	0	0	0	0
筋骨格系胸痛 Musculoskeletal chest pain	0	0	0	0	0	0
関節炎 Arthritis	0	1 (0.5%)	1 (0.2%)	0	0	0
脊椎痛 Spinal pain	1 (0.5%)	0	1 (0.2%)	0	0	0
側腹部痛 Flank pain	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
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筋肉疲労 Muscle fatigue	0	0	0	0	0	0
顎痛 Pain in jaw	0	0	0	0	0	0
変形性関節症 Osteoarthritis	0	0	0	0	0	0
腱炎 Tendonitis	0	0	0	0	0	0
滑液包炎 Bursitis	0	0	0	0	0	0
筋骨格硬直 Musculoskeletal stiffness	0	0	0	0	0	0
滑液貯留 Bursal fluid accumulation	0	0	0	0	0	0
足変形 Foot deformity	0	0	0	0	0	0
痛風性関節炎 Gouty arthritis	0	0	0	0	0	0
骨減少症 Osteopenia	0	0	0	0	0	0
シェーグレン症候群 Sjogren's syndrome	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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変形性脊椎症 Spinal osteoarthritis	0	0	0	0	0	0
開口障害 Trismus	0	0	0	0	0	0
頚部痛 Neck pain	0	0	0	0	0	0
反応性関節炎 Arthritis reactive	0	0	0	0	0	0
骨病変 Bone lesion	0	0	0	0	0	0
胸壁血腫 Chest wall haematoma	0	0	0	1 (0.6%)	0	1 (0.3%)
筋膜炎 Fasciitis	0	0	0	0	0	0
関節滲出液 Joint effusion	0	0	0	0	0	0
四肢不快感 Limb discomfort	0	0	0	0	1 (0.5%)	1 (0.3%)
骨溶解 Osteolysis	0	0	0	0	0	0
骨硬化症 Osteosclerosis	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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関節周囲炎 Periarthritis	0	0	0	0	1 (0.5%)	1 (0.3%)
腱痛 Tendon pain	0	0	0	0	0	0
皮膚および皮下組織障害 Skin and subcutaneous tissue disorders	19 (8.9%)	9 (4.2%)	28 (6.5%)	11 (6.4%)	21 (10.7%)	32 (8.7%)
そう痒症 Pruritus	3 (1.4%)	1 (0.5%)	4 (0.9%)	1 (0.6%)	3 (1.5%)	4 (1.1%)
寝汗 Night sweats	2 (0.9%)	0	2 (0.5%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
発疹 Rash	4 (1.9%)	0	4 (0.9%)	1 (0.6%)	7 (3.6%)	8 (2.2%)
紅斑 Erythema	5 (2.3%)	0	5 (1.2%)	1 (0.6%)	0	1 (0.3%)
斑状出血 Ecchymosis	2 (0.9%)	1 (0.5%)	3 (0.7%)	0	0	0
脱毛症 Alopecia	0	0	0	1 (0.6%)	0	1 (0.3%)
皮膚潰瘍 Skin ulcer	1 (0.5%)	0	1 (0.2%)	0	0	0
斑状丘疹状皮疹 Rash maculo-papular	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
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	治験薬との因果関係がある有害事象					
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点状出血 Petechiae	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	2 (1.0%)	2 (0.5%)
多汗症 Hyperhidrosis	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
皮膚病変 Skin lesion	0	0	0	0	0	0
皮膚乾燥 Dry skin	1 (0.5%)	0	1 (0.2%)	0	0	0
紅斑性皮疹 Rash erythematous	1 (0.5%)	0	1 (0.2%)	0	0	0
接触皮膚炎 Dermatitis contact	0	0	0	0	0	0
湿疹 Eczema	0	0	0	0	0	0
過角化 Hyperkeratosis	0	0	0	0	0	0
皮膚疼痛 Pain of skin	0	2 (0.9%)	2 (0.5%)	0	0	0
皮膚出血 Skin haemorrhage	0	0	0	0	0	0
毛細血管拡張症 Telangiectasia	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
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表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
全身性そう痒症 Pruritus generalised	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
光線角化症 Actinic keratosis	0	0	0	0	0	0
アレルギー性皮膚炎 Dermatitis allergic	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
全身性皮疹 Rash generalised	1 (0.5%)	0	1 (0.2%)	0	0	0
斑状皮疹 Rash macular	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
丘疹性皮疹 Rash papular	0	0	0	0	2 (1.0%)	2 (0.5%)
薬疹 Drug eruption	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
嵌入爪 Ingrowing nail	0	0	0	0	0	0
乾癬 Psoriasis	0	0	0	0	0	0
紫斑 Purpura	0	0	0	1 (0.6%)	0	1 (0.3%)
水原性そう痒症 Aquagenic pruritus	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
水疱 Blister	0	0	0	0	0	0
血性水疱 Blood blister	0	0	0	0	0	0
紅色症 Erythrosis	0	0	0	0	0	0
間擦疹 Intertrigo	0	0	0	0	0	0
手掌・足底発赤知覚不全症候群 Palmar-plantar erythrodysaesthesia syndrome	0	1 (0.5%)	1 (0.2%)	0	0	0
口囲皮膚炎 Perioral dermatitis	0	0	0	0	0	0
毛孔性皮疹 Rash follicular	1 (0.5%)	0	1 (0.2%)	0	0	0
そう痒性皮疹 Rash pruritic	0	1 (0.5%)	1 (0.2%)	0	0	0
脂腺過形成 Sebaceous hyperplasia	0	0	0	0	0	0
中毒性皮疹 Toxic skin eruption	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
冷汗 Cold sweat	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
皮膚嚢腫 Dermal cyst	0	0	0	0	0	0
全身性剥脱性皮膚炎 Dermatitis exfoliative generalised	0	0	0	0	0	0
皮膚症 Dermatosis	0	0	0	1 (0.6%)	0	1 (0.3%)
酒さ Rosacea	0	0	0	0	0	0
皮膚剥脱 Skin exfoliation	0	0	0	0	0	0
皮膚脆弱性 Skin fragility	0	0	0	1 (0.6%)	0	1 (0.3%)
顔面腫脹 Swelling face	0	0	0	0	1 (0.5%)	1 (0.3%)
蕁麻疹 Urticaria	0	0	0	0	0	0
代謝および栄養障害 Metabolism and nutrition disorders	13 (6.1%)	17 (7.9%)	30 (7.0%)	11 (6.4%)	13 (6.6%)	24 (6.5%)
食欲減退 Decreased appetite	3 (1.4%)	7 (3.2%)	10 (2.3%)	2 (1.2%)	5 (2.5%)	7 (1.9%)
ビタミンＢ１欠乏 Vitamin B1 deficiency	5 (2.3%)	5 (2.3%)	10 (2.3%)	4 (2.3%)	2 (1.0%)	6 (1.6%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
高尿酸血症 Hyperuricaemia	2 (0.9%)	3 (1.4%)	5 (1.2%)	2 (1.2%)	1 (0.5%)	3 (0.8%)
高カリウム血症 Hyperkalaemia	3 (1.4%)	0	3 (0.7%)	0	0	0
低カリウム血症 Hypokalaemia	0	0	0	0	0	0
低マグネシウム血症 Hypomagnesaemia	0	0	0	0	0	0
低カルシウム血症 Hypocalcaemia	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
脱水 Dehydration	0	0	0	0	0	0
ビタミンD欠乏 Vitamin D deficiency	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
痛風 Gout	0	0	0	0	0	0
糖尿病 Diabetes mellitus	0	0	0	0	1 (0.5%)	1 (0.3%)
低ナトリウム血症 Hyponatraemia	0	0	0	0	0	0
低血糖 Hypoglycaemia	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
高血糖 Hyperglycaemia	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
ビタミンB群欠乏 Vitamin B complex deficiency	1 (0.5%)	0	1 (0.2%)	0	0	0
鉄欠乏 Iron deficiency	0	0	0	0	0	0
鉄過剰 Iron overload	0	0	0	0	0	0
体液貯留 Fluid retention	0	0	0	1 (0.6%)	0	1 (0.3%)
高カルシウム血症 Hypercalcaemia	0	0	0	0	0	0
高マグネシウム血症 Hypermagnesaemia	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
低アルブミン血症 Hypoalbuminaemia	0	0	0	0	0	0
低リン酸血症 Hypophosphataemia	0	0	0	0	0	0
葉酸欠乏 Folate deficiency	0	1 (0.5%)	1 (0.2%)	0	0	0
ヘモジデリン沈着症 Haemosiderosis	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
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System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
血液量増加症 Hypervolaemia	0	0	0	0	0	0
栄養障害 Malnutrition	0	0	0	0	0	0
多飲症 Polydipsia	0	1 (0.5%)	1 (0.2%)	0	0	0
腫瘍崩壊症候群 Tumour lysis syndrome	0	0	0	0	0	0
ビタミンK欠乏 Vitamin K deficiency	0	0	0	0	0	0
高トリグリセリド血症 Hypertriglyceridaemia	0	0	0	0	0	0
異常体重減少 Abnormal loss of weight	0	0	0	0	0	0
電解質失調 Electrolyte imbalance	0	0	0	0	0	0
高コレステロール血症 Hypercholesterolaemia	0	0	0	0	0	0
高フェリチン血症 Hyperferritinaemia	0	0	0	0	0	0
ビタミンＢ６欠乏 Vitamin B6 deficiency	0	0	0	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
血管障害 Vascular disorders	31 (14.5%)	9 (4.2%)	40 (9.3%)	7 (4.1%)	9 (4.6%)	16 (4.3%)
高血圧 Hypertension	3 (1.4%)	3 (1.4%)	6 (1.4%)	1 (0.6%)	3 (1.5%)	4 (1.1%)
低血圧 Hypotension	14 (6.5%)	0	14 (3.3%)	0	2 (1.0%)	2 (0.5%)
潮紅 Flushing	13 (6.1%)	0	13 (3.0%)	1 (0.6%)	3 (1.5%)	4 (1.1%)
血腫 Haematoma	2 (0.9%)	3 (1.4%)	5 (1.2%)	2 (1.2%)	0	2 (0.5%)
ほてり Hot flush	0	3 (1.4%)	3 (0.7%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
静脈炎 Phlebitis	0	0	0	0	0	0
出血 Haemorrhage	0	0	0	0	0	0
起立性低血圧 Orthostatic hypotension	0	0	0	1 (0.6%)	0	1 (0.3%)
末梢動脈閉塞性疾患 Peripheral arterial occlusive disease	0	0	0	0	0	0
表在性血栓性静脈炎 Thrombophlebitis superficial	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
四肢静脈血栓症 Venous thrombosis limb	0	0	0	0	0	0
大動脈硬化症 Aortic arteriosclerosis	0	0	0	0	0	0
大動脈解離 Aortic dissection	0	0	0	0	0	0
大動脈血栓症 Aortic thrombosis	1 (0.5%)	0	1 (0.2%)	0	0	0
本態性高血圧症 Essential hypertension	0	0	0	0	0	0
高血圧クリーゼ Hypertensive crisis	0	0	0	0	0	0
末梢冷感 Peripheral coldness	1 (0.5%)	0	1 (0.2%)	0	0	0
末梢性虚血 Peripheral ischaemia	0	0	0	0	0	0
末梢静脈疾患 Peripheral venous disease	0	0	0	0	0	0
静脈穿刺不良 Poor venous access	0	0	0	0	0	0
血栓性静脈炎 Thrombophlebitis	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
大動脈狭窄 Aortic stenosis	0	0	0	0	0	0
動脈硬化症 Arteriosclerosis	0	0	0	0	0	0
末梢循環不良 Poor peripheral circulation	0	0	0	0	0	0
静脈瘤 Varicose vein	0	0	0	0	0	0
血管拡張 Vasodilatation	0	0	0	1 (0.6%)	0	1 (0.3%)
臨床検査 Investigations	16 (7.5%)	18 (8.3%)	34 (7.9%)	14 (8.2%)	15 (7.6%)	29 (7.9%)
アラニンアミノトランスフェラーゼ増加 Alanine aminotransferase increased	7 (3.3%)	4 (1.9%)	11 (2.6%)	1 (0.6%)	4 (2.0%)	5 (1.4%)
γ－グルタミルトランスフェラーゼ増加 Gamma-glutamyltransferase increased	2 (0.9%)	5 (2.3%)	7 (1.6%)	2 (1.2%)	0	2 (0.5%)
アスパラギン酸アミノトランスフェラーゼ増加 Aspartate aminotransferase increased	6 (2.8%)	3 (1.4%)	9 (2.1%)	0	3 (1.5%)	3 (0.8%)
血中クレアチニン増加 Blood creatinine increased	4 (1.9%)	1 (0.5%)	5 (1.2%)	3 (1.8%)	5 (2.5%)	8 (2.2%)
血中アルカリホスファターゼ増加 Blood alkaline phosphatase increased	2 (0.9%)	4 (1.9%)	6 (1.4%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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体重減少 Weight decreased	0	0	0	1 (0.6%)	0	1 (0.3%)
体重増加 Weight increased	0	3 (1.4%)	3 (0.7%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
血中ビリルビン増加 Blood bilirubin increased	1 (0.5%)	2 (0.9%)	3 (0.7%)	3 (1.8%)	0	3 (0.8%)
心電図ＱＴ延長 Electrocardiogram QT prolonged	1 (0.5%)	2 (0.9%)	3 (0.7%)	0	0	0
活性化部分トロンボプラスチン時間延長 Activated partial thromboplastin time prolonged	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
心雑音 Cardiac murmur	0	0	0	0	0	0
腎クレアチニン・クリアランス減少 Creatinine renal clearance decreased	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
総蛋白増加 Protein total increased	0	0	0	0	0	0
リパーゼ増加 Lipase increased	1 (0.5%)	0	1 (0.2%)	0	0	0
トランスアミナーゼ上昇 Transaminases increased	0	1 (0.5%)	1 (0.2%)	0	0	0
国際標準比増加 International normalised ratio increased	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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血中鉄減少 Blood iron decreased	0	0	0	0	0	0
ヘマトクリット増加 Haematocrit increased	0	0	0	0	0	0
出血時間延長 Bleeding time prolonged	0	1 (0.5%)	1 (0.2%)	0	0	0
血中重炭酸塩減少 Blood bicarbonate decreased	1 (0.5%)	0	1 (0.2%)	0	0	0
血中クレアチンホスホキナーゼ増加 Blood creatine phosphokinase increased	0	0	0	0	0	0
血中乳酸増加 Blood lactic acid increased	0	0	0	0	0	0
体温上昇 Body temperature increased	0	0	0	0	0	0
心電図ＳＴ部分下降 Electrocardiogram ST segment depression	0	0	0	0	0	0
心電図異常 Electrocardiogram abnormal	0	0	0	0	0	0
ヘモグロビン増加 Haemoglobin increased	0	0	0	0	0	0
ヘプシジン減少 Hepcidin decreased	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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リンパ節触知 Lymph node palpable	0	0	0	0	0	0
好中球数増加 Neutrophil count increased	0	0	0	0	0	0
脈拍欠損 Pulse absent	0	0	0	0	0	0
血中乳酸脱水素酵素増加 Blood lactate dehydrogenase increased	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
プロトロンビン時間延長 Prothrombin time prolonged	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
抗リン脂質抗体陽性 Antiphospholipid antibodies positive	0	0	0	0	0	0
血中葉酸減少 Blood folate decreased	0	0	0	0	0	0
血中尿素増加 Blood urea increased	0	0	0	0	0	0
胸部X線異常 Chest X-ray abnormal	0	0	0	0	0	0
骨盤コンピュータ断層撮影異常 Computerised tomogram pelvis abnormal	0	0	0	0	0	0
肝酵素上昇 Hepatic enzyme increased	0	0	0	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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肝機能検査異常 Liver function test abnormal	0	0	0	0	0	0
平均赤血球容積減少 Mean cell volume decreased	0	0	0	0	0	0
血清フェリチン増加 Serum ferritin increased	0	0	0	0	0	0
傷害、中毒および処置合併症 Injury, poisoning and procedural complications	4 (1.9%)	5 (2.3%)	9 (2.1%)	1 (0.6%)	4 (2.0%)	5 (1.4%)
挫傷 Contusion	3 (1.4%)	4 (1.9%)	7 (1.6%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
転倒 Fall	0	0	0	0	1 (0.5%)	1 (0.3%)
皮膚擦過傷 Skin abrasion	0	0	0	0	0	0
皮膚裂傷 Skin laceration	0	0	0	0	0	0
四肢損傷 Limb injury	0	0	0	0	0	0
処置による疼痛 Procedural pain	0	0	0	0	0	0
処置後出血 Post procedural haemorrhage	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
創傷 Wound	0	0	0	0	0	0
靱帯捻挫 Ligament sprain	0	0	0	0	0	0
眼窩周囲血腫 Periorbital haematoma	0	0	0	0	0	0
頭部損傷 Head injury	0	0	0	0	0	0
過量投与 Overdose	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
膝蓋骨骨折 Patella fracture	0	0	0	0	0	0
腱断裂 Tendon rupture	0	0	0	0	0	0
腹部損傷 Abdominal injury	0	0	0	0	0	0
節足動物咬傷 Arthropod bite	0	0	0	0	0	0
眼挫傷 Eye contusion	0	0	0	0	0	0
大腿骨骨折 Femur fracture	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
手骨折 Hand fracture	0	0	0	0	0	0
低圧症 Hypobarism	0	0	0	0	0	0
靱帯断裂 Ligament rupture	0	0	0	0	0	0
四肢圧挫損傷 Limb crushing injury	0	0	0	0	0	0
口腔内損傷 Mouth injury	0	0	0	0	0	0
処置後合併症 Post procedural complication	0	0	0	0	0	0
処置後挫傷 Post procedural contusion	0	0	0	0	0	0
術後譫妄 Postoperative delirium	0	0	0	0	0	0
肋骨骨折 Rib fracture	0	0	0	0	0	0
引っかき傷 Scratch	0	0	0	0	0	0
漿液腫 Seroma	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
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System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
脊椎圧迫骨折 Spinal compression fracture	0	0	0	0	0	0
輸血反応 Transfusion reaction	0	0	0	0	0	0
輸血関連合併症 Transfusion related complication	0	0	0	0	0	0
外傷性血腫 Traumatic haematoma	1 (0.5%)	0	1 (0.2%)	0	0	0
創合併症 Wound complication	0	0	0	0	0	0
足骨折 Foot fracture	0	0	0	0	0	0
吻合部狭窄 Anastomotic stenosis	0	0	0	0	0	0
顔面骨骨折 Facial bones fracture	0	0	0	0	0	0
筋損傷 Muscle injury	0	0	0	0	0	0
処置による悪心 Procedural nausea	0	0	0	0	0	0
骨格損傷 Skeletal injury	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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外傷性血胸 Traumatic haemothorax	0	0	0	0	0	0
腎および尿路障害 Renal and urinary disorders	5 (2.3%)	2 (0.9%)	7 (1.6%)	5 (2.9%)	8 (4.1%)	13 (3.5%)
腎不全 Renal failure	1 (0.5%)	2 (0.9%)	3 (0.7%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
排尿困難 Dysuria	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
頻尿 Pollakiuria	0	0	0	0	1 (0.5%)	1 (0.3%)
急性腎障害 Acute kidney injury	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
血尿 Haematuria	0	0	0	0	1 (0.5%)	1 (0.3%)
腎結石症 Nephrolithiasis	1 (0.5%)	0	1 (0.2%)	0	0	0
腎仙痛 Renal colic	0	0	0	1 (0.6%)	0	1 (0.3%)
慢性腎臓病 Chronic kidney disease	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
腎機能障害 Renal impairment	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

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	治験薬との因果関係がある有害事象					
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System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
夜間頻尿 Nocturia	0	0	0	0	1 (0.5%)	1 (0.3%)
尿失禁 Urinary incontinence	0	0	0	0	0	0
着色尿 Chromaturia	0	0	0	0	0	0
多尿 Polyuria	0	0	0	0	0	0
蛋白尿 Proteinuria	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
白血球尿 Leukocyturia	0	0	0	0	0	0
出血性膀胱炎 Cystitis haemorrhagic	0	0	0	0	0	0
中毒性ネフロパシー Nephropathy toxic	0	0	0	0	0	0
腎動脈狭窄症 Renal artery stenosis	0	0	0	0	0	0
膀胱ポリープ Urinary bladder polyp	0	0	0	0	0	0
尿閉 Urinary retention	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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	治験薬との因果関係がある有害事象					
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尿路痛 Urinary tract pain	0	0	0	0	0	0
尿管結石症 Ureterolithiasis	0	0	0	0	0	0
眼障害 Eye disorders	15 (7.0%)	7 (3.2%)	22 (5.1%)	6 (3.5%)	11 (5.6%)	17 (4.6%)
霧視 Vision blurred	5 (2.3%)	2 (0.9%)	7 (1.6%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
皮質白内障 Cataract cortical	1 (0.5%)	2 (0.9%)	3 (0.7%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
核性白内障 Cataract nuclear	3 (1.4%)	0	3 (0.7%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
ドライアイ Dry eye	0	1 (0.5%)	1 (0.2%)	0	2 (1.0%)	2 (0.5%)
視力低下 Visual acuity reduced	1 (0.5%)	0	1 (0.2%)	0	2 (1.0%)	2 (0.5%)
嚢下白内障 Cataract subcapsular	0	0	0	1 (0.6%)	0	1 (0.3%)
眼痛 Eye pain	0	0	0	1 (0.6%)	0	1 (0.3%)
流涙増加 Lacrimation increased	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)

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	治験薬との因果関係がある有害事象					
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System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
視力障害 Visual impairment	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
白内障 Cataract	1 (0.5%)	0	1 (0.2%)	0	0	0
角膜炎 Keratitis	0	0	0	0	0	0
複視 Diplopia	0	0	0	0	0	0
眼出血 Eye haemorrhage	0	1 (0.5%)	1 (0.2%)	0	0	0
眼刺激 Eye irritation	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
眼瞼浮腫 Eyelid oedema	0	0	0	0	1 (0.5%)	1 (0.3%)
黄斑変性 Macular degeneration	1 (0.5%)	0	1 (0.2%)	0	0	0
網膜出血 Retinal haemorrhage	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
結膜上皮侵入 Conjunctivalisation	0	0	0	0	0	0
眼球浮腫 Eye oedema	0	1 (0.5%)	1 (0.2%)	0	0	0

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	治験薬との因果関係がある有害事象					
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眼部腫脹 Eye swelling	0	0	0	0	0	0
星状硝子体症 Hyalosis asteroid	0	0	0	0	0	0
眼窩浮腫 Orbital oedema	1 (0.5%)	0	1 (0.2%)	0	0	0
眼窩周囲浮腫 Periorbital oedema	0	0	0	0	0	0
光視症 Photopsia	1 (0.5%)	0	1 (0.2%)	0	0	0
眼瞼腫脹 Swelling of eyelid	0	0	0	0	0	0
硝子体浮遊物 Vitreous floaters	1 (0.5%)	0	1 (0.2%)	0	0	0
結膜出血 Conjunctival haemorrhage	0	0	0	0	0	0
糖尿病網膜症 Diabetic retinopathy	0	0	0	0	1 (0.5%)	1 (0.3%)
眼充血 Ocular hyperaemia	0	0	0	0	1 (0.5%)	1 (0.3%)
眼瞼炎 Blepharitis	0	0	0	0	0	0

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眼瞼下垂 Eyelid ptosis	0	0	0	0	0	0
緑内障 Glaucoma	0	0	0	0	0	0
睫毛の成長 Growth of eyelashes	0	0	0	0	1 (0.5%)	1 (0.3%)
マイボーム腺機能不全 Meibomian gland dysfunction	0	0	0	0	1 (0.5%)	1 (0.3%)
網膜瘢痕 Retinal scar	0	0	0	0	0	0
硝子体変性 Vitreous degeneration	0	0	0	0	0	0
精神障害 Psychiatric disorders	1 (0.5%)	4 (1.9%)	5 (1.2%)	2 (1.2%)	1 (0.5%)	3 (0.8%)
不安 Anxiety	0	0	0	0	0	0
不眠症 Insomnia	0	3 (1.4%)	3 (0.7%)	1 (0.6%)	0	1 (0.3%)
うつ病 Depression	0	0	0	0	0	0
錯乱状態 Confusional state	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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精神状態変化 Mental status changes	0	0	0	0	1 (0.5%)	1 (0.3%)
神経過敏 Nervousness	1 (0.5%)	0	1 (0.2%)	0	0	0
激越 Agitation	0	0	0	0	0	0
不安障害 Anxiety disorder	0	0	0	0	0	0
精神緩慢 Bradyphrenia	0	1 (0.5%)	1 (0.2%)	0	0	0
幻覚 Hallucination	0	0	0	0	0	0
初期不眠症 Initial insomnia	0	0	0	0	0	0
悪夢 Nightmare	0	1 (0.5%)	1 (0.2%)	0	0	0
リビドー減退 Libido decreased	0	0	0	0	0	0
感情障害 Affective disorder	0	0	0	0	0	0
抑うつ気分 Depressed mood	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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失見当識 Disorientation	0	0	0	1 (0.6%)	0	1 (0.3%)
睡眠障害 Sleep disorder	0	0	0	0	0	0
自殺念慮 Suicidal ideation	0	0	0	0	0	0
心臓障害 Cardiac disorders	5 (2.3%)	3 (1.4%)	8 (1.9%)	1 (0.6%)	3 (1.5%)	4 (1.1%)
心房細動 Atrial fibrillation	2 (0.9%)	0	2 (0.5%)	0	0	0
狭心症 Angina pectoris	0	0	0	0	1 (0.5%)	1 (0.3%)
心不全 Cardiac failure	0	0	0	0	0	0
動悸 Palpitations	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
頻脈 Tachycardia	0	0	0	0	0	0
急性心筋梗塞 Acute myocardial infarction	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
うっ血性心不全 Cardiac failure congestive	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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急性心不全 Cardiac failure acute	0	0	0	0	0	0
心拡大 Cardiomegaly	0	0	0	0	0	0
左室不全 Left ventricular failure	0	0	0	0	0	0
心房粗動 Atrial flutter	0	0	0	0	0	0
洞性徐脈 Sinus bradycardia	0	1 (0.5%)	1 (0.2%)	0	0	0
不安定狭心症 Angina unstable	0	0	0	0	0	0
完全房室ブロック Atrioventricular block complete	1 (0.5%)	0	1 (0.2%)	0	0	0
徐脈 Bradycardia	0	0	0	0	0	0
期外収縮 Extrasystoles	1 (0.5%)	0	1 (0.2%)	0	0	0
高血圧性心疾患 Hypertensive heart disease	0	1 (0.5%)	1 (0.2%)	0	0	0
左室機能不全 Left ventricular dysfunction	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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僧帽弁閉鎖不全症 Mitral valve incompetence	0	0	0	0	0	0
心嚢液貯留 Pericardial effusion	1 (0.5%)	0	1 (0.2%)	0	0	0
上室性頻脈 Supraventricular tachycardia	0	0	0	0	0	0
三尖弁閉鎖不全症 Tricuspid valve incompetence	0	0	0	0	0	0
第一度房室ブロック Atrioventricular block first degree	0	0	0	1 (0.6%)	0	1 (0.3%)
心停止 Cardiac arrest	0	0	0	0	0	0
慢性心不全 Cardiac failure chronic	0	0	0	0	0	0
心臓弁膜疾患 Cardiac valve disease	0	0	0	0	0	0
拡張機能障害 Diastolic dysfunction	0	0	0	0	1 (0.5%)	1 (0.3%)
心筋虚血 Myocardial ischaemia	0	0	0	0	0	0
耳および迷路障害 Ear and labyrinth disorders	7 (3.3%)	2 (0.9%)	9 (2.1%)	0	2 (1.0%)	2 (0.5%)

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
回転性めまい Vertigo	5 (2.3%)	0	5 (1.2%)	0	2 (1.0%)	2 (0.5%)
耳鳴 Tinnitus	2 (0.9%)	2 (0.9%)	4 (0.9%)	0	0	0
耳痛 Ear pain	0	0	0	0	0	0
耳不快感 Ear discomfort	0	0	0	0	0	0
聴力低下 Hypoacusis	0	0	0	0	0	0
耳閉 Ear congestion	0	0	0	0	0	0
難聴 Deafness	0	0	0	0	0	0
耳出血 Ear haemorrhage	0	0	0	0	0	0
乗物酔い Motion sickness	0	0	0	0	0	0
突発性難聴 Sudden hearing loss	0	0	0	0	0	0
鼓膜穿孔 Tympanic membrane perforation	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
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） Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
皮膚有棘細胞癌 Squamous cell carcinoma of skin	0	0	0	0	0	0
基底細胞癌 Basal cell carcinoma	0	0	0	0	0	0
急性骨髄性白血病 Acute myeloid leukaemia	0	0	0	0	0	0
膵管内乳頭粘液性腫瘍 Intraductal papillary mucinous neoplasm	0	0	0	0	0	0
骨髄線維症 Myelofibrosis	0	0	0	0	1 (0.5%)	1 (0.3%)
悪性黒色腫 Malignant melanoma	0	0	0	0	0	0
メラノサイト性母斑 Melanocytic naevus	0	0	0	0	0	0
膀胱移行上皮癌 Bladder transitional cell carcinoma	0	0	0	0	0	0
再発マントル細胞リンパ腫 Mantle cell lymphoma recurrent	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
鼻の良性新生物 Nasal neoplasm benign	0	0	0	0	0	0
食道扁平上皮癌 Oesophageal squamous cell carcinoma	0	0	0	0	0	0
卵巣明細胞癌 Ovarian clear cell carcinoma	0	0	0	0	0	0
再発前立腺癌 Prostate cancer recurrent	0	0	0	0	0	0
脾臓辺縁帯リンパ腫 Splenic marginal zone lymphoma	0	0	0	0	0	0
急性骨髄性白血病への転化 Transformation to acute myeloid leukaemia	0	0	0	0	0	0
子宮癌 Uterine cancer	0	0	0	0	0	0
脂漏性角化症 Seborrhoeic keratosis	0	0	0	0	0	0
子宮平滑筋腫 Uterine leiomyoma	0	0	0	0	0	0
乳腺線維腺腫 Fibroadenoma of breast	0	0	0	0	0	0
骨血管腫 Haemangioma of bone	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
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Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
白赤芽球症 Leukoerythroblastosis	0	0	0	0	0	0
遠隔転移を伴う扁平上皮癌 Metastatic squamous cell carcinoma	0	0	0	0	0	0
前立腺癌 Prostate cancer	0	0	0	0	0	0
直腸癌 Rectal cancer	0	0	0	1 (0.6%)	0	1 (0.3%)
鼻副鼻腔乳頭腫 Sinonasal papilloma	0	0	0	0	0	0
生殖系および乳房障害 Reproductive system and breast disorders	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
良性前立腺肥大症 Benign prostatic hyperplasia	0	0	0	0	0	0
腟出血 Vaginal haemorrhage	0	0	0	0	0	0
腟分泌物 Vaginal discharge	0	0	0	0	1 (0.5%)	1 (0.3%)
月経過多 Menorrhagia	0	0	0	0	0	0
会陰痛 Perineal pain	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
陰嚢浮腫 Scrotal oedema	0	0	0	0	0	0
自発陰茎勃起 Spontaneous penile erection	0	0	0	0	0	0
腟ポリープ Vaginal polyp	0	0	0	0	0	0
外陰腟の炎症 Vulvovaginal inflammation	0	0	0	0	0	0
外陰腟痛 Vulvovaginal pain	0	0	0	0	0	0
精巣上体嚢胞 Epididymal cyst	0	0	0	0	0	0
子宮頚部びらん Uterine cervical erosion	0	0	0	0	0	0
腟脱 Vaginal prolapse	0	0	0	0	0	0
肝胆道系障害 Hepatobiliary disorders	0	1 (0.5%)	1 (0.2%)	2 (1.2%)	1 (0.5%)	3 (0.8%)
胆道仙痛 Biliary colic	0	0	0	0	0	0
胆石症 Cholelithiasis	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
肝機能異常 Hepatic function abnormal	0	1 (0.5%)	1 (0.2%)	0	0	0
肝細胞損傷 Hepatocellular injury	0	0	0	0	0	0
過形成性胆嚢症 Hyperplastic cholecystopathy	0	0	0	0	0	0
黄疸眼 Ocular icterus	0	0	0	1 (0.6%)	0	1 (0.3%)
急性胆嚢炎 Cholecystitis acute	0	0	0	0	0	0
胆汁うっ滞 Cholestasis	0	0	0	1 (0.6%)	0	1 (0.3%)
肝硬変 Hepatic cirrhosis	0	0	0	0	0	0
肝不全 Hepatic failure	0	0	0	0	1 (0.5%)	1 (0.3%)
門脈圧亢進症 Portal hypertension	0	0	0	0	0	0
先天性、家族性および遺伝性障害 Congenital, familial and genetic disorders	0	0	0	0	0	0
ジルベール症候群 Gilbert's syndrome	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-1 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	治験薬との因果関係がある有害事象					
	DB Phase			OL Phase (Week 24 Onward)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
陰嚢水瘤 Hydrocele	0	0	0	0	0	0
包茎 Phimosis	0	0	0	0	0	0
内分泌障害 Endocrine disorders	0	0	0	0	0	0
低アルドステロン症 Hypoaldosteronism	0	0	0	0	0	0
甲状腺機能低下症 Hypothyroidism	0	0	0	0	0	0
甲状腺腫瘤 Thyroid mass	0	0	0	0	0	0
外科および内科処置 Surgical and medical procedures	0	0	0	0	0	0
抜歯 Tooth extraction	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSRTable 15.11.2.2.1.1, Table 15.11.2.3.1.3
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_DB_table_ae.sas 2.003.469.900

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
有害事象発現例数 ANY EVENT	157 (91.8%)	190 (96.4%)	347 (94.3%)	397 (96.6%)
感染症および寄生虫症 Infections and infestations	88 (51.5%)	111 (56.3%)	199 (54.1%)	237 (57.7%)
尿路感染 Urinary tract infection	20 (11.7%)	23 (11.7%)	43 (11.7%)	49 (11.9%)
肺炎 Pneumonia	20 (11.7%)	19 (9.6%)	39 (10.6%)	43 (10.5%)
上気道感染 Upper respiratory tract infection	18 (10.5%)	18 (9.1%)	36 (9.8%)	47 (11.4%)
上咽頭炎 Nasopharyngitis	7 (4.1%)	14 (7.1%)	21 (5.7%)	28 (6.8%)
気管支炎 Bronchitis	8 (4.7%)	12 (6.1%)	20 (5.4%)	22 (5.4%)
胃腸炎 Gastroenteritis	5 (2.9%)	8 (4.1%)	13 (3.5%)	15 (3.6%)
気道感染 Respiratory tract infection	4 (2.3%)	9 (4.6%)	13 (3.5%)	15 (3.6%)
帯状疱疹 Herpes zoster	8 (4.7%)	3 (1.5%)	11 (3.0%)	14 (3.4%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
膀胱炎 Cystitis	6 (3.5%)	4 (2.0%)	10 (2.7%)	14 (3.4%)
口腔ヘルペス Oral herpes	4 (2.3%)	6 (3.0%)	10 (2.7%)	13 (3.2%)
インフルエンザ Influenza	2 (1.2%)	8 (4.1%)	10 (2.7%)	11 (2.7%)
副鼻腔炎 Sinusitis	3 (1.8%)	7 (3.6%)	10 (2.7%)	10 (2.4%)
下気道感染 Lower respiratory tract infection	4 (2.3%)	4 (2.0%)	8 (2.2%)	11 (2.7%)
敗血症 Sepsis	6 (3.5%)	2 (1.0%)	8 (2.2%)	10 (2.4%)
蜂巣炎 Cellulitis	4 (2.3%)	2 (1.0%)	6 (1.6%)	9 (2.2%)
大腸菌性尿路感染 Escherichia urinary tract infection	2 (1.2%)	2 (1.0%)	4 (1.1%)	5 (1.2%)
肺感染 Lung infection	4 (2.3%)	0	4 (1.1%)	5 (1.2%)
口腔カンジダ症 Oral candidiasis	2 (1.2%)	1 (0.5%)	3 (0.8%)	5 (1.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
憩室炎 Diverticulitis	1 (0.6%)	2 (1.0%)	3 (0.8%)	4 (1.0%)
ウイルス感染 Viral infection	1 (0.6%)	2 (1.0%)	3 (0.8%)	4 (1.0%)
クロストリジウム・ディフィシレ大腸炎 Clostridium difficile colitis	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
結膜炎 Conjunctivitis	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
耳感染 Ear infection	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
せつ Furuncle	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
単純ヘルペス Herpes simplex	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
中耳炎 Otitis media	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
真菌感染 Fungal infection	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
皮膚真菌感染 Fungal skin infection	2 (1.2%)	0	2 (0.5%)	3 (0.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
消化管感染 Gastrointestinal infection	2 (1.2%)	0	2 (0.5%)	3 (0.7%)
限局性感染 Localised infection	2 (1.2%)	0	2 (0.5%)	3 (0.7%)
外耳炎 Otitis externa	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
細菌性肺炎 Pneumonia bacterial	2 (1.2%)	0	2 (0.5%)	3 (0.7%)
腎盂腎炎 Pyelonephritis	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
ボレリア感染 Borrelia infection	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
クロストリジウム・ディフィシレ感染 Clostridium difficile infection	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
丹毒 Erysipelas	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
サルモネラ菌性胃腸炎 Gastroenteritis salmonella	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
ウイルス性胃腸炎 Gastroenteritis viral	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
陰部ヘルペス Genital herpes	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
咽頭炎 Pharyngitis	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
ウイルス性肺炎 Pneumonia viral	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
扁桃炎 Tonsillitis	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
水痘帯状疱疹ウイルス感染 Varicella zoster virus infection	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
創傷感染 Wound infection	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
皮膚感染 Skin infection	1 (0.6%)	0	1 (0.3%)	5 (1.2%)
鼻炎 Rhinitis	0	1 (0.5%)	1 (0.3%)	3 (0.7%)
毛包炎 Folliculitis	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
歯肉炎 Gingivitis	0	1 (0.5%)	1 (0.3%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
喉頭炎 Laryngitis	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
歯周炎 Periodontitis	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
腹部敗血症 Abdominal sepsis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
四肢膿瘍 Abscess limb	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
菌血症 Bacteraemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
気管支肺アスペルギルス症 Bronchopulmonary aspergillosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
カンジダ感染 Candida infection	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
医療機器関連感染 Device related infection	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
感染性腸炎 Enteritis infectious	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
感染性小腸結腸炎 Enterocolitis infectious	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
大腸菌感染 Escherichia infection	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
眼感染 Eye infection	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
真菌性食道炎 Fungal oesophagitis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
壊疽 Gangrene	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
消化器カンジダ症 Gastrointestinal candidiasis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
ヘルペス性皮膚炎 Herpes dermatitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
感染性皮膚嚢腫 Infected dermal cyst	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
感染性皮膚潰瘍 Infected skin ulcer	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
迷路炎 Labyrinthitis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
筋膿瘍 Muscle abscess	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
鼻ヘルペス Nasal herpes	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
神経ボレリア症 Neuroborreliosis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
百日咳 Pertussis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
ピコルナウイルス感染 Picornavirus infection	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ＲＳウイルス肺炎 Pneumonia respiratory syncytial viral	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
術後創感染 Postoperative wound infection	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肺敗血症 Pulmonary sepsis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肺結核 Pulmonary tuberculosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
敗血症性ショック Septic shock	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
セラチア性菌血症 Serratia bacteraemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
赤痢菌感染 Shigella infection	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
唾液腺炎 Sialoadenitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
皮下組織膿瘍 Subcutaneous abscess	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
破傷風 Tetanus	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
歯膿瘍 Tooth abscess	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
歯感染 Tooth infection	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
結核 Tuberculosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
前庭神経炎 Vestibular neuronitis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ウイルス性ぶどう膜炎 Viral uveitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
癜風 Tinea versicolour	0	0	0	3 (0.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
肛門膿瘍 Anal abscess	0	0	0	1 (0.2%)
大腸菌性敗血症 Escherichia sepsis	0	0	0	1 (0.2%)
感染 Infection	0	0	0	1 (0.2%)
口唇感染 Lip infection	0	0	0	1 (0.2%)
ライム病 Lyme disease	0	0	0	1 (0.2%)
処置後感染 Post procedural infection	0	0	0	1 (0.2%)
腎盂膀胱炎 Pyelocystitis	0	0	0	1 (0.2%)
陰嚢膿瘍 Scrotal abscess	0	0	0	1 (0.2%)
皮膚細菌感染 Skin bacterial infection	0	0	0	1 (0.2%)
ブドウ球菌感染 Staphylococcal infection	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
レンサ球菌性敗血症 Streptococcal sepsis	0	0	0	1 (0.2%)
腟感染 Vaginal infection	0	0	0	1 (0.2%)
胃腸障害 Gastrointestinal disorders	70 (40.9%)	105 (53.3%)	175 (47.6%)	233 (56.7%)
下痢 Diarrhoea	30 (17.5%)	39 (19.8%)	69 (18.8%)	99 (24.1%)
悪心 Nausea	16 (9.4%)	39 (19.8%)	55 (14.9%)	85 (20.7%)
腹痛 Abdominal pain	13 (7.6%)	27 (13.7%)	40 (10.9%)	61 (14.8%)
便秘 Constipation	13 (7.6%)	19 (9.6%)	32 (8.7%)	51 (12.4%)
嘔吐 Vomiting	8 (4.7%)	12 (6.1%)	20 (5.4%)	37 (9.0%)
胃食道逆流性疾患 Gastrooesophageal reflux disease	4 (2.3%)	11 (5.6%)	15 (4.1%)	21 (5.1%)
消化不良 Dyspepsia	6 (3.5%)	9 (4.6%)	15 (4.1%)	18 (4.4%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
上腹部痛 Abdominal pain upper	6 (3.5%)	7 (3.6%)	13 (3.5%)	22 (5.4%)
腹部膨満 Abdominal distension	4 (2.3%)	8 (4.1%)	12 (3.3%)	19 (4.6%)
腹水 Ascites	3 (1.8%)	4 (2.0%)	7 (1.9%)	8 (1.9%)
腹部不快感 Abdominal discomfort	3 (1.8%)	3 (1.5%)	6 (1.6%)	14 (3.4%)
胃炎 Gastritis	3 (1.8%)	2 (1.0%)	5 (1.4%)	6 (1.5%)
食道静脈瘤 Varices oesophageal	2 (1.2%)	3 (1.5%)	5 (1.4%)	6 (1.5%)
口内乾燥 Dry mouth	2 (1.2%)	2 (1.0%)	4 (1.1%)	10 (2.4%)
歯痛 Toothache	1 (0.6%)	3 (1.5%)	4 (1.1%)	7 (1.7%)
痔核 Haemorrhoids	0	4 (2.0%)	4 (1.1%)	6 (1.5%)
直腸出血 Rectal haemorrhage	0	4 (2.0%)	4 (1.1%)	6 (1.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
鼠径ヘルニア Inguinal hernia	4 (2.3%)	0	4 (1.1%)	5 (1.2%)
下腹部痛 Abdominal pain lower	1 (0.6%)	3 (1.5%)	4 (1.1%)	4 (1.0%)
びらん性胃炎 Gastritis erosive	2 (1.2%)	2 (1.0%)	4 (1.1%)	4 (1.0%)
大腸炎 Colitis	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
心窩部不快感 Epigastric discomfort	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
裂孔ヘルニア Hiatus hernia	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
口腔内出血 Mouth haemorrhage	0	3 (1.5%)	3 (0.8%)	3 (0.7%)
口内炎 Stomatitis	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
鼓腸 Flatulence	1 (0.6%)	1 (0.5%)	2 (0.5%)	5 (1.2%)
歯肉出血 Gingival bleeding	0	2 (1.0%)	2 (0.5%)	3 (0.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
肛門失禁 Anal incontinence	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
口角口唇炎 Angular cheilitis	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
齲歯 Dental caries	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
憩室 Diverticulum	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
食道静脈瘤出血 Oesophageal varices haemorrhage	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
口腔内痛 Oral pain	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
口唇炎 Cheilitis	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
嚥下障害 Dysphagia	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
胃潰瘍 Gastric ulcer	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
口腔内潰瘍形成 Mouth ulceration	1 (0.6%)	0	1 (0.3%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
レッチング Retching	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
小腸閉塞 Small intestinal obstruction	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
腹部硬直 Abdominal rigidity	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
異常便 Abnormal faeces	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
水疱性出血性口峡炎 Angina bullosa haemorrhagica	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
アフタ性潰瘍 Aphthous ulcer	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
慢性胃炎 Chronic gastritis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
便意切迫 Defaecation urgency	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
歯組織の壊死 Dental necrosis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
出血性十二指腸潰瘍 Duodenal ulcer haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
十二指腸炎 Duodenitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
腸炎 Enterocolitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
腹膜垂炎 Epiploic appendagitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
食中毒 Food poisoning	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
胃障害 Gastric disorder	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
胃出血 Gastric haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
出血性胃潰瘍 Gastric ulcer haemorrhage	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
胃腸障害 Gastrointestinal disorder	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
胃腸出血 Gastrointestinal haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
消化管運動障害 Gastrointestinal motility disorder	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
消化器痛 Gastrointestinal pain	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
胃腸音異常 Gastrointestinal sounds abnormal	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
歯肉潰瘍 Gingival ulceration	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
舌痛 Glossodynia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
吐血 Haematemesis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
口の感覚鈍麻 Hypoaesthesia oral	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
イレウス Ileus	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
腸梗塞 Intestinal infarction	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
腹腔内血腫 Intra-abdominal haematoma	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
下部消化管出血 Lower gastrointestinal haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
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System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
メレナ Melaena	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
口腔粘膜血腫 Oral mucosa haematoma	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
膵嚢胞 Pancreatic cyst	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
膵脂肪変性 Pancreatic steatosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
膵炎 Pancreatitis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
歯周病 Periodontal disease	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
咳嗽後嘔吐 Post-tussive vomiting	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
小腸出血 Small intestinal haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
埋伏歯 Tooth impacted	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
臍ヘルニア Umbilical hernia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
上部消化管出血 Upper gastrointestinal haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
内臓静脈血栓症 Visceral venous thrombosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
小腸炎 Enteritis	0	0	0	2 (0.5%)
肛門周囲痛 Proctalgia	0	0	0	2 (0.5%)
軟便 Faeces soft	0	0	0	1 (0.2%)
胃ポリープ Gastric polyps	0	0	0	1 (0.2%)
血便排泄 Haematochezia	0	0	0	1 (0.2%)
痔出血 Haemorrhoidal haemorrhage	0	0	0	1 (0.2%)
口唇痛 Lip pain	0	0	0	1 (0.2%)
腸間膜静脈血栓症 Mesenteric vein thrombosis	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
嚥下痛 Odynophagia	0	0	0	1 (0.2%)
食道炎 Oesophagitis	0	0	0	1 (0.2%)
消化性潰瘍 Peptic ulcer	0	0	0	1 (0.2%)
舌紅斑 Tongue erythema	0	0	0	1 (0.2%)
一般・全身障害および投与部位の状態 General disorders and administration site conditions	65 (38.0%)	85 (43.1%)	150 (40.8%)	204 (49.6%)
疲労 Fatigue	17 (9.9%)	39 (19.8%)	56 (15.2%)	84 (20.4%)
発熱 Pyrexia	17 (9.9%)	14 (7.1%)	31 (8.4%)	43 (10.5%)
末梢性浮腫 Oedema peripheral	16 (9.4%)	10 (5.1%)	26 (7.1%)	32 (7.8%)
無力症 Asthenia	13 (7.6%)	12 (6.1%)	25 (6.8%)	36 (8.8%)
胸痛 Chest pain	2 (1.2%)	8 (4.1%)	10 (2.7%)	16 (3.9%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
インフルエンザ様疾患 Influenza like illness	4 (2.3%)	6 (3.0%)	10 (2.7%)	14 (3.4%)
末梢腫脹 Peripheral swelling	4 (2.3%)	1 (0.5%)	5 (1.4%)	9 (2.2%)
早期満腹 Early satiety	1 (0.6%)	3 (1.5%)	4 (1.1%)	6 (1.5%)
悪寒 Chills	1 (0.6%)	3 (1.5%)	4 (1.1%)	5 (1.2%)
倦怠感 Malaise	1 (0.6%)	2 (1.0%)	3 (0.8%)	7 (1.7%)
非心臓性胸痛 Non-cardiac chest pain	1 (0.6%)	2 (1.0%)	3 (0.8%)	5 (1.2%)
疼痛 Pain	2 (1.2%)	1 (0.5%)	3 (0.8%)	5 (1.2%)
胸部不快感 Chest discomfort	1 (0.6%)	2 (1.0%)	3 (0.8%)	4 (1.0%)
熱感 Feeling hot	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
死亡 Death	0	2 (1.0%)	2 (0.5%)	3 (0.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
歩行障害 Gait disturbance	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
全身性浮腫 Generalised oedema	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
粘膜の炎症 Mucosal inflammation	2 (1.2%)	0	2 (0.5%)	3 (0.7%)
浮腫 Oedema	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
全身健康状態悪化 General physical health deterioration	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
治癒不良 Impaired healing	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
腫脹 Swelling	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
口渇 Thirst	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
カテーテル留置部位疼痛 Catheter site pain	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
医療機器関連合併症 Complication associated with device	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
不快感 Discomfort	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
薬剤離脱症候群 Drug withdrawal syndrome	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
顔面浮腫 Face oedema	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
高熱 Hyperthermia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
注入部位疼痛 Infusion site pain	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
注射部位出血 Injection site haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
多臓器機能不全症候群 Multiple organ dysfunction syndrome	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
乾燥症 Xerosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
重力性浮腫 Gravitational oedema	0	0	0	2 (0.5%)
捻髪音 Crepitations	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
顔面痛 Facial pain	0	0	0	1 (0.2%)
硬結 Induration	0	0	0	1 (0.2%)
炎症 Inflammation	0	0	0	1 (0.2%)
突然死 Sudden death	0	0	0	1 (0.2%)
血液およびリンパ系障害 Blood and lymphatic system disorders	66 (38.6%)	84 (42.6%)	150 (40.8%)	191 (46.5%)
貧血 Anaemia	41 (24.0%)	32 (16.2%)	73 (19.8%)	93 (22.6%)
血小板減少症 Thrombocytopenia	29 (17.0%)	40 (20.3%)	69 (18.8%)	94 (22.9%)
好中球減少症 Neutropenia	7 (4.1%)	8 (4.1%)	15 (4.1%)	20 (4.9%)
白血球増加症 Leukocytosis	3 (1.8%)	9 (4.6%)	12 (3.3%)	16 (3.9%)
白血球減少症 Leukopenia	5 (2.9%)	6 (3.0%)	11 (3.0%)	13 (3.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
血小板増加症 Thrombocytosis	2 (1.2%)	6 (3.0%)	8 (2.2%)	12 (2.9%)
リンパ球減少症 Lymphopenia	2 (1.2%)	3 (1.5%)	5 (1.4%)	6 (1.5%)
脾腫 Splenomegaly	4 (2.3%)	1 (0.5%)	5 (1.4%)	6 (1.5%)
脾臓梗塞 Splenic infarction	4 (2.3%)	0	4 (1.1%)	5 (1.2%)
赤血球増加症 Polycythaemia	0	3 (1.5%)	3 (0.8%)	3 (0.7%)
発熱性好中球減少症 Febrile neutropenia	2 (1.2%)	0	2 (0.5%)	3 (0.7%)
内出血発生の増加傾向 Increased tendency to bruise	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
脾血腫 Splenic haematoma	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
骨髄毒性 Bone marrow toxicity	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
凝血異常 Coagulopathy	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
溶血 Haemolysis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
溶血性貧血 Haemolytic anaemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
過粘稠度症候群 Hyperviscosity syndrome	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
鉄欠乏性貧血 Iron deficiency anaemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肥満細胞症 Mastocytosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
好中球増加症 Neutrophilia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
脾臓障害 Spleen disorder	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
脾臓血栓症 Splenic thrombosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
特発性血腫 Spontaneous haematoma	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
低プロトロンビン血症 Hypoprothrombinaemia	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
リンパ節石灰化 Lymph node calcification	0	0	0	1 (0.2%)
リンパ節症 Lymphadenopathy	0	0	0	1 (0.2%)
リンパ球増加症 Lymphocytosis	0	0	0	1 (0.2%)
微小血管症性溶血性貧血 Microangiopathic haemolytic anaemia	0	0	0	1 (0.2%)
神経系障害 Nervous system disorders	65 (38.0%)	80 (40.6%)	145 (39.4%)	203 (49.4%)
浮動性めまい Dizziness	18 (10.5%)	25 (12.7%)	43 (11.7%)	72 (17.5%)
末梢性感覚ニューロパチー Peripheral sensory neuropathy	15 (8.8%)	28 (14.2%)	43 (11.7%)	61 (14.8%)
頭痛 Headache	13 (7.6%)	24 (12.2%)	37 (10.1%)	68 (16.5%)
錯感覚 Paraesthesia	6 (3.5%)	11 (5.6%)	17 (4.6%)	28 (6.8%)
感覚鈍麻 Hypoaesthesia	7 (4.1%)	6 (3.0%)	13 (3.5%)	15 (3.6%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
失神 Syncope	6 (3.5%)	3 (1.5%)	9 (2.4%)	12 (2.9%)
嗜眠 Lethargy	4 (2.3%)	2 (1.0%)	6 (1.6%)	7 (1.7%)
坐骨神経痛 Sciatica	1 (0.6%)	5 (2.5%)	6 (1.6%)	6 (1.5%)
平衡障害 Balance disorder	3 (1.8%)	1 (0.5%)	4 (1.1%)	6 (1.5%)
失神寸前の状態 Presyncope	2 (1.2%)	1 (0.5%)	3 (0.8%)	8 (1.9%)
健忘 Amnesia	1 (0.6%)	2 (1.0%)	3 (0.8%)	4 (1.0%)
味覚異常 Dysgeusia	2 (1.2%)	1 (0.5%)	3 (0.8%)	4 (1.0%)
末梢性ニューロパチー Neuropathy peripheral	2 (1.2%)	1 (0.5%)	3 (0.8%)	4 (1.0%)
傾眠 Somnolence	1 (0.6%)	2 (1.0%)	3 (0.8%)	4 (1.0%)
脳血管発作 Cerebrovascular accident	3 (1.8%)	0	3 (0.8%)	3 (0.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
一過性脳虚血発作 Transient ischaemic attack	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
神経痛 Neuralgia	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
灼熱感 Burning sensation	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
意識消失 Loss of consciousness	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
感覚障害 Sensory disturbance	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
声帯麻痺 Vocal cord paralysis	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
記憶障害 Memory impairment	0	1 (0.5%)	1 (0.3%)	3 (0.7%)
振戦 Tremor	1 (0.6%)	0	1 (0.3%)	3 (0.7%)
注意力障害 Disturbance in attention	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
体位性めまい Dizziness postural	1 (0.6%)	0	1 (0.3%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
異常感覚 Dysaesthesia	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
蟻走感 Formication	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
末梢性運動ニューロパチー Peripheral motor neuropathy	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
味覚消失 Ageusia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
運動失調 Ataxia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
小脳卒中 Cerebellar stroke	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
大脳萎縮 Cerebral atrophy	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
脳微小血管症 Cerebral microangiopathy	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
大脳静脈血栓症 Cerebral venous thrombosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
脳血管不全 Cerebrovascular insufficiency	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
認知障害 Cognitive disorder	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
認知症 Dementia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
脱髄 Demyelination	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
前頭側頭型認知症 Frontotemporal dementia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
出血性卒中 Haemorrhagic stroke	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
不全片麻痺 Hemiparesis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ラクナ梗塞 Lacunar infarction	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
白質脳症 Leukoencephalopathy	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ミオトニー Myotonia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
眼振 Nystagmus	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
後頭神経痛 Occipital neuralgia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
パーキンソン病 Parkinson's disease	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
末梢性感覚運動ニューロパチー Peripheral sensorimotor neuropathy	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
多発ニューロパチー Polyneuropathy	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
ヘルペス後神経痛 Post herpetic neuralgia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
下肢静止不能症候群 Restless legs syndrome	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
副鼻腔炎に伴う頭痛 Sinus headache	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
くも膜下出血 Subarachnoid haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
三叉神経痛 Trigeminal neuralgia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
味覚障害 Taste disorder	0	0	0	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
脳虚血 Cerebral ischaemia	0	0	0	1 (0.2%)
頚腕症候群 Cervicobrachial syndrome	0	0	0	1 (0.2%)
前兆を伴う片頭痛 Migraine with aura	0	0	0	1 (0.2%)
神経系障害 Nervous system disorder	0	0	0	1 (0.2%)
代謝および栄養障害 Metabolism and nutrition disorders	63 (36.8%)	70 (35.5%)	133 (36.1%)	161 (39.2%)
食欲減退 Decreased appetite	15 (8.8%)	15 (7.6%)	30 (8.2%)	40 (9.7%)
高尿酸血症 Hyperuricaemia	12 (7.0%)	14 (7.1%)	26 (7.1%)	34 (8.3%)
ビタミンＢ１欠乏 Vitamin B1 deficiency	8 (4.7%)	11 (5.6%)	19 (5.2%)	25 (6.1%)
高カリウム血症 Hyperkalaemia	10 (5.8%)	3 (1.5%)	13 (3.5%)	18 (4.4%)
低カリウム血症 Hypokalaemia	4 (2.3%)	9 (4.6%)	13 (3.5%)	17 (4.1%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
痛風 Gout	6 (3.5%)	3 (1.5%)	9 (2.4%)	12 (2.9%)
糖尿病 Diabetes mellitus	2 (1.2%)	6 (3.0%)	8 (2.2%)	8 (1.9%)
低カルシウム血症 Hypocalcaemia	3 (1.8%)	4 (2.0%)	7 (1.9%)	10 (2.4%)
低ナトリウム血症 Hyponatraemia	3 (1.8%)	4 (2.0%)	7 (1.9%)	9 (2.2%)
高血糖 Hyperglycaemia	3 (1.8%)	4 (2.0%)	7 (1.9%)	8 (1.9%)
脱水 Dehydration	2 (1.2%)	3 (1.5%)	5 (1.4%)	7 (1.7%)
低血糖 Hypoglycaemia	2 (1.2%)	3 (1.5%)	5 (1.4%)	6 (1.5%)
低マグネシウム血症 Hypomagnesaemia	2 (1.2%)	2 (1.0%)	4 (1.1%)	10 (2.4%)
鉄欠乏 Iron deficiency	2 (1.2%)	2 (1.0%)	4 (1.1%)	6 (1.5%)
低アルブミン血症 Hypoalbuminaemia	3 (1.8%)	1 (0.5%)	4 (1.1%)	5 (1.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
高コレステロール血症 Hypercholesterolaemia	1 (0.6%)	3 (1.5%)	4 (1.1%)	4 (1.0%)
高トリグリセリド血症 Hypertriglyceridaemia	2 (1.2%)	2 (1.0%)	4 (1.1%)	4 (1.0%)
ビタミンD欠乏 Vitamin D deficiency	2 (1.2%)	1 (0.5%)	3 (0.8%)	6 (1.5%)
体液貯留 Fluid retention	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
鉄過剰 Iron overload	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
ビタミンB群欠乏 Vitamin B complex deficiency	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
高カルシウム血症 Hypercalcaemia	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
高脂血症 Hyperlipidaemia	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
低リン酸血症 Hypophosphataemia	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
異常体重減少 Abnormal loss of weight	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
悪液質 Cachexia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
コントロール不良の糖尿病 Diabetes mellitus inadequate control	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
脂質異常症 Dyslipidaemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
電解質失調 Electrolyte imbalance	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
水分過負荷 Fluid overload	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
葉酸欠乏 Folate deficiency	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
高フェリチン血症 Hyperferritinaemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
高マグネシウム血症 Hypermagnesaemia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
高ナトリウム血症 Hypernatraemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
低蛋白血症 Hypoproteinaemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
代謝性アシドーシス Metabolic acidosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ビタミン群欠乏 Multi-vitamin deficiency	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
偽高カリウム血症 Pseudohyperkalaemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
腫瘍崩壊症候群 Tumour lysis syndrome	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
２型糖尿病 Type 2 diabetes mellitus	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
ビタミンＢ１２欠乏 Vitamin B12 deficiency	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ビタミンＢ６欠乏 Vitamin B6 deficiency	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ヘモジデリン沈着症 Haemosiderosis	0	0	0	1 (0.2%)
栄養障害 Malnutrition	0	0	0	1 (0.2%)
ビタミンＫ欠乏 Vitamin K deficiency	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
筋骨格系および結合組織障害 Musculoskeletal and connective tissue disorders	47 (27.5%)	82 (41.6%)	129 (35.1%)	169 (41.1%)
四肢痛 Pain in extremity	11 (6.4%)	19 (9.6%)	30 (8.2%)	43 (10.5%)
背部痛 Back pain	10 (5.8%)	19 (9.6%)	29 (7.9%)	37 (9.0%)
関節痛 Arthralgia	10 (5.8%)	13 (6.6%)	23 (6.3%)	35 (8.5%)
骨痛 Bone pain	4 (2.3%)	12 (6.1%)	16 (4.3%)	19 (4.6%)
筋骨格痛 Musculoskeletal pain	6 (3.5%)	8 (4.1%)	14 (3.8%)	21 (5.1%)
筋肉痛 Myalgia	5 (2.9%)	7 (3.6%)	12 (3.3%)	17 (4.1%)
筋力低下 Muscular weakness	6 (3.5%)	3 (1.5%)	9 (2.4%)	10 (2.4%)
筋痙縮 Muscle spasms	1 (0.6%)	5 (2.5%)	6 (1.6%)	13 (3.2%)
脊椎痛 Spinal pain	0	5 (2.5%)	5 (1.4%)	8 (1.9%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
変形性関節症 Osteoarthritis	2 (1.2%)	2 (1.0%)	4 (1.1%)	4 (1.0%)
関節炎 Arthritis	2 (1.2%)	1 (0.5%)	3 (0.8%)	4 (1.0%)
滑液包炎 Bursitis	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
筋骨格硬直 Musculoskeletal stiffness	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
肩回旋筋腱板症候群 Rotator cuff syndrome	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
側腹部痛 Flank pain	0	2 (1.0%)	2 (0.5%)	4 (1.0%)
鼠径部痛 Groin pain	0	2 (1.0%)	2 (0.5%)	4 (1.0%)
筋骨格系胸痛 Musculoskeletal chest pain	2 (1.2%)	0	2 (0.5%)	3 (0.7%)
顎痛 Pain in jaw	2 (1.2%)	0	2 (0.5%)	3 (0.7%)
反応性関節炎 Arthritis reactive	2 (1.2%)	0	2 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
椎間板突出 Intervertebral disc protrusion	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
関節滲出液 Joint effusion	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
頚部痛 Neck pain	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
痛風性関節炎 Gouty arthritis	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
骨減少症 Osteopenia	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
変形性脊椎症 Spinal osteoarthritis	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
骨病変 Bone lesion	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
胸壁血腫 Chest wall haematoma	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ピロリン酸カルシウム結晶性軟骨石灰化症 Chondrocalcinosis pyrophosphate	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肋軟骨炎 Costochondritis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
筋膜炎 Fasciitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
関節腫脹 Joint swelling	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
四肢不快感 Limb discomfort	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
運動性低下 Mobility decreased	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
筋萎縮 Muscle atrophy	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
筋肉疲労 Muscle fatigue	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
筋肉内出血 Muscle haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
骨溶解 Osteolysis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
骨粗鬆症 Osteoporosis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
骨硬化症 Osteosclerosis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
関節周囲炎 Periarthritis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
腱痛 Tendon pain	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
椎骨病変 Vertebral lesion	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
滑液貯留 Bursal fluid accumulation	0	0	0	1 (0.2%)
足変形 Foot deformity	0	0	0	1 (0.2%)
シェーグレン症候群 Sjogren's syndrome	0	0	0	1 (0.2%)
腱炎 Tendonitis	0	0	0	1 (0.2%)
呼吸器、胸郭および縦隔障害 Respiratory, thoracic and mediastinal disorders	57 (33.3%)	70 (35.5%)	127 (34.5%)	164 (39.9%)
咳嗽 Cough	23 (13.5%)	34 (17.3%)	57 (15.5%)	73 (17.8%)
呼吸困難 Dyspnoea	15 (8.8%)	19 (9.6%)	34 (9.2%)	51 (12.4%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
鼻出血 Epistaxis	8 (4.7%)	12 (6.1%)	20 (5.4%)	28 (6.8%)
胸水 Pleural effusion	1 (0.6%)	6 (3.0%)	7 (1.9%)	7 (1.7%)
口腔咽頭痛 Oropharyngeal pain	4 (2.3%)	2 (1.0%)	6 (1.6%)	8 (1.9%)
労作性呼吸困難 Dyspnoea exertional	2 (1.2%)	3 (1.5%)	5 (1.4%)	11 (2.7%)
湿性咳嗽 Productive cough	2 (1.2%)	3 (1.5%)	5 (1.4%)	8 (1.9%)
低酸素症 Hypoxia	2 (1.2%)	3 (1.5%)	5 (1.4%)	7 (1.7%)
慢性閉塞性肺疾患 Chronic obstructive pulmonary disease	3 (1.8%)	2 (1.0%)	5 (1.4%)	6 (1.5%)
呼吸不全 Respiratory failure	2 (1.2%)	3 (1.5%)	5 (1.4%)	6 (1.5%)
肺塞栓症 Pulmonary embolism	3 (1.8%)	1 (0.5%)	4 (1.1%)	4 (1.0%)
喘息 Asthma	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
胸膜炎 Pleurisy	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
発声障害 Dysphonia	1 (0.6%)	1 (0.5%)	2 (0.5%)	4 (1.0%)
鼻漏 Rhinorrhoea	2 (1.2%)	0	2 (0.5%)	4 (1.0%)
急性呼吸不全 Acute respiratory failure	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
慢性気管支炎 Bronchitis chronic	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
肺硬化 Lung consolidation	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
肺水腫 Pulmonary oedema	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
喘鳴 Wheezing	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
ラ音 Rales	1 (0.6%)	0	1 (0.3%)	3 (0.7%)
喀血 Haemoptysis	0	1 (0.5%)	1 (0.3%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
しゃっくり Hiccups	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
鼻閉 Nasal congestion	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
肺肉芽腫 Pulmonary granuloma	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
上気道咳症候群 Upper-airway cough syndrome	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
急性肺水腫 Acute pulmonary oedema	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
胞隔炎 Alveolitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
気管支拡張症 Bronchiectasis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
カタル Catarrh	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肺気腫 Emphysema	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
低換気 Hypoventilation	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
喉頭の炎症 Laryngeal inflammation	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
肺障害 Lung disorder	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
鼻乾燥 Nasal dryness	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
口腔咽頭不快感 Oropharyngeal discomfort	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
起坐呼吸 Orthopnoea	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
誤嚥性肺炎 Pneumonia aspiration	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肺高血圧症 Pulmonary hypertension	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肺腫瘤 Pulmonary mass	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
呼吸停止 Respiratory arrest	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
副鼻腔うっ血 Sinus congestion	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
副鼻腔痛 Sinus pain	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
睡眠時無呼吸症候群 Sleep apnoea syndrome	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
頻呼吸 Tachypnoea	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
咽喉乾燥 Dry throat	0	0	0	1 (0.2%)
発作性夜間呼吸困難 Dyspnoea paroxysmal nocturnal	0	0	0	1 (0.2%)
呼吸時疼痛 Painful respiration	0	0	0	1 (0.2%)
咽頭潰瘍 Pharyngeal ulceration	0	0	0	1 (0.2%)
肺線維症 Pulmonary fibrosis	0	0	0	1 (0.2%)
逆流性喉頭炎 Reflux laryngitis	0	0	0	1 (0.2%)
咽喉絞扼感 Throat tightness	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
皮膚および皮下組織障害 Skin and subcutaneous tissue disorders	55 (32.2%)	69 (35.0%)	124 (33.7%)	153 (37.2%)
そう痒症 Pruritus	12 (7.0%)	20 (10.2%)	32 (8.7%)	40 (9.7%)
寝汗 Night sweats	12 (7.0%)	17 (8.6%)	29 (7.9%)	35 (8.5%)
発疹 Rash	10 (5.8%)	12 (6.1%)	22 (6.0%)	30 (7.3%)
多汗症 Hyperhidrosis	2 (1.2%)	9 (4.6%)	11 (3.0%)	11 (2.7%)
紅斑 Erythema	4 (2.3%)	3 (1.5%)	7 (1.9%)	14 (3.4%)
点状出血 Petechiae	1 (0.6%)	3 (1.5%)	4 (1.1%)	7 (1.7%)
全身性そう痒症 Pruritus generalised	1 (0.6%)	3 (1.5%)	4 (1.1%)	5 (1.2%)
斑状丘疹状皮疹 Rash maculo-papular	1 (0.6%)	2 (1.0%)	3 (0.8%)	6 (1.5%)
全身性皮疹 Rash generalised	1 (0.6%)	2 (1.0%)	3 (0.8%)	4 (1.0%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
皮膚出血 Skin haemorrhage	2 (1.2%)	1 (0.5%)	3 (0.8%)	4 (1.0%)
光線角化症 Actinic keratosis	3 (1.8%)	0	3 (0.8%)	3 (0.7%)
脱毛症 Alopecia	1 (0.6%)	1 (0.5%)	2 (0.5%)	5 (1.2%)
斑状出血 Ecchymosis	1 (0.6%)	1 (0.5%)	2 (0.5%)	5 (1.2%)
アレルギー性皮膚炎 Dermatitis allergic	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
斑状皮疹 Rash macular	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
冷汗 Cold sweat	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
皮膚嚢腫 Dermal cyst	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
丘疹性皮疹 Rash papular	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
酒さ Rosacea	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
皮膚剥脱 Skin exfoliation	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
中毒性皮疹 Toxic skin eruption	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
紅斑性皮疹 Rash erythematous	1 (0.6%)	0	1 (0.3%)	3 (0.7%)
皮膚病変 Skin lesion	1 (0.6%)	0	1 (0.3%)	3 (0.7%)
皮膚潰瘍 Skin ulcer	1 (0.6%)	0	1 (0.3%)	3 (0.7%)
水疱 Blister	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
薬疹 Drug eruption	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
過角化 Hyperkeratosis	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
嵌入爪 Ingrowing nail	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
皮膚炎 Dermatitis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
全身性剥脱性皮膚炎 Dermatitis exfoliative generalised	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
皮膚症 Dermatosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
過敏性血管炎 Hypersensitivity vasculitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
間擦疹 Intertrigo	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
苔癬様角化症 Lichenoid keratosis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
爪変色 Nail discolouration	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
丘疹 Papule	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
乾癬 Psoriasis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
紫斑 Purpura	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
皮膚障害 Skin disorder	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
皮膚脆弱性 Skin fragility	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
顔面腫脹 Swelling face	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
蕁麻疹 Urticaria	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
接触皮膚炎 Dermatitis contact	0	0	0	2 (0.5%)
皮膚乾燥 Dry skin	0	0	0	2 (0.5%)
血性水疱 Blood blister	0	0	0	1 (0.2%)
湿疹 Eczema	0	0	0	1 (0.2%)
紅色症 Erythrosis	0	0	0	1 (0.2%)
毛孔性皮疹 Rash follicular	0	0	0	1 (0.2%)
毛細血管拡張症 Telangiectasia	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
臨床検査 Investigations	43 (25.1%)	43 (21.8%)	86 (23.4%)	112 (27.3%)
血中クレアチニン増加 Blood creatinine increased	10 (5.8%)	10 (5.1%)	20 (5.4%)	25 (6.1%)
アラニンアミノトランスフェラーゼ増加 Alanine aminotransferase increased	5 (2.9%)	11 (5.6%)	16 (4.3%)	25 (6.1%)
アスパラギン酸アミノトランスフェラーゼ増加 Aspartate aminotransferase increased	3 (1.8%)	10 (5.1%)	13 (3.5%)	19 (4.6%)
体重減少 Weight decreased	8 (4.7%)	4 (2.0%)	12 (3.3%)	16 (3.9%)
血中ビリルビン増加 Blood bilirubin increased	6 (3.5%)	6 (3.0%)	12 (3.3%)	14 (3.4%)
γ－グルタミルトランスフェラーゼ増加 Gamma-glutamyltransferase increased	3 (1.8%)	7 (3.6%)	10 (2.7%)	16 (3.9%)
活性化部分トロンボプラスチン時間延長 Activated partial thromboplastin time prolonged	2 (1.2%)	5 (2.5%)	7 (1.9%)	8 (1.9%)
体重増加 Weight increased	3 (1.8%)	2 (1.0%)	5 (1.4%)	7 (1.7%)
腎クレアチニン・クリアランス減少 Creatinine renal clearance decreased	3 (1.8%)	2 (1.0%)	5 (1.4%)	6 (1.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
血中葉酸減少 Blood folate decreased	3 (1.8%)	0	3 (0.8%)	3 (0.7%)
血中乳酸脱水素酵素増加 Blood lactate dehydrogenase increased	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
ヘマトクリット増加 Haematocrit increased	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
ヘモグロビン増加 Haemoglobin increased	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
血中アルカリホスファターゼ増加 Blood alkaline phosphatase increased	1 (0.6%)	1 (0.5%)	2 (0.5%)	4 (1.0%)
トランスアミナーゼ上昇 Transaminases increased	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
芽球細胞数増加 Blast cell count increased	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
血中クロール増加 Blood chloride increased	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
血中鉄減少 Blood iron decreased	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
国際標準比増加 International normalised ratio increased	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
プロトロンビン時間延長 Prothrombin time prolonged	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
心電図ＱＴ延長 Electrocardiogram QT prolonged	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
総蛋白増加 Protein total increased	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
抗リン脂質抗体陽性 Antiphospholipid antibodies positive	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
血中クレアチンホスホキナーゼ増加 Blood creatine phosphokinase increased	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
血中鉄増加 Blood iron increased	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
血圧上昇 Blood pressure increased	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
血中尿素増加 Blood urea increased	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
胸部Ｘ線異常 Chest X-ray abnormal	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
骨盤コンピュータ断層撮影異常 Computerised tomogram pelvis abnormal	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	有害事象（因果関係を問わない）			
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System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
大腿動脈雑音 Femoral bruit	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
糸球体濾過率減少 Glomerular filtration rate decreased	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肝酵素上昇 Hepatic enzyme increased	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
眼圧上昇 Intraocular pressure increased	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
肝機能検査異常 Liver function test abnormal	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肝機能検査値上昇 Liver function test increased	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
平均赤血球容積減少 Mean cell volume decreased	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
血清フェリチン増加 Serum ferritin increased	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
ビタミンＢ１減少 Vitamin B1 decreased	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
尿中白血球陽性 White blood cells urine positive	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	有害事象（因果関係を問わない）			
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System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
心雑音 Cardiac murmur	0	0	0	2 (0.5%)
血中重炭酸塩減少 Blood bicarbonate decreased	0	0	0	1 (0.2%)
血中乳酸増加 Blood lactic acid increased	0	0	0	1 (0.2%)
心電図ＳＴ部分下降 Electrocardiogram ST segment depression	0	0	0	1 (0.2%)
心電図異常 Electrocardiogram abnormal	0	0	0	1 (0.2%)
ヘプシジン減少 Hepcidin decreased	0	0	0	1 (0.2%)
リパーゼ増加 Lipase increased	0	0	0	1 (0.2%)
リンパ節触知 Lymph node palpable	0	0	0	1 (0.2%)
好中球数増加 Neutrophil count increased	0	0	0	1 (0.2%)
血管障害 Vascular disorders	33 (19.3%)	45 (22.8%)	78 (21.2%)	114 (27.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
高血圧 Hypertension	10 (5.8%)	19 (9.6%)	29 (7.9%)	37 (9.0%)
低血圧 Hypotension	8 (4.7%)	9 (4.6%)	17 (4.6%)	33 (8.0%)
血腫 Haematoma	5 (2.9%)	6 (3.0%)	11 (3.0%)	16 (3.9%)
ほてり Hot flush	1 (0.6%)	4 (2.0%)	5 (1.4%)	8 (1.9%)
潮紅 Flushing	1 (0.6%)	3 (1.5%)	4 (1.1%)	17 (4.1%)
静脈炎 Phlebitis	2 (1.2%)	1 (0.5%)	3 (0.8%)	5 (1.2%)
大動脈狭窄 Aortic stenosis	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
深部静脈血栓症 Deep vein thrombosis	0	3 (1.5%)	3 (0.8%)	3 (0.7%)
動脈硬化症 Arteriosclerosis	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
起立性低血圧 Orthostatic hypotension	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
表在性血栓性静脈炎 Thrombophlebitis superficial	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
静脈瘤 Varicose vein	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
大動脈硬化症 Aortic arteriosclerosis	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
出血 Haemorrhage	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
末梢動脈閉塞性疾患 Peripheral arterial occlusive disease	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
四肢静脈血栓症 Venous thrombosis limb	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
末梢動脈狭窄 Peripheral artery stenosis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
末梢循環不良 Poor peripheral circulation	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
血栓症 Thrombosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
血管拡張 Vasodilatation	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
大動脈解離 Aortic dissection	0	0	0	1 (0.2%)
大動脈血栓症 Aortic thrombosis	0	0	0	1 (0.2%)
本態性高血圧症 Essential hypertension	0	0	0	1 (0.2%)
末梢冷感 Peripheral coldness	0	0	0	1 (0.2%)
静脈穿刺不良 Poor venous access	0	0	0	1 (0.2%)
血栓性静脈炎 Thrombophlebitis	0	0	0	1 (0.2%)
腎および尿路障害 Renal and urinary disorders	39 (22.8%)	32 (16.2%)	71 (19.3%)	88 (21.4%)
急性腎障害 Acute kidney injury	5 (2.9%)	6 (3.0%)	11 (3.0%)	13 (3.2%)
腎不全 Renal failure	6 (3.5%)	4 (2.0%)	10 (2.7%)	12 (2.9%)
腎機能障害 Renal impairment	5 (2.9%)	3 (1.5%)	8 (2.2%)	10 (2.4%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
排尿困難 Dysuria	3 (1.8%)	4 (2.0%)	7 (1.9%)	10 (2.4%)
慢性腎臓病 Chronic kidney disease	5 (2.9%)	2 (1.0%)	7 (1.9%)	8 (1.9%)
血尿 Haematuria	3 (1.8%)	3 (1.5%)	6 (1.6%)	9 (2.2%)
蛋白尿 Proteinuria	4 (2.3%)	2 (1.0%)	6 (1.6%)	6 (1.5%)
頻尿 Pollakiuria	1 (0.6%)	3 (1.5%)	4 (1.1%)	7 (1.7%)
夜間頻尿 Nocturia	3 (1.8%)	1 (0.5%)	4 (1.1%)	6 (1.5%)
腎仙痛 Renal colic	2 (1.2%)	2 (1.0%)	4 (1.1%)	4 (1.0%)
腎結石症 Nephrolithiasis	1 (0.6%)	1 (0.5%)	2 (0.5%)	4 (1.0%)
尿失禁 Urinary incontinence	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
膀胱痙縮 Bladder spasm	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
尿路結石 Calculus urinary	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
高血圧性腎症 Hypertensive nephropathy	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
緊張性膀胱 Hypertonic bladder	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
白血球尿 Leukocyturia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
排尿異常 Micturition disorder	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
尿意切迫 Micturition urgency	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
腎症 Nephropathy	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ネフローゼ症候群 Nephrotic syndrome	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
腎嚢胞 Renal cyst	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
腎障害 Renal disorder	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
腎尿細管壊死 Renal tubular necrosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
尿管結石症 Ureterolithiasis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
尿道障害 Urethral disorder	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
着色尿 Chromaturia	0	0	0	2 (0.5%)
多尿 Polyuria	0	0	0	2 (0.5%)
膀胱ポリープ Urinary bladder polyp	0	0	0	1 (0.2%)
尿閉 Urinary retention	0	0	0	1 (0.2%)
尿路痛 Urinary tract pain	0	0	0	1 (0.2%)
眼障害 Eye disorders	31 (18.1%)	28 (14.2%)	59 (16.0%)	81 (19.7%)
核性白内障 Cataract nuclear	8 (4.7%)	6 (3.0%)	14 (3.8%)	17 (4.1%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
皮質白内障 Cataract cortical	3 (1.8%)	5 (2.5%)	8 (2.2%)	11 (2.7%)
霧視 Vision blurred	5 (2.9%)	1 (0.5%)	6 (1.6%)	11 (2.7%)
視力障害 Visual impairment	2 (1.2%)	3 (1.5%)	5 (1.4%)	6 (1.5%)
ドライアイ Dry eye	1 (0.6%)	4 (2.0%)	5 (1.4%)	5 (1.2%)
結膜出血 Conjunctival haemorrhage	3 (1.8%)	1 (0.5%)	4 (1.1%)	4 (1.0%)
嚢下白内障 Cataract subcapsular	3 (1.8%)	0	3 (0.8%)	4 (1.0%)
網膜出血 Retinal haemorrhage	3 (1.8%)	0	3 (0.8%)	4 (1.0%)
糖尿病網膜症 Diabetic retinopathy	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
流涙増加 Lacrimation increased	1 (0.6%)	1 (0.5%)	2 (0.5%)	4 (1.0%)
眼痛 Eye pain	2 (1.2%)	0	2 (0.5%)	3 (0.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
視力低下 Visual acuity reduced	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
複視 Diplopia	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
眼出血 Eye haemorrhage	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
緑内障 Glaucoma	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
眼充血 Ocular hyperaemia	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
白内障 Cataract	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
眼刺激 Eye irritation	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
眼瞼浮腫 Eyelid oedema	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
角膜炎 Keratitis	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
黄斑変性 Macular degeneration	1 (0.6%)	0	1 (0.3%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
眼瞼腫脹 Swelling of eyelid	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
硝子体浮遊物 Vitreous floaters	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
眼瞼炎 Blepharitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
眼瞼紅斑 Erythema of eyelid	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
眼瞼下垂 Eyelid ptosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
睫毛の成長 Growth of eyelashes	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
マイボーム腺機能不全 Meibomian gland dysfunction	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
網膜剥離 Retinal detachment	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
網膜瘢痕 Retinal scar	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
閃輝暗点 Scintillating scotoma	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
硝子体変性 Vitreous degeneration	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
眼部腫脹 Eye swelling	0	0	0	1 (0.2%)
星状硝子体症 Hyalosis asteroid	0	0	0	1 (0.2%)
眼窩浮腫 Orbital oedema	0	0	0	1 (0.2%)
眼窩周囲浮腫 Periorbital oedema	0	0	0	1 (0.2%)
光視症 Photopsia	0	0	0	1 (0.2%)
傷害、中毒および処置合併症 Injury, poisoning and procedural complications	30 (17.5%)	29 (14.7%)	59 (16.0%)	78 (19.0%)
転倒 Fall	9 (5.3%)	9 (4.6%)	18 (4.9%)	23 (5.6%)
挫傷 Contusion	9 (5.3%)	5 (2.5%)	14 (3.8%)	29 (7.1%)
四肢損傷 Limb injury	3 (1.8%)	2 (1.0%)	5 (1.4%)	7 (1.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
処置による疼痛 Procedural pain	2 (1.2%)	2 (1.0%)	4 (1.1%)	5 (1.2%)
処置後出血 Post procedural haemorrhage	3 (1.8%)	1 (0.5%)	4 (1.1%)	4 (1.0%)
皮膚裂傷 Skin laceration	0	3 (1.5%)	3 (0.8%)	5 (1.2%)
創傷 Wound	2 (1.2%)	0	2 (0.5%)	4 (1.0%)
皮膚擦過傷 Skin abrasion	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
脊椎圧迫骨折 Spinal compression fracture	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
足骨折 Foot fracture	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
頭部損傷 Head injury	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
過量投与 Overdose	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
眼窩周囲血腫 Periorbital haematoma	0	1 (0.5%)	1 (0.3%)	3 (0.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
膝蓋骨骨折 Patella fracture	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
創合併症 Wound complication	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
吻合部狭窄 Anastomotic stenosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
背部損傷 Back injury	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
第 1 度熱傷 Burns first degree	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
一酸化炭素中毒 Carbon monoxide poisoning	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
歯科修復不成功 Dental restoration failure	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
耳部損傷 Ear injury	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
顔面骨骨折 Facial bones fracture	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
発熱性非溶血性輸血反応 Febrile nonhaemolytic transfusion reaction	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
上腕骨骨折 Humerus fracture	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
筋損傷 Muscle injury	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肉離れ Muscle strain	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
処置後炎症 Post procedural inflammation	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
処置による悪心 Procedural nausea	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
肋骨骨折 Rib fracture	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
交通事故 Road traffic accident	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
骨格損傷 Skeletal injury	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
皮膚損傷 Skin injury	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
脊椎骨折 Spinal fracture	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
脾破裂 Splenic rupture	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
皮下血腫 Subcutaneous haematoma	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
硬膜下血腫 Subdural haematoma	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
硬膜下出血 Subdural haemorrhage	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
腱断裂 Tendon rupture	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
外傷性血胸 Traumatic haemothorax	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
尺骨骨折 Ulna fracture	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
創部分泌 Wound secretion	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
節足動物咬傷 Arthropod bite	0	0	0	1 (0.2%)
四肢圧挫損傷 Limb crushing injury	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
処置後合併症 Post procedural complication	0	0	0	1 (0.2%)
処置後挫傷 Post procedural contusion	0	0	0	1 (0.2%)
術後譫妄 Postoperative delirium	0	0	0	1 (0.2%)
引っかき傷 Scratch	0	0	0	1 (0.2%)
外傷性血腫 Traumatic haematoma	0	0	0	1 (0.2%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） Neoplasms benign, malignant and unspecified (incl cysts and polyps)	32 (18.7%)	25 (12.7%)	57 (15.5%)	65 (15.8%)
基底細胞癌 Basal cell carcinoma	7 (4.1%)	4 (2.0%)	11 (3.0%)	12 (2.9%)
皮膚有棘細胞癌 Squamous cell carcinoma of skin	5 (2.9%)	4 (2.0%)	9 (2.4%)	11 (2.7%)
急性骨髄性白血病 Acute myeloid leukaemia	4 (2.3%)	3 (1.5%)	7 (1.9%)	8 (1.9%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
骨髄線維症 Myelofibrosis	3 (1.8%)	4 (2.0%)	7 (1.9%)	8 (1.9%)
悪性黒色腫 Malignant melanoma	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
メラノサイト性母斑 Melanocytic naevus	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
ボーエン病 Bowen's disease	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
脂漏性角化症 Seborrhoeic keratosis	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
子宮平滑筋腫 Uterine leiomyoma	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
子宮癌 Uterine cancer	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
良性腺腫 Adenoma benign	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
血管筋脂肪腫 Angiomyolipoma	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
再発膀胱移行上皮癌 Bladder transitional cell carcinoma recurrent	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
慢性リンパ性白血病 Chronic lymphocytic leukaemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
慢性骨髄性白血病 Chronic myeloid leukaemia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
眼瞼腫瘍 Eyelid tumour	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
乳腺線維腺腫 Fibroadenoma of breast	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
骨血管腫 Haemangioma of bone	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
ランゲルハンス細胞肉腫 Langerhans cell sarcoma	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
白赤芽球症 Leukoerythroblastosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
表皮内悪性黒色腫 Malignant melanoma in situ	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
リンパ節転移 Metastases to lymph nodes	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
遠隔転移を伴う扁平上皮癌 Metastatic squamous cell carcinoma	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
新生物 Neoplasm	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
原発性骨髄線維症 Primary myelofibrosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
前立腺癌 Prostate cancer	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
直腸癌 Rectal cancer	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
セミノーマ Seminoma	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
鼻副鼻腔乳頭腫 Sinonasal papilloma	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
皮膚癌 Skin cancer	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
皮膚乳頭腫 Skin papilloma	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
舌扁平上皮癌 Squamous cell carcinoma of the tongue	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
急性骨髄性白血病への転化 Transformation to acute myeloid leukaemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
腫瘍熱 Tumour associated fever	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
膀胱移行上皮癌 Bladder transitional cell carcinoma	0	0	0	1 (0.2%)
膵管内乳頭粘液性腫瘍 Intraductal papillary mucinous neoplasm	0	0	0	1 (0.2%)
食道扁平上皮癌 Oesophageal squamous cell carcinoma	0	0	0	1 (0.2%)
卵巣明細胞癌 Ovarian clear cell carcinoma	0	0	0	1 (0.2%)
脾臓辺縁帯リンパ腫 Splenic marginal zone lymphoma	0	0	0	1 (0.2%)
心臓障害 Cardiac disorders	28 (16.4%)	27 (13.7%)	55 (14.9%)	70 (17.0%)
心房細動 Atrial fibrillation	9 (5.3%)	9 (4.6%)	18 (4.9%)	26 (6.3%)
心不全 Cardiac failure	7 (4.1%)	4 (2.0%)	11 (3.0%)	13 (3.2%)
心房粗動 Atrial flutter	4 (2.3%)	2 (1.0%)	6 (1.6%)	7 (1.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
動悸 Palpitations	1 (0.6%)	4 (2.0%)	5 (1.4%)	7 (1.7%)
急性心筋梗塞 Acute myocardial infarction	1 (0.6%)	2 (1.0%)	3 (0.8%)	6 (1.5%)
うっ血性心不全 Cardiac failure congestive	2 (1.2%)	1 (0.5%)	3 (0.8%)	4 (1.0%)
心停止 Cardiac arrest	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
狭心症 Angina pectoris	0	2 (1.0%)	2 (0.5%)	6 (1.5%)
頻脈 Tachycardia	2 (1.2%)	0	2 (0.5%)	4 (1.0%)
大動脈弁狭窄 Aortic valve stenosis	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
徐脈 Bradycardia	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
冠動脈疾患 Coronary artery disease	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
僧帽弁閉鎖不全症 Mitral valve incompetence	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
心筋梗塞 Myocardial infarction	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
不安定狭心症 Angina unstable	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
期外収縮 Extrasystoles	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
房室ブロック Atrioventricular block	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
第一度房室ブロック Atrioventricular block first degree	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
慢性心不全 Cardiac failure chronic	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
心臓弁膜疾患 Cardiac valve disease	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
心筋症 Cardiomyopathy	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
拡張機能障害 Diastolic dysfunction	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
左室機能不全 Left ventricular dysfunction	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
左室不全 Left ventricular failure	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
心筋虚血 Myocardial ischaemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
洞性徐脈 Sinus bradycardia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
洞性頻脈 Sinus tachycardia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
上室性期外収縮 Supraventricular extrasystoles	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
完全房室ブロック Atrioventricular block complete	0	0	0	1 (0.2%)
心拡大 Cardiomegaly	0	0	0	1 (0.2%)
心嚢液貯留 Pericardial effusion	0	0	0	1 (0.2%)
上室性頻脈 Supraventricular tachycardia	0	0	0	1 (0.2%)
三尖弁閉鎖不全症 Tricuspid valve incompetence	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
精神障害 Psychiatric disorders	25 (14.6%)	22 (11.2%)	47 (12.8%)	60 (14.6%)
不眠症 Insomnia	11 (6.4%)	6 (3.0%)	17 (4.6%)	21 (5.1%)
うつ病 Depression	8 (4.7%)	4 (2.0%)	12 (3.3%)	15 (3.6%)
不安 Anxiety	6 (3.5%)	2 (1.0%)	8 (2.2%)	14 (3.4%)
錯乱状態 Confusional state	3 (1.8%)	2 (1.0%)	5 (1.4%)	6 (1.5%)
リビドー減退 Libido decreased	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
失見当識 Disorientation	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
幻覚 Hallucination	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
精神状態変化 Mental status changes	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
神経過敏 Nervousness	0	1 (0.5%)	1 (0.3%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
感情障害 Affective disorder	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
譫妄 Delirium	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
妄想 Delusion	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
抑うつ気分 Depressed mood	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
睡眠障害 Sleep disorder	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
身体疾患による睡眠障害、不眠症型 Sleep disorder due to general medical condition, insomnia type	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
自殺念慮 Suicidal ideation	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
激越 Agitation	0	0	0	1 (0.2%)
耳および迷路障害 Ear and labyrinth disorders	10 (5.8%)	14 (7.1%)	24 (6.5%)	36 (8.8%)
回転性めまい Vertigo	5 (2.9%)	8 (4.1%)	13 (3.5%)	20 (4.9%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
耳鳴 Tinnitus	0	3 (1.5%)	3 (0.8%)	5 (1.2%)
耳痛 Ear pain	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
聴力低下 Hypoacusis	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
難聴 Deafness	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
片耳難聴 Deafness unilateral	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
耳出血 Ear haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
乗物酔い Motion sickness	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
耳異常感覚 Paraesthesia ear	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
突発性難聴 Sudden hearing loss	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
鼓膜穿孔 Tympanic membrane perforation	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
耳不快感 Ear discomfort	0	0	0	1 (0.2%)
肝胆道系障害 Hepatobiliary disorders	9 (5.3%)	10 (5.1%)	19 (5.2%)	20 (4.9%)
胆石症 Cholelithiasis	5 (2.9%)	1 (0.5%)	6 (1.6%)	6 (1.5%)
急性胆嚢炎 Cholecystitis acute	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
肝障害 Liver disorder	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
黄疸眼 Ocular icterus	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
門脈圧亢進症 Portal hypertension	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
胆汁うっ滞 Cholestasis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肝硬変 Hepatic cirrhosis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
肝不全 Hepatic failure	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
肝機能異常 Hepatic function abnormal	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
脂肪肝 Hepatic steatosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肝腫大 Hepatomegaly	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
門脈血栓症 Portal vein thrombosis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
過形成性胆嚢症 Hyperplastic cholecystopathy	0	0	0	1 (0.2%)
生殖系および乳房障害 Reproductive system and breast disorders	8 (4.7%)	9 (4.6%)	17 (4.6%)	22 (5.4%)
良性前立腺肥大症 Benign prostatic hyperplasia	3 (1.8%)	5 (2.5%)	8 (2.2%)	9 (2.2%)
腟出血 Vaginal haemorrhage	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
乳房過形成 Breast hyperplasia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
精巣上体嚢胞 Epididymal cyst	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
勃起不全 Erectile dysfunction	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
閉経後出血 Postmenopausal haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
精巣腫脹 Testicular swelling	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
子宮頚部びらん Uterine cervical erosion	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
子宮出血 Uterine haemorrhage	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
腟分泌物 Vaginal discharge	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
腟脱 Vaginal prolapse	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
会陰痛 Perineal pain	0	0	0	1 (0.2%)
外陰腟の炎症 Vulvovaginal inflammation	0	0	0	1 (0.2%)
外陰腟痛 Vulvovaginal pain	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
内分泌障害 Endocrine disorders	2 (1.2%)	3 (1.5%)	5 (1.4%)	7 (1.7%)
甲状腺腫瘤 Thyroid mass	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
甲状腺機能低下症 Hypothyroidism	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
甲状腺腫 Goitre	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
甲状腺炎 Thyroiditis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
低アルドステロン症 Hypoaldosteronism	0	0	0	1 (0.2%)
免疫系障害 Immune system disorders	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
薬物過敏症 Drug hypersensitivity	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
過敏症 Hypersensitivity	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
季節性アレルギー Seasonal allergy	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	有害事象（因果関係を問わない）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
外科および内科処置 Surgical and medical procedures	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
抜歯 Tooth extraction	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
先天性、家族性および遺伝性障害 Congenital, familial and genetic disorders	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
陰嚢水瘤 Hydrocele	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
有害事象発現例数 ANY EVENT	92 (53.8%)	127 (64.5%)	219 (59.5%)	288 (70.1%)
感染症および寄生虫症 Infections and infestations	21 (12.3%)	16 (8.1%)	37 (10.1%)	41 (10.0%)
尿路感染 Urinary tract infection	4 (2.3%)	4 (2.0%)	8 (2.2%)	9 (2.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
肺炎 Pneumonia	4 (2.3%)	3 (1.5%)	7 (1.9%)	8 (1.9%)
上気道感染 Upper respiratory tract infection	4 (2.3%)	1 (0.5%)	5 (1.4%)	5 (1.2%)
上咽頭炎 Nasopharyngitis	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
気管支炎 Bronchitis	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
胃腸炎 Gastroenteritis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
気道感染 Respiratory tract infection	0	0	0	0
帯状疱疹 Herpes zoster	4 (2.3%)	0	4 (1.1%)	7 (1.7%)
膀胱炎 Cystitis	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
口腔ヘルペス Oral herpes	1 (0.6%)	4 (2.0%)	5 (1.4%)	5 (1.2%)
インフルエンザ Influenza	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
副鼻腔炎 Sinusitis	0	0	0	0
下気道感染 Lower respiratory tract infection	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
敗血症 Sepsis	0	0	0	0
蜂巣炎 Cellulitis	0	0	0	0
大腸菌性尿路感染 Escherichia urinary tract infection	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
肺感染 Lung infection	0	0	0	0
口腔カンジダ症 Oral candidiasis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
憩室炎 Diverticulitis	0	0	0	0
ウイルス感染 Viral infection	0	0	0	0
クロストリジウム・ディフィシレ大腸炎 Clostridium difficile colitis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
結膜炎 Conjunctivitis	0	0	0	0
耳感染 Ear infection	0	0	0	0
せつ Furuncle	0	0	0	0
単純ヘルペス Herpes simplex	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
中耳炎 Otitis media	0	0	0	0
真菌感染 Fungal infection	0	0	0	0
皮膚真菌感染 Fungal skin infection	0	0	0	0
消化管感染 Gastrointestinal infection	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
限局性感染 Localised infection	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
外耳炎 Otitis externa	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
細菌性肺炎 Pneumonia bacterial	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
腎盂腎炎 Pyelonephritis	0	0	0	0
ボレリア感染 Borrelia infection	0	0	0	0
クロストリジウム・ディフィシレ感染 Clostridium difficile infection	0	0	0	0
丹毒 Erysipelas	0	0	0	0
サルモネラ菌性胃腸炎 Gastroenteritis salmonella	0	0	0	0
ウイルス性胃腸炎 Gastroenteritis viral	0	0	0	0
陰部ヘルペス Genital herpes	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
咽頭炎 Pharyngitis	0	0	0	0
ウイルス性肺炎 Pneumonia viral	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
扁桃炎 Tonsillitis	0	0	0	0
水痘帯状疱疹ウイルス感染 Varicella zoster virus infection	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
創傷感染 Wound infection	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
皮膚感染 Skin infection	0	0	0	1 (0.2%)
鼻炎 Rhinitis	0	0	0	0
毛包炎 Folliculitis	0	0	0	0
歯肉炎 Gingivitis	0	0	0	0
喉頭炎 Laryngitis	0	0	0	0
歯周炎 Periodontitis	0	0	0	0
腹部敗血症 Abdominal sepsis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
四肢膿瘍 Abscess limb	0	0	0	0
菌血症 Bacteraemia	0	0	0	0
気管支肺アスペルギルス症 Bronchopulmonary aspergillosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
カンジダ感染 Candida infection	0	0	0	0
医療機器関連感染 Device related infection	0	0	0	0
感染性腸炎 Enteritis infectious	0	0	0	0
感染性小腸結腸炎 Enterocolitis infectious	0	0	0	0
大腸菌感染 Escherichia infection	0	0	0	0
眼感染 Eye infection	0	0	0	0
真菌性食道炎 Fungal oesophagitis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
壊疽 Gangrene	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
消化器カンジダ症 Gastrointestinal candidiasis	0	0	0	0
ヘルペス性皮膚炎 Herpes dermatitis	0	0	0	0
感染性皮膚嚢腫 Infected dermal cyst	0	0	0	0
感染性皮膚潰瘍 Infected skin ulcer	0	0	0	0
迷路炎 Labyrinthitis	0	0	0	0
筋膿瘍 Muscle abscess	0	0	0	0
鼻ヘルペス Nasal herpes	0	0	0	0
神経ボレリア症 Neuroborreliosis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
百日咳 Pertussis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
ピコルナウイルス感染 Picornavirus infection	0	0	0	0
ＲＳウイルス肺炎 Pneumonia respiratory syncytial viral	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
術後創感染 Postoperative wound infection	0	0	0	0
肺敗血症 Pulmonary sepsis	0	0	0	0
肺結核 Pulmonary tuberculosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
敗血症性ショック Septic shock	0	0	0	0
セラチア性菌血症 Serratia bacteraemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
赤痢菌感染 Shigella infection	0	0	0	0
唾液腺炎 Sialoadenitis	0	0	0	0
皮下組織膿瘍 Subcutaneous abscess	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
破傷風 Tetanus	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
歯膿瘍 Tooth abscess	0	0	0	0
歯感染 Tooth infection	0	0	0	0
結核 Tuberculosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
前庭神経炎 Vestibular neuronitis	0	0	0	0
ウイルス性ぶどう膜炎 Viral uveitis	0	0	0	0
癬風 Tinea versicolour	0	0	0	0
肛門膿瘍 Anal abscess	0	0	0	0
大腸菌性敗血症 Escherichia sepsis	0	0	0	0
感染 Infection	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
口唇感染 Lip infection	0	0	0	0
ライム病 Lyme disease	0	0	0	0
処置後感染 Post procedural infection	0	0	0	0
腎盂膀胱炎 Pyelocystitis	0	0	0	0
陰嚢膿瘍 Scrotal abscess	0	0	0	0
皮膚細菌感染 Skin bacterial infection	0	0	0	0
ブドウ球菌感染 Staphylococcal infection	0	0	0	0
レンサ球菌性敗血症 Streptococcal sepsis	0	0	0	0
腟感染 Vaginal infection	0	0	0	0
胃腸障害 Gastrointestinal disorders	12 (7.0%)	40 (20.3%)	52 (14.1%)	95 (23.1%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
下痢 Diarrhoea	3 (1.8%)	14 (7.1%)	17 (4.6%)	34 (8.3%)
悪心 Nausea	1 (0.6%)	21 (10.7%)	22 (6.0%)	44 (10.7%)
腹痛 Abdominal pain	2 (1.2%)	5 (2.5%)	7 (1.9%)	14 (3.4%)
便秘 Constipation	0	0	0	2 (0.5%)
嘔吐 Vomiting	1 (0.6%)	4 (2.0%)	5 (1.4%)	10 (2.4%)
胃食道逆流性疾患 Gastrooesophageal reflux disease	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
消化不良 Dyspepsia	1 (0.6%)	2 (1.0%)	3 (0.8%)	4 (1.0%)
上腹部痛 Abdominal pain upper	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
腹部膨満 Abdominal distension	1 (0.6%)	0	1 (0.3%)	4 (1.0%)
腹水 Ascites	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
腹部不快感 Abdominal discomfort	0	1 (0.5%)	1 (0.3%)	3 (0.7%)
胃炎 Gastritis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
食道静脈瘤 Varices oesophageal	0	0	0	0
口内乾燥 Dry mouth	0	1 (0.5%)	1 (0.3%)	3 (0.7%)
歯痛 Toothache	0	0	0	0
痔核 Haemorrhoids	0	0	0	0
直腸出血 Rectal haemorrhage	0	0	0	1 (0.2%)
鼠径ヘルニア Inguinal hernia	0	0	0	0
下腹部痛 Abdominal pain lower	0	0	0	0
びらん性胃炎 Gastritis erosive	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
大腸炎 Colitis	0	0	0	0
心窩部不快感 Epigastric discomfort	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
裂孔ヘルニア Hiatus hernia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
口腔内出血 Mouth haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
口内炎 Stomatitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
鼓腸 Flatulence	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
歯肉出血 Gingival bleeding	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
肛門失禁 Anal incontinence	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
口角口唇炎 Angular cheilitis	0	0	0	0
齲歯 Dental caries	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
憩室 Diverticulum	0	0	0	0
食道静脈瘤出血 Oesophageal varices haemorrhage	0	0	0	0
口腔内痛 Oral pain	0	0	0	0
口唇炎 Cheilitis	0	0	0	0
嚥下障害 Dysphagia	0	0	0	0
胃潰瘍 Gastric ulcer	0	0	0	0
口腔内潰瘍形成 Mouth ulceration	0	0	0	0
レッチング Retching	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
小腸閉塞 Small intestinal obstruction	0	0	0	0
腹部硬直 Abdominal rigidity	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
異常便 Abnormal faeces	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
水疱性出血性口峡炎 Angina bullosa haemorrhagica	0	0	0	0
アフタ性潰瘍 Aphthous ulcer	0	0	0	0
慢性胃炎 Chronic gastritis	0	0	0	0
便意切迫 Defaecation urgency	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
歯組織の壊死 Dental necrosis	0	0	0	0
出血性十二指腸潰瘍 Duodenal ulcer haemorrhage	0	0	0	0
十二指腸炎 Duodenitis	0	0	0	0
腸炎 Enterocolitis	0	0	0	0
腹膜垂炎 Epiploic appendagitis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
食中毒 Food poisoning	0	0	0	0
胃障害 Gastric disorder	0	0	0	0
胃出血 Gastric haemorrhage	0	0	0	0
出血性胃潰瘍 Gastric ulcer haemorrhage	0	0	0	0
胃腸障害 Gastrointestinal disorder	0	0	0	0
胃腸出血 Gastrointestinal haemorrhage	0	0	0	0
消化管運動障害 Gastrointestinal motility disorder	0	0	0	0
消化器痛 Gastrointestinal pain	0	0	0	0
胃腸音異常 Gastrointestinal sounds abnormal	0	0	0	0
歯肉潰瘍 Gingival ulceration	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
舌痛 Glossodynia	0	0	0	0
吐血 Haematemesis	0	0	0	0
口の感覚鈍麻 Hypoaesthesia oral	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
イレウス Ileus	0	0	0	0
腸梗塞 Intestinal infarction	0	0	0	0
腹腔内血腫 Intra-abdominal haematoma	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
下部消化管出血 Lower gastrointestinal haemorrhage	0	0	0	0
メレナ Melaena	0	0	0	0
口腔粘膜血腫 Oral mucosa haematoma	0	0	0	0
膵嚢胞 Pancreatic cyst	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
膵脂肪変性 Pancreatic steatosis	0	0	0	0
膵炎 Pancreatitis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
歯周病 Periodontal disease	0	0	0	0
咳嗽後嘔吐 Post-tussive vomiting	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
小腸出血 Small intestinal haemorrhage	0	0	0	0
埋伏歯 Tooth impacted	0	0	0	0
臍ヘルニア Umbilical hernia	0	0	0	0
上部消化管出血 Upper gastrointestinal haemorrhage	0	0	0	0
内臓静脈血栓症 Visceral venous thrombosis	0	0	0	0
小腸炎 Enteritis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
肛門周囲痛 Proctalgia	0	0	0	0
軟便 Faeces soft	0	0	0	0
胃ポリープ Gastric polyps	0	0	0	0
血便排泄 Haematochezia	0	0	0	1 (0.2%)
痔出血 Haemorrhoidal haemorrhage	0	0	0	0
口唇痛 Lip pain	0	0	0	0
腸間膜静脈血栓症 Mesenteric vein thrombosis	0	0	0	0
嚥下痛 Odynophagia	0	0	0	0
食道炎 Oesophagitis	0	0	0	0
消化性潰瘍 Peptic ulcer	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
舌紅斑 Tongue erythema	0	0	0	0
一般・全身障害および投与部位の状態 General disorders and administration site conditions	13 (7.6%)	30 (15.2%)	43 (11.7%)	66 (16.1%)
疲労 Fatigue	2 (1.2%)	14 (7.1%)	16 (4.3%)	30 (7.3%)
発熱 Pyrexia	3 (1.8%)	2 (1.0%)	5 (1.4%)	8 (1.9%)
末梢性浮腫 Oedema peripheral	2 (1.2%)	3 (1.5%)	5 (1.4%)	5 (1.2%)
無力症 Asthenia	6 (3.5%)	6 (3.0%)	12 (3.3%)	16 (3.9%)
胸痛 Chest pain	0	0	0	1 (0.2%)
インフルエンザ様疾患 Influenza like illness	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
末梢腫脹 Peripheral swelling	0	0	0	0
早期満腹 Early satiety	0	2 (1.0%)	2 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
悪寒 Chills	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
倦怠感 Malaise	0	1 (0.5%)	1 (0.3%)	3 (0.7%)
非心臓性胸痛 Non-cardiac chest pain	0	0	0	0
疼痛 Pain	0	0	0	0
胸部不快感 Chest discomfort	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
熱感 Feeling hot	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
死亡 Death	0	0	0	0
歩行障害 Gait disturbance	0	0	0	1 (0.2%)
全身性浮腫 Generalised oedema	0	0	0	0
粘膜の炎症 Mucosal inflammation	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
浮腫 Oedema	0	0	0	0
全身健康状態悪化 General physical health deterioration	0	0	0	0
治癒不良 Impaired healing	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
腫脹 Swelling	0	0	0	0
口渇 Thirst	0	0	0	0
カテーテル留置部位疼痛 Catheter site pain	0	0	0	0
医療機器関連合併症 Complication associated with device	0	0	0	0
不快感 Discomfort	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
薬剤離脱症候群 Drug withdrawal syndrome	0	0	0	0
顔面浮腫 Face oedema	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
高熱 Hyperthermia	0	0	0	0
注入部位疼痛 Infusion site pain	0	0	0	0
注射部位出血 Injection site haemorrhage	0	0	0	0
多臓器機能不全症候群 Multiple organ dysfunction syndrome	0	0	0	0
乾燥症 Xerosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
重力性浮腫 Gravitational oedema	0	0	0	2 (0.5%)
捻髪音 Crepitations	0	0	0	0
顔面痛 Facial pain	0	0	0	0
硬結 Induration	0	0	0	0
炎症 Inflammation	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
突然死 Sudden death	0	0	0	0
血液およびリンパ系障害 Blood and lymphatic system disorders	32 (18.7%)	48 (24.4%)	80 (21.7%)	110 (26.8%)
貧血 Anaemia	17 (9.9%)	12 (6.1%)	29 (7.9%)	39 (9.5%)
血小板減少症 Thrombocytopenia	18 (10.5%)	30 (15.2%)	48 (13.0%)	71 (17.3%)
好中球減少症 Neutropenia	7 (4.1%)	6 (3.0%)	13 (3.5%)	17 (4.1%)
白血球増加症 Leukocytosis	1 (0.6%)	3 (1.5%)	4 (1.1%)	7 (1.7%)
白血球減少症 Leukopenia	4 (2.3%)	6 (3.0%)	10 (2.7%)	12 (2.9%)
血小板増加症 Thrombocytosis	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
リンパ球減少症 Lymphopenia	1 (0.6%)	3 (1.5%)	4 (1.1%)	4 (1.0%)
脾腫 Splenomegaly	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
脾臓梗塞 Splenic infarction	0	0	0	0
赤血球増加症 Polycythaemia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
発熱性好中球減少症 Febrile neutropenia	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
内出血発生の増加傾向 Increased tendency to bruise	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
脾血腫 Splenic haematoma	0	0	0	0
骨髄毒性 Bone marrow toxicity	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
凝血異常 Coagulopathy	0	0	0	0
溶血 Haemolysis	0	0	0	0
溶血性貧血 Haemolytic anaemia	0	0	0	0
過粘稠度症候群 Hyperviscosity syndrome	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
鉄欠乏性貧血 Iron deficiency anaemia	0	0	0	0
肥満細胞症 Mastocytosis	0	0	0	0
好中球増加症 Neutrophilia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
脾臓障害 Spleen disorder	0	0	0	0
脾臓血栓症 Splenic thrombosis	0	0	0	0
特発性血腫 Spontaneous haematoma	0	0	0	0
低プロトロンビン血症 Hypoprothrombinaemia	0	0	0	0
リンパ節石灰化 Lymph node calcification	0	0	0	0
リンパ節症 Lymphadenopathy	0	0	0	0
リンパ球増加症 Lymphocytosis	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
微小血管症性溶血性貧血 Microangiopathic haemolytic anaemia	0	0	0	0
神経系障害 Nervous system disorders	27 (15.8%)	51 (25.9%)	78 (21.2%)	131 (31.9%)
浮動性めまい Dizziness	4 (2.3%)	13 (6.6%)	17 (4.6%)	40 (9.7%)
末梢性感覚ニューロパチー Peripheral sensory neuropathy	10 (5.8%)	20 (10.2%)	30 (8.2%)	46 (11.2%)
頭痛 Headache	3 (1.8%)	10 (5.1%)	13 (3.5%)	38 (9.2%)
錯感覚 Paraesthesia	3 (1.8%)	7 (3.6%)	10 (2.7%)	21 (5.1%)
感覚鈍麻 Hypoaesthesia	2 (1.2%)	3 (1.5%)	5 (1.4%)	6 (1.5%)
失神 Syncope	1 (0.6%)	2 (1.0%)	3 (0.8%)	4 (1.0%)
嗜眠 Lethargy	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
坐骨神経痛 Sciatica	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
平衡障害 Balance disorder	0	0	0	2 (0.5%)
失神寸前の状態 Presyncope	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
健忘 Amnesia	0	0	0	0
味覚異常 Dysgeusia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
末梢性ニューロパチー Neuropathy peripheral	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
傾眠 Somnolence	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
脳血管発作 Cerebrovascular accident	0	0	0	0
一過性脳虚血発作 Transient ischaemic attack	0	0	0	0
神経痛 Neuralgia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
灼熱感 Burning sensation	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
意識消失 Loss of consciousness	0	0	0	0
感覚障害 Sensory disturbance	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
声帯麻痺 Vocal cord paralysis	0	0	0	0
記憶障害 Memory impairment	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
振戦 Tremor	1 (0.6%)	0	1 (0.3%)	3 (0.7%)
注意力障害 Disturbance in attention	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
体位性めまい Dizziness postural	0	0	0	0
異常感覚 Dysaesthesia	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
蟻走感 Formication	0	0	0	0
末梢性運動ニューロパチー Peripheral motor neuropathy	0	1 (0.5%)	1 (0.3%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
味覚消失 Ageusia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
運動失調 Ataxia	0	0	0	0
小脳卒中 Cerebellar stroke	0	0	0	0
大脳萎縮 Cerebral atrophy	0	0	0	0
脳微小血管症 Cerebral microangiopathy	0	0	0	0
大脳静脈血栓症 Cerebral venous thrombosis	0	0	0	0
脳血管不全 Cerebrovascular insufficiency	0	0	0	0
認知障害 Cognitive disorder	0	0	0	0
認知症 Dementia	0	0	0	0
脱髄 Demyelination	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
前頭側頭型認知症 Frontotemporal dementia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
出血性卒中 Haemorrhagic stroke	0	0	0	0
不全片麻痺 Hemiparesis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ラクナ梗塞 Lacunar infarction	0	0	0	0
白質脳症 Leukoencephalopathy	0	0	0	0
ミオトニー Myotonia	0	0	0	0
眼振 Nystagmus	0	0	0	0
後頭神経痛 Occipital neuralgia	0	0	0	0
パーキンソン病 Parkinson's disease	0	0	0	0
末梢性感覚運動ニューロパチー Peripheral sensorimotor neuropathy	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
多発ニューロパチー Polyneuropathy	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
ヘルペス後神経痛 Post herpetic neuralgia	0	0	0	0
下肢静止不能症候群 Restless legs syndrome	0	0	0	0
副鼻腔炎に伴う頭痛 Sinus headache	0	0	0	0
くも膜下出血 Subarachnoid haemorrhage	0	0	0	0
三叉神経痛 Trigeminal neuralgia	0	0	0	0
味覚障害 Taste disorder	0	0	0	2 (0.5%)
脳虚血 Cerebral ischaemia	0	0	0	0
頚腕症候群 Cervicobrachial syndrome	0	0	0	0
前兆を伴う片頭痛 Migraine with aura	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
神経系障害 Nervous system disorder	0	0	0	1 (0.2%)
代謝および栄養障害 Metabolism and nutrition disorders	13 (7.6%)	21 (10.7%)	34 (9.2%)	45 (10.9%)
食欲減退 Decreased appetite	2 (1.2%)	6 (3.0%)	8 (2.2%)	11 (2.7%)
高尿酸血症 Hyperuricaemia	2 (1.2%)	1 (0.5%)	3 (0.8%)	5 (1.2%)
ビタミンＢ１欠乏 Vitamin B1 deficiency	5 (2.9%)	4 (2.0%)	9 (2.4%)	13 (3.2%)
高カリウム血症 Hyperkalaemia	0	0	0	3 (0.7%)
低カリウム血症 Hypokalaemia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
痛風 Gout	0	0	0	0
糖尿病 Diabetes mellitus	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
低カルシウム血症 Hypocalcaemia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
低ナトリウム血症 Hyponatraemia	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
高血糖 Hyperglycaemia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
脱水 Dehydration	0	0	0	0
低血糖 Hypoglycaemia	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
低マグネシウム血症 Hypomagnesaemia	0	0	0	0
鉄欠乏 Iron deficiency	0	0	0	0
低アルブミン血症 Hypoalbuminaemia	0	0	0	0
高コレステロール血症 Hypercholesterolaemia	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
高トリグリセリド血症 Hypertriglyceridaemia	0	0	0	0
ビタミンD欠乏 Vitamin D deficiency	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
体液貯留 Fluid retention	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
鉄過剰 Iron overload	0	0	0	0
ビタミンＢ群欠乏 Vitamin B complex deficiency	0	0	0	1 (0.2%)
高カルシウム血症 Hypercalcaemia	0	0	0	0
高脂血症 Hyperlipidaemia	0	0	0	0
低リン酸血症 Hypophosphataemia	0	0	0	0
異常体重減少 Abnormal loss of weight	0	0	0	0
悪液質 Cachexia	0	0	0	0
コントロール不良の糖尿病 Diabetes mellitus inadequate control	0	0	0	0
脂質異常症 Dyslipidaemia	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
電解質失調 Electrolyte imbalance	0	0	0	0
水分過負荷 Fluid overload	0	0	0	0
葉酸欠乏 Folate deficiency	0	0	0	0
高フェリチン血症 Hyperferritinaemia	0	0	0	0
高マグネシウム血症 Hypermagnesaemia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
高ナトリウム血症 Hypernatraemia	0	0	0	0
低蛋白血症 Hypoproteinaemia	0	0	0	0
代謝性アシドーシス Metabolic acidosis	0	0	0	0
ビタミン群欠乏 Multi-vitamin deficiency	0	0	0	0
偽高カリウム血症 Pseudohyperkalaemia	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	OL Phase (Week 24 Onward)			Overall Exposed to MMB
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腫瘍崩壊症候群 Tumour lysis syndrome	0	0	0	0
２型糖尿病 Type 2 diabetes mellitus	0	0	0	0
ビタミンＢ１２欠乏 Vitamin B12 deficiency	0	0	0	0
ビタミンＢ６欠乏 Vitamin B6 deficiency	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ヘモジデリン沈着症 Haemosiderosis	0	0	0	0
栄養障害 Malnutrition	0	0	0	0
ビタミンＫ欠乏 Vitamin K deficiency	0	0	0	0
筋骨格系および結合組織障害 Musculoskeletal and connective tissue disorders	7 (4.1%)	20 (10.2%)	27 (7.3%)	41 (10.0%)
四肢痛 Pain in extremity	1 (0.6%)	6 (3.0%)	7 (1.9%)	10 (2.4%)
背部痛 Back pain	0	1 (0.5%)	1 (0.3%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
関節痛 Arthralgia	1 (0.6%)	2 (1.0%)	3 (0.8%)	6 (1.5%)
骨痛 Bone pain	1 (0.6%)	5 (2.5%)	6 (1.6%)	6 (1.5%)
筋骨格痛 Musculoskeletal pain	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
筋肉痛 Myalgia	2 (1.2%)	6 (3.0%)	8 (2.2%)	10 (2.4%)
筋力低下 Muscular weakness	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
筋痙縮 Muscle spasms	0	3 (1.5%)	3 (0.8%)	7 (1.7%)
脊椎痛 Spinal pain	0	0	0	1 (0.2%)
変形性関節症 Osteoarthritis	0	0	0	0
関節炎 Arthritis	0	0	0	0
滑液包炎 Bursitis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
筋骨格硬直 Musculoskeletal stiffness	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
肩回旋筋腱板症候群 Rotator cuff syndrome	0	0	0	0
側腹部痛 Flank pain	0	0	0	0
鼠径部痛 Groin pain	0	0	0	0
筋骨格系胸痛 Musculoskeletal chest pain	0	0	0	0
顎痛 Pain in jaw	0	0	0	0
反応性関節炎 Arthritis reactive	0	0	0	0
椎間板突出 Intervertebral disc protrusion	0	0	0	0
関節滲出液 Joint effusion	0	0	0	0
頚部痛 Neck pain	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
痛風性関節炎 Gouty arthritis	0	0	0	0
骨減少症 Osteopenia	0	0	0	0
変形性脊椎症 Spinal osteoarthritis	0	0	0	0
骨病変 Bone lesion	0	0	0	0
胸壁血腫 Chest wall haematoma	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ピロリン酸カルシウム結晶性軟骨石灰化症 Chondrocalcinosis pyrophosphate	0	0	0	0
肋軟骨炎 Costochondritis	0	0	0	0
筋膜炎 Fasciitis	0	0	0	0
関節腫脹 Joint swelling	0	0	0	0
四肢不快感 Limb discomfort	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
運動性低下 Mobility decreased	0	0	0	0
筋萎縮 Muscle atrophy	0	0	0	0
筋肉疲労 Muscle fatigue	0	0	0	0
筋肉内出血 Muscle haemorrhage	0	0	0	0
骨溶解 Osteolysis	0	0	0	0
骨粗鬆症 Osteoporosis	0	0	0	0
骨硬化症 Osteosclerosis	0	0	0	0
関節周囲炎 Periarthritis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
腱痛 Tendon pain	0	0	0	0
椎骨病変 Vertebral lesion	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
滑液貯留 Bursal fluid accumulation	0	0	0	0
足変形 Foot deformity	0	0	0	0
シェーグレン症候群 Sjogren's syndrome	0	0	0	1 (0.2%)
腱炎 Tendonitis	0	0	0	0
呼吸器、胸郭および縦隔障害 Respiratory, thoracic and mediastinal disorders	10 (5.8%)	13 (6.6%)	23 (6.3%)	32 (7.8%)
咳嗽 Cough	5 (2.9%)	7 (3.6%)	12 (3.3%)	16 (3.9%)
呼吸困難 Dyspnoea	1 (0.6%)	4 (2.0%)	5 (1.4%)	9 (2.2%)
鼻出血 Epistaxis	1 (0.6%)	3 (1.5%)	4 (1.1%)	5 (1.2%)
胸水 Pleural effusion	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
口腔咽頭痛 Oropharyngeal pain	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
労作性呼吸困難 Dyspnoea exertional	0	0	0	2 (0.5%)
湿性咳嗽 Productive cough	0	0	0	0
低酸素症 Hypoxia	0	0	0	0
慢性閉塞性肺疾患 Chronic obstructive pulmonary disease	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
呼吸不全 Respiratory failure	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肺塞栓症 Pulmonary embolism	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
喘息 Asthma	0	0	0	0
胸膜炎 Pleurisy	0	0	0	0
発声障害 Dysphonia	0	0	0	0
鼻漏 Rhinorrhoea	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
急性呼吸不全 Acute respiratory failure	0	0	0	0
慢性気管支炎 Bronchitis chronic	0	0	0	0
肺硬化 Lung consolidation	0	0	0	0
肺水腫 Pulmonary oedema	0	0	0	0
喘鳴 Wheezing	0	0	0	0
ラ音 Rales	0	0	0	1 (0.2%)
喀血 Haemoptysis	0	0	0	0
しゃっくり Hiccups	0	0	0	0
鼻閉 Nasal congestion	0	0	0	0
肺肉芽腫 Pulmonary granuloma	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
上気道咳症候群 Upper-airway cough syndrome	0	0	0	0
急性肺水腫 Acute pulmonary oedema	0	0	0	0
胞隔炎 Alveolitis	0	0	0	0
気管支拡張症 Bronchiectasis	0	0	0	0
カタル Catarrh	0	0	0	0
肺気腫 Emphysema	0	0	0	0
低換気 Hypoventilation	0	0	0	0
喉頭の炎症 Laryngeal inflammation	0	0	0	0
肺障害 Lung disorder	0	0	0	0
鼻乾燥 Nasal dryness	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
口腔咽頭不快感 Oropharyngeal discomfort	0	0	0	0
起坐呼吸 Orthopnoea	0	0	0	0
誤嚥性肺炎 Pneumonia aspiration	0	0	0	0
肺高血圧症 Pulmonary hypertension	0	0	0	0
肺腫瘤 Pulmonary mass	0	0	0	0
呼吸停止 Respiratory arrest	0	0	0	0
副鼻腔うっ血 Sinus congestion	0	0	0	0
副鼻腔痛 Sinus pain	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
睡眠時無呼吸症候群 Sleep apnoea syndrome	0	0	0	0
頻呼吸 Tachypnoea	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
咽喉乾燥 Dry throat	0	0	0	0
発作性夜間呼吸困難 Dyspnoea paroxysmal nocturnal	0	0	0	0
呼吸時疼痛 Painful respiration	0	0	0	0
咽頭潰瘍 Pharyngeal ulceration	0	0	0	0
肺線維症 Pulmonary fibrosis	0	0	0	0
逆流性喉頭炎 Reflux laryngitis	0	0	0	0
咽喉絞扼感 Throat tightness	0	0	0	0
皮膚および皮下組織障害 Skin and subcutaneous tissue disorders	14 (8.2%)	23 (11.7%)	37 (10.1%)	55 (13.4%)
そう痒症 Pruritus	2 (1.2%)	3 (1.5%)	5 (1.4%)	8 (1.9%)
寝汗 Night sweats	2 (1.2%)	2 (1.0%)	4 (1.1%)	6 (1.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
発疹 Rash	1 (0.6%)	7 (3.6%)	8 (2.2%)	12 (2.9%)
多汗症 Hyperhidrosis	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
紅斑 Erythema	2 (1.2%)	1 (0.5%)	3 (0.8%)	8 (1.9%)
点状出血 Petechiae	0	3 (1.5%)	3 (0.8%)	4 (1.0%)
全身性そう痒症 Pruritus generalised	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
斑状丘疹状皮疹 Rash maculo-papular	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
全身性皮疹 Rash generalised	0	0	0	1 (0.2%)
皮膚出血 Skin haemorrhage	0	0	0	0
光線角化症 Actinic keratosis	0	0	0	0
脱毛症 Alopecia	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
斑状出血 Ecchymosis	0	0	0	2 (0.5%)
アレルギー性皮膚炎 Dermatitis allergic	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
斑状皮疹 Rash macular	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
冷汗 Cold sweat	0	0	0	0
皮膚嚢腫 Dermal cyst	0	0	0	0
丘疹性皮疹 Rash papular	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
酒さ Rosacea	0	0	0	0
皮膚剥脱 Skin exfoliation	0	0	0	0
中毒性皮疹 Toxic skin eruption	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
紅斑性皮疹 Rash erythematous	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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Population: Safety Analysis Set
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
皮膚病変 Skin lesion	0	0	0	0
皮膚潰瘍 Skin ulcer	0	0	0	1 (0.2%)
水疱 Blister	0	0	0	0
薬疹 Drug eruption	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
過角化 Hyperkeratosis	0	0	0	0
嵌入爪 Ingrowing nail	0	0	0	0
皮膚炎 Dermatitis	0	0	0	0
全身性剥脱性皮膚炎 Dermatitis exfoliative generalised	0	0	0	0
皮膚症 Dermatosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
過敏性血管炎 Hypersensitivity vasculitis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
間擦疹 Intertrigo	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
苔癬様角化症 Lichenoid keratosis	0	0	0	0
爪変色 Nail discolouration	0	0	0	0
丘疹 Papule	0	0	0	0
乾癬 Psoriasis	0	0	0	0
紫斑 Purpura	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
皮膚障害 Skin disorder	0	0	0	0
皮膚脆弱性 Skin fragility	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
顔面腫脹 Swelling face	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
蕁麻疹 Urticaria	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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Population: Safety Analysis Set
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
接触皮膚炎 Dermatitis contact	0	0	0	0
皮膚乾燥 Dry skin	0	0	0	1 (0.2%)
血性水疱 Blood blister	0	0	0	0
湿疹 Eczema	0	0	0	0
紅色症 Erythrosis	0	0	0	0
毛孔性皮疹 Rash follicular	0	0	0	1 (0.2%)
毛細血管拡張症 Telangiectasia	0	0	0	0
臨床検査 Investigations	18 (10.5%)	21 (10.7%)	39 (10.6%)	51 (12.4%)
血中クレアチニン増加 Blood creatinine increased	4 (2.3%)	5 (2.5%)	9 (2.4%)	13 (3.2%)
アラニンアミノトランスフェラーゼ増加 Alanine aminotransferase increased	2 (1.2%)	6 (3.0%)	8 (2.2%)	15 (3.6%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
アスパラギン酸アミノトランスフェラーゼ増加 Aspartate aminotransferase increased	1 (0.6%)	5 (2.5%)	6 (1.6%)	11 (2.7%)
体重減少 Weight decreased	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
血中ビリルビン増加 Blood bilirubin increased	4 (2.3%)	2 (1.0%)	6 (1.6%)	7 (1.7%)
γ－グルタミルトランスフェラーゼ増加 Gamma-glutamyltransferase increased	2 (1.2%)	2 (1.0%)	4 (1.1%)	6 (1.5%)
活性化部分トロンボプラスチン時間延長 Activated partial thromboplastin time prolonged	1 (0.6%)	4 (2.0%)	5 (1.4%)	6 (1.5%)
体重増加 Weight increased	2 (1.2%)	2 (1.0%)	4 (1.1%)	4 (1.0%)
腎クレアチニン・クリアランス減少 Creatinine renal clearance decreased	2 (1.2%)	2 (1.0%)	4 (1.1%)	6 (1.5%)
血中葉酸減少 Blood folate decreased	0	0	0	0
血中乳酸脱水素酵素増加 Blood lactate dehydrogenase increased	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
ヘマトクリット増加 Haematocrit increased	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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	治験薬との因果関係がある有害事象			
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System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
ヘモグロビン増加 Haemoglobin increased	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
血中アルカリホスファターゼ増加 Blood alkaline phosphatase increased	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
トランスアミナーゼ上昇 Transaminases increased	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
芽球細胞数増加 Blast cell count increased	0	0	0	0
血中クロール増加 Blood chloride increased	0	0	0	0
血中鉄減少 Blood iron decreased	0	0	0	0
国際標準比増加 International normalised ratio increased	0	0	0	0
プロトロンビン時間延長 Prothrombin time prolonged	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
心電図ＱＴ延長 Electrocardiogram QT prolonged	0	0	0	1 (0.2%)
総蛋白増加 Protein total increased	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
抗リン脂質抗体陽性 Antiphospholipid antibodies positive	0	0	0	0
血中クレアチンホスホキナーゼ増加 Blood creatine phosphokinase increased	0	0	0	0
血中鉄増加 Blood iron increased	0	0	0	0
血圧上昇 Blood pressure increased	0	0	0	0
血中尿素増加 Blood urea increased	0	0	0	0
胸部X線異常 Chest X-ray abnormal	0	0	0	0
骨盤コンピュータ断層撮影異常 Computerised tomogram pelvis abnormal	0	0	0	0
大腿動脈雑音 Femoral bruit	0	0	0	0
糸球体濾過率減少 Glomerular filtration rate decreased	0	0	0	0
肝酵素上昇 Hepatic enzyme increased	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
眼圧上昇 Intraocular pressure increased	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
肝機能検査異常 Liver function test abnormal	0	0	0	0
肝機能検査値上昇 Liver function test increased	0	0	0	0
平均赤血球容積減少 Mean cell volume decreased	0	0	0	0
血清フェリチン増加 Serum ferritin increased	0	0	0	0
ビタミンＢ１減少 Vitamin B1 decreased	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
尿中白血球陽性 White blood cells urine positive	0	0	0	0
心雑音 Cardiac murmur	0	0	0	0
血中重炭酸塩減少 Blood bicarbonate decreased	0	0	0	1 (0.2%)
血中乳酸増加 Blood lactic acid increased	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
心電図ＳＴ部分下降 Electrocardiogram ST segment depression	0	0	0	0
心電図異常 Electrocardiogram abnormal	0	0	0	0
ヘプシジン減少 Hepcidin decreased	0	0	0	0
リパーゼ増加 Lipase increased	0	0	0	1 (0.2%)
リンパ節触知 Lymph node palpable	0	0	0	0
好中球数増加 Neutrophil count increased	0	0	0	0
血管障害 Vascular disorders	8 (4.7%)	11 (5.6%)	19 (5.2%)	45 (10.9%)
高血圧 Hypertension	1 (0.6%)	3 (1.5%)	4 (1.1%)	7 (1.7%)
低血圧 Hypotension	1 (0.6%)	2 (1.0%)	3 (0.8%)	16 (3.9%)
血腫 Haematoma	2 (1.2%)	2 (1.0%)	4 (1.1%)	6 (1.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
ほてり Hot flush	1 (0.6%)	3 (1.5%)	4 (1.1%)	4 (1.0%)
潮紅 Flushing	1 (0.6%)	3 (1.5%)	4 (1.1%)	17 (4.1%)
静脈炎 Phlebitis	0	0	0	0
大動脈狭窄 Aortic stenosis	0	0	0	0
深部静脈血栓症 Deep vein thrombosis	0	0	0	0
動脈硬化症 Arteriosclerosis	0	0	0	0
起立性低血圧 Orthostatic hypotension	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
表在性血栓性静脈炎 Thrombophlebitis superficial	0	0	0	0
静脈瘤 Varicose vein	0	0	0	0
大動脈硬化症 Aortic arteriosclerosis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
出血 Haemorrhage	0	0	0	0
末梢動脈閉塞性疾患 Peripheral arterial occlusive disease	0	0	0	0
四肢静脈血栓症 Venous thrombosis limb	0	0	0	0
末梢動脈狭窄 Peripheral artery stenosis	0	0	0	0
末梢循環不良 Poor peripheral circulation	0	0	0	0
血栓症 Thrombosis	0	0	0	0
血管拡張 Vasodilatation	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
大動脈解離 Aortic dissection	0	0	0	0
大動脈血栓症 Aortic thrombosis	0	0	0	1 (0.2%)
本態性高血圧症 Essential hypertension	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
末梢冷感 Peripheral coldness	0	0	0	1 (0.2%)
静脈穿刺不良 Poor venous access	0	0	0	0
血栓性静脈炎 Thrombophlebitis	0	0	0	0
腎および尿路障害 Renal and urinary disorders	9 (5.3%)	9 (4.6%)	18 (4.9%)	20 (4.9%)
急性腎障害 Acute kidney injury	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
腎不全 Renal failure	3 (1.8%)	2 (1.0%)	5 (1.4%)	6 (1.5%)
腎機能障害 Renal impairment	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
排尿困難 Dysuria	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
慢性腎臓病 Chronic kidney disease	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
血尿 Haematuria	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
蛋白尿 Proteinuria	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
頻尿 Pollakiuria	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
夜間頻尿 Nocturia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
腎仙痛 Renal colic	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
腎結石症 Nephrolithiasis	0	0	0	1 (0.2%)
尿失禁 Urinary incontinence	0	0	0	0
膀胱痙縮 Bladder spasm	0	0	0	0
尿路結石 Calculus urinary	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
高血圧性腎症 Hypertensive nephropathy	0	0	0	0
緊張性膀胱 Hypertonic bladder	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
白血球尿 Leukocyturia	0	0	0	0
排尿異常 Micturition disorder	0	0	0	0
尿意切迫 Micturition urgency	0	0	0	0
腎症 Nephropathy	0	0	0	0
ネフローゼ症候群 Nephrotic syndrome	0	0	0	0
腎嚢胞 Renal cyst	0	0	0	0
腎障害 Renal disorder	0	0	0	0
腎尿細管壊死 Renal tubular necrosis	0	0	0	0
尿管結石症 Ureterolithiasis	0	0	0	0
尿道障害 Urethral disorder	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
着色尿 Chromaturia	0	0	0	0
多尿 Polyuria	0	0	0	0
膀胱ポリープ Urinary bladder polyp	0	0	0	0
尿閉 Urinary retention	0	0	0	0
尿路痛 Urinary tract pain	0	0	0	0
眼障害 Eye disorders	8 (4.7%)	15 (7.6%)	23 (6.3%)	36 (8.8%)
核性白内障 Cataract nuclear	3 (1.8%)	2 (1.0%)	5 (1.4%)	7 (1.7%)
皮質白内障 Cataract cortical	1 (0.6%)	2 (1.0%)	3 (0.8%)	4 (1.0%)
霧視 Vision blurred	1 (0.6%)	1 (0.5%)	2 (0.5%)	7 (1.7%)
視力障害 Visual impairment	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
ドライアイ Dry eye	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
結膜出血 Conjunctival haemorrhage	0	0	0	0
嚢下白内障 Cataract subcapsular	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
網膜出血 Retinal haemorrhage	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
糖尿病網膜症 Diabetic retinopathy	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
流涙増加 Lacrimation increased	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
眼痛 Eye pain	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
視力低下 Visual acuity reduced	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
複視 Diplopia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
眼出血 Eye haemorrhage	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
緑内障 Glaucoma	0	0	0	0
眼充血 Ocular hyperaemia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
白内障 Cataract	0	0	0	1 (0.2%)
眼刺激 Eye irritation	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
眼瞼浮腫 Eyelid oedema	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
角膜炎 Keratitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
黄斑変性 Macular degeneration	0	0	0	1 (0.2%)
眼瞼腫脹 Swelling of eyelid	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
硝子体浮遊物 Vitreous floaters	0	0	0	1 (0.2%)
眼瞼炎 Blepharitis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
眼瞼紅斑 Erythema of eyelid	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
眼瞼下垂 Eyelid ptosis	0	0	0	0
睫毛の成長 Growth of eyelashes	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
マイボーム腺機能不全 Meibomian gland dysfunction	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
網膜剥離 Retinal detachment	0	0	0	0
網膜瘢痕 Retinal scar	0	0	0	0
閃輝暗点 Scintillating scotoma	0	0	0	0
硝子体変性 Vitreous degeneration	0	0	0	0
眼部腫脹 Eye swelling	0	0	0	0
星状硝子体症 Hyalosis asteroid	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
眼窩浮腫 Orbital oedema	0	0	0	1 (0.2%)
眼窩周囲浮腫 Periorbital oedema	0	0	0	0
光視症 Photopsia	0	0	0	1 (0.2%)
傷害、中毒および処置合併症 Injury, poisoning and procedural complications	4 (2.3%)	6 (3.0%)	10 (2.7%)	14 (3.4%)
転倒 Fall	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
挫傷 Contusion	2 (1.2%)	3 (1.5%)	5 (1.4%)	8 (1.9%)
四肢損傷 Limb injury	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
処置による疼痛 Procedural pain	0	0	0	0
処置後出血 Post procedural haemorrhage	0	0	0	0
皮膚裂傷 Skin laceration	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
創傷 Wound	0	0	0	0
皮膚擦過傷 Skin abrasion	0	0	0	0
脊椎圧迫骨折 Spinal compression fracture	0	0	0	0
足骨折 Foot fracture	0	0	0	0
頭部損傷 Head injury	0	0	0	0
過量投与 Overdose	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
眼窩周囲血腫 Periorbital haematoma	0	0	0	0
膝蓋骨骨折 Patella fracture	0	0	0	0
創合併症 Wound complication	0	0	0	0
吻合部狭窄 Anastomotic stenosis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
背部損傷 Back injury	0	0	0	0
第 1 度熱傷 Burns first degree	0	0	0	0
一酸化炭素中毒 Carbon monoxide poisoning	0	0	0	0
歯科修復不成功 Dental restoration failure	0	0	0	0
耳部損傷 Ear injury	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
顔面骨骨折 Facial bones fracture	0	0	0	0
発熱性非溶血性輸血反応 Febrile nonhaemolytic transfusion reaction	0	0	0	0
上腕骨骨折 Humerus fracture	0	0	0	0
筋損傷 Muscle injury	0	0	0	0
肉離れ Muscle strain	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
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System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
処置後炎症 Post procedural inflammation	0	0	0	0
処置による悪心 Procedural nausea	0	0	0	0
肋骨骨折 Rib fracture	0	0	0	0
交通事故 Road traffic accident	0	0	0	0
骨格損傷 Skeletal injury	0	0	0	0
皮膚損傷 Skin injury	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
脊椎骨折 Spinal fracture	0	0	0	0
脾破裂 Splenic rupture	0	0	0	0
皮下血腫 Subcutaneous haematoma	0	0	0	0
硬膜下血腫 Subdural haematoma	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
硬膜下出血 Subdural haemorrhage	0	0	0	0
腱断裂 Tendon rupture	0	0	0	0
外傷性血胸 Traumatic haemothorax	0	0	0	0
尺骨骨折 Ulna fracture	0	0	0	0
創部分泌 Wound secretion	0	0	0	0
節足動物咬傷 Arthropod bite	0	0	0	0
四肢圧挫損傷 Limb crushing injury	0	0	0	0
処置後合併症 Post procedural complication	0	0	0	0
処置後挫傷 Post procedural contusion	0	0	0	0
術後譫妄 Postoperative delirium	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
引っかき傷 Scratch	0	0	0	0
外傷性血腫 Traumatic haematoma	0	0	0	1 (0.2%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (1.2%)	4 (2.0%)	6 (1.6%)	6 (1.5%)
基底細胞癌 Basal cell carcinoma	0	0	0	0
皮膚有棘細胞癌 Squamous cell carcinoma of skin	0	0	0	0
急性骨髄性白血病 Acute myeloid leukaemia	0	0	0	0
骨髄線維症 Myelofibrosis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
悪性黒色腫 Malignant melanoma	0	0	0	0
メラノサイト性母斑 Melanocytic naevus	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
ボーエン病 Bowen's disease	0	0	0	0
脂漏性角化症 Seborrhoeic keratosis	0	0	0	0
子宮平滑筋腫 Uterine leiomyoma	0	0	0	0
子宮癌 Uterine cancer	0	0	0	0
良性腺腫 Adenoma benign	0	0	0	0
血管筋脂肪腫 Angiomyolipoma	0	0	0	0
再発膀胱移行上皮癌 Bladder transitional cell carcinoma recurrent	0	0	0	0
慢性リンパ性白血病 Chronic lymphocytic leukaemia	0	0	0	0
慢性骨髄性白血病 Chronic myeloid leukaemia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
眼瞼腫瘍 Eyelid tumour	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
乳腺線維腺腫 Fibroadenoma of breast	0	0	0	0
骨血管腫 Haemangioma of bone	0	0	0	0
ランゲルハンス細胞肉腫 Langerhans cell sarcoma	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
白赤芽球症 Leukoerythroblastosis	0	0	0	0
表皮内悪性黒色腫 Malignant melanoma in situ	0	0	0	0
リンパ節転移 Metastases to lymph nodes	0	0	0	0
遠隔転移を伴う扁平上皮癌 Metastatic squamous cell carcinoma	0	0	0	0
新生物 Neoplasm	0	0	0	0
原発性骨髄線維症 Primary myelofibrosis	0	0	0	0
前立腺癌 Prostate cancer	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
直腸癌 Rectal cancer	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
セミノーマ Seminoma	0	0	0	0
鼻副鼻腔乳頭腫 Sinonasal papilloma	0	0	0	0
皮膚癌 Skin cancer	0	0	0	0
皮膚乳頭腫 Skin papilloma	0	0	0	0
舌扁平上皮癌 Squamous cell carcinoma of the tongue	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
急性骨髄性白血病への転化 Transformation to acute myeloid leukaemia	0	0	0	0
腫瘍熱 Tumour associated fever	0	0	0	0
膀胱移行上皮癌 Bladder transitional cell carcinoma	0	0	0	0
膵管内乳頭粘液性腫瘍 Intraductal papillary mucinous neoplasm	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
食道扁平上皮癌 Oesophageal squamous cell carcinoma	0	0	0	0
卵巣明細胞癌 Ovarian clear cell carcinoma	0	0	0	0
脾臓辺縁帯リンパ腫 Splenic marginal zone lymphoma	0	0	0	0
心臓障害 Cardiac disorders	2 (1.2%)	3 (1.5%)	5 (1.4%)	9 (2.2%)
心房細動 Atrial fibrillation	0	0	0	2 (0.5%)
心不全 Cardiac failure	0	0	0	0
心房粗動 Atrial flutter	0	0	0	0
動悸 Palpitations	0	0	0	1 (0.2%)
急性心筋梗塞 Acute myocardial infarction	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
うっ血性心不全 Cardiac failure congestive	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
心停止 Cardiac arrest	0	0	0	0
狭心症 Angina pectoris	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
頻脈 Tachycardia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
大動脈弁狭窄 Aortic valve stenosis	0	0	0	0
徐脈 Bradycardia	0	0	0	0
冠動脈疾患 Coronary artery disease	0	0	0	0
僧帽弁閉鎖不全症 Mitral valve incompetence	0	0	0	0
心筋梗塞 Myocardial infarction	0	0	0	0
不安定狭心症 Angina unstable	0	0	0	0
期外収縮 Extrasystoles	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
房室ブロック Atrioventricular block	0	0	0	0
第一度房室ブロック Atrioventricular block first degree	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
慢性心不全 Cardiac failure chronic	0	0	0	0
心臓弁膜疾患 Cardiac valve disease	0	0	0	0
心筋症 Cardiomyopathy	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
拡張機能障害 Diastolic dysfunction	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
左室機能不全 Left ventricular dysfunction	0	0	0	0
左室不全 Left ventricular failure	0	0	0	0
心筋虚血 Myocardial ischaemia	0	0	0	0
洞性徐脈 Sinus bradycardia	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
洞性頻脈 Sinus tachycardia	0	0	0	0
上室性期外収縮 Supraventricular extrasystoles	0	0	0	0
完全房室ブロック Atrioventricular block complete	0	0	0	1 (0.2%)
心拡大 Cardiomegaly	0	0	0	0
心嚢液貯留 Pericardial effusion	0	0	0	1 (0.2%)
上室性頻脈 Supraventricular tachycardia	0	0	0	0
三尖弁閉鎖不全症 Tricuspid valve incompetence	0	0	0	0
精神障害 Psychiatric disorders	3 (1.8%)	1 (0.5%)	4 (1.1%)	5 (1.2%)
不眠症 Insomnia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
うつ病 Depression	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
不安 Anxiety	0	0	0	0
錯乱状態 Confusional state	0	0	0	0
リビドー減退 Libido decreased	0	0	0	0
失見当識 Disorientation	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
幻覚 Hallucination	0	0	0	0
精神状態変化 Mental status changes	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
神経過敏 Nervousness	0	0	0	1 (0.2%)
感情障害 Affective disorder	0	0	0	0
譫妄 Delirium	0	0	0	0
妄想 Delusion	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
抑うつ気分 Depressed mood	0	0	0	0
睡眠障害 Sleep disorder	0	0	0	0
身体疾患による睡眠障害、不眠症型 Sleep disorder due to general medical condition, insomnia type	0	0	0	0
自殺念慮 Suicidal ideation	0	0	0	0
激越 Agitation	0	0	0	0
耳および迷路障害 Ear and labyrinth disorders	0	3 (1.5%)	3 (0.8%)	10 (2.4%)
回転性めまい Vertigo	0	3 (1.5%)	3 (0.8%)	8 (1.9%)
耳鳴 Tinnitus	0	0	0	2 (0.5%)
耳痛 Ear pain	0	0	0	0
聴力低下 Hypoacusis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
難聴 Deafness	0	0	0	0
片耳難聴 Deafness unilateral	0	0	0	0
耳出血 Ear haemorrhage	0	0	0	0
乗物酔い Motion sickness	0	0	0	0
耳異常感覚 Paraesthesia ear	0	0	0	0
突発性難聴 Sudden hearing loss	0	0	0	0
鼓膜穿孔 Tympanic membrane perforation	0	0	0	0
耳不快感 Ear discomfort	0	0	0	0
肝胆道系障害 Hepatobiliary disorders	3 (1.8%)	1 (0.5%)	4 (1.1%)	4 (1.0%)
胆石症 Cholelithiasis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
急性胆嚢炎 Cholecystitis acute	0	0	0	0
肝障害 Liver disorder	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
黄疸眼 Ocular icterus	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
門脈圧亢進症 Portal hypertension	0	0	0	0
胆汁うっ滞 Cholestasis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肝硬変 Hepatic cirrhosis	0	0	0	0
肝不全 Hepatic failure	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
肝機能異常 Hepatic function abnormal	0	0	0	0
脂肪肝 Hepatic steatosis	0	0	0	0
肝腫大 Hepatomegaly	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
門脈血栓症 Portal vein thrombosis	0	0	0	0
過形成性胆嚢症 Hyperplastic cholecystopathy	0	0	0	0
生殖系および乳房障害 Reproductive system and breast disorders	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
良性前立腺肥大症 Benign prostatic hyperplasia	0	0	0	0
腟出血 Vaginal haemorrhage	0	0	0	0
乳房過形成 Breast hyperplasia	0	0	0	0
精巣上体嚢胞 Epididymal cyst	0	0	0	0
勃起不全 Erectile dysfunction	0	0	0	0
閉経後出血 Postmenopausal haemorrhage	0	0	0	0
精巣腫脹 Testicular swelling	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

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	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
子宮頚部びらん Uterine cervical erosion	0	0	0	0
子宮出血 Uterine haemorrhage	0	0	0	0
腟分泌物 Vaginal discharge	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
腟脱 Vaginal prolapse	0	0	0	0
会陰痛 Perineal pain	0	0	0	1 (0.2%)
外陰腟の炎症 Vulvovaginal inflammation	0	0	0	0
外陰腟痛 Vulvovaginal pain	0	0	0	0
内分泌障害 Endocrine disorders	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
甲状腺腫瘤 Thyroid mass	0	0	0	0
甲状腺機能低下症 Hypothyroidism	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
甲状腺腫 Goitre	0	0	0	0
甲状腺炎 Thyroiditis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
低アルドステロン症 Hypoaldosteronism	0	0	0	0
免疫系障害 Immune system disorders	0	0	0	0
薬物過敏症 Drug hypersensitivity	0	0	0	0
過敏症 Hypersensitivity	0	0	0	0
季節性アレルギー Seasonal allergy	0	0	0	0
外科および内科処置 Surgical and medical procedures	0	0	0	0
抜歯 Tooth extraction	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-2 すべての有害事象及び治験薬と関連がある有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	治験薬との因果関係がある有害事象			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
先天性、家族性および遺伝性障害 Congenital, familial and genetic disorders	0	0	0	0
陰嚢水瘤 Hydrocele	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, Table 15.11.2.3.1.4
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_OL_table_ae.sas 2.003.120.280

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
有害事象発現例数 ANY EVENT	198 (92.5%)	206 (95.4%)	404 (94.0%)	134 (78.4%)	177 (89.8%)	311 (84.5%)
胃腸障害 Gastrointestinal disorders	103 (48.1%)	98 (45.4%)	201 (46.7%)	39 (22.8%)	80 (40.6%)	119 (32.3%)
下痢 Diarrhoea	39 (18.2%)	43 (19.9%)	82 (19.1%)	18 (10.5%)	28 (14.2%)	46 (12.5%)
腹痛 Abdominal pain	22 (10.3%)	25 (11.6%)	47 (10.9%)	5 (2.9%)	15 (7.6%)	20 (5.4%)
悪心 Nausea	34 (15.9%)	8 (3.7%)	42 (9.8%)	6 (3.5%)	28 (14.2%)	34 (9.2%)
便秘 Constipation	21 (9.8%)	15 (6.9%)	36 (8.4%)	6 (3.5%)	9 (4.6%)	15 (4.1%)
嘔吐 Vomiting	20 (9.3%)	8 (3.7%)	28 (6.5%)	6 (3.5%)	8 (4.1%)	14 (3.8%)
上腹部痛 Abdominal pain upper	10 (4.7%)	10 (4.6%)	20 (4.7%)	3 (1.8%)	4 (2.0%)	7 (1.9%)
腹部膨満 Abdominal distension	7 (3.3%)	7 (3.2%)	14 (3.3%)	1 (0.6%)	4 (2.0%)	5 (1.4%)
消化不良 Dyspepsia	3 (1.4%)	9 (4.2%)	12 (2.8%)	3 (1.8%)	6 (3.0%)	9 (2.4%)
腹部不快感 Abdominal discomfort	8 (3.7%)	3 (1.4%)	11 (2.6%)	1 (0.6%)	2 (1.0%)	3 (0.8%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
胃食道逆流性疾患 Gastrooesophageal reflux disease	6 (2.8%)	3 (1.4%)	9 (2.1%)	1 (0.6%)	7 (3.6%)	8 (2.2%)
鼓腸 Flatulence	3 (1.4%)	6 (2.8%)	9 (2.1%)	0	1 (0.5%)	1 (0.3%)
口内乾燥 Dry mouth	6 (2.8%)	2 (0.9%)	8 (1.9%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
歯痛 Toothache	3 (1.4%)	2 (0.9%)	5 (1.2%)	0	2 (1.0%)	2 (0.5%)
口腔内潰瘍形成 Mouth ulceration	1 (0.5%)	4 (1.9%)	5 (1.2%)	0	0	0
痔核 Haemorrhoids	2 (0.9%)	1 (0.5%)	3 (0.7%)	0	3 (1.5%)	3 (0.8%)
歯肉出血 Gingival bleeding	1 (0.5%)	2 (0.9%)	3 (0.7%)	0	1 (0.5%)	1 (0.3%)
鼠径ヘルニア Inguinal hernia	2 (0.9%)	1 (0.5%)	3 (0.7%)	1 (0.6%)	0	1 (0.3%)
口内炎 Stomatitis	0	3 (1.4%)	3 (0.7%)	0	1 (0.5%)	1 (0.3%)
小腸炎 Enteritis	2 (0.9%)	1 (0.5%)	3 (0.7%)	0	0	0
腹水 Ascites	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	2 (1.0%)	3 (0.8%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
直腸出血 Rectal haemorrhage	2 (0.9%)	0	2 (0.5%)	0	2 (1.0%)	2 (0.5%)
口唇炎 Cheilitis	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
アフタ性潰瘍 Aphthous ulcer	0	2 (0.9%)	2 (0.5%)	0	0	0
腸炎 Enterocolitis	0	2 (0.9%)	2 (0.5%)	0	0	0
肛門周囲痛 Proctalgia	2 (0.9%)	0	2 (0.5%)	0	0	0
胃炎 Gastritis	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
食道静脈瘤 Varices oesophageal	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
嚥下障害 Dysphagia	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
レッチング Retching	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
小腸閉塞 Small intestinal obstruction	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
下腹部痛 Abdominal pain lower	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
肛門出血 Anal haemorrhage	0	1 (0.5%)	1 (0.2%)	0	0	0
憩室穿孔 Diverticular perforation	0	1 (0.5%)	1 (0.2%)	0	0	0
びらん性食道炎 Erosive oesophagitis	0	1 (0.5%)	1 (0.2%)	0	0	0
変色便 Faeces discoloured	0	1 (0.5%)	1 (0.2%)	0	0	0
軟便 Faeces soft	1 (0.5%)	0	1 (0.2%)	0	0	0
胃ポリープ Gastric polyps	1 (0.5%)	0	1 (0.2%)	0	0	0
胃潰瘍 Gastric ulcer	1 (0.5%)	0	1 (0.2%)	0	0	0
血便排泄 Haematochezia	1 (0.5%)	0	1 (0.2%)	0	0	0
痔出血 Haemorrhoidal haemorrhage	1 (0.5%)	0	1 (0.2%)	0	0	0
イレウス Ileus	0	1 (0.5%)	1 (0.2%)	0	0	0
口唇痛 Lip pain	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
メレナ Melaena	0	1 (0.5%)	1 (0.2%)	0	0	0
腸間膜静脈血栓症 Mesenteric vein thrombosis	1 (0.5%)	0	1 (0.2%)	0	0	0
嚥下痛 Odynophagia	1 (0.5%)	0	1 (0.2%)	0	0	0
食道痛 Oesophageal pain	0	1 (0.5%)	1 (0.2%)	0	0	0
食道炎 Oesophagitis	1 (0.5%)	0	1 (0.2%)	0	0	0
消化性潰瘍 Peptic ulcer	1 (0.5%)	0	1 (0.2%)	0	0	0
腹膜出血 Peritoneal haemorrhage	0	1 (0.5%)	1 (0.2%)	0	0	0
亜イレウス Subileus	0	1 (0.5%)	1 (0.2%)	0	0	0
舌紅斑 Tongue erythema	1 (0.5%)	0	1 (0.2%)	0	0	0
肛門失禁 Anal incontinence	0	0	0	0	2 (1.0%)	2 (0.5%)
口角口唇炎 Angular cheilitis	0	0	0	2 (1.2%)	0	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
心窩部不快感 Epigastric discomfort	0	0	0	0	2 (1.0%)	2 (0.5%)
口腔内痛 Oral pain	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
腹部硬直 Abdominal rigidity	0	0	0	0	1 (0.5%)	1 (0.3%)
便意切迫 Defaecation urgency	0	0	0	0	1 (0.5%)	1 (0.3%)
齲歯 Dental caries	0	0	0	0	1 (0.5%)	1 (0.3%)
出血性十二指腸潰瘍 Duodenal ulcer haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)
食中毒 Food poisoning	0	0	0	1 (0.6%)	0	1 (0.3%)
胃出血 Gastric haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)
出血性胃潰瘍 Gastric ulcer haemorrhage	0	0	0	1 (0.6%)	0	1 (0.3%)
びらん性胃炎 Gastritis erosive	0	0	0	0	1 (0.5%)	1 (0.3%)
胃腸出血 Gastrointestinal haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
消化器痛 Gastrointestinal pain	0	0	0	1 (0.6%)	0	1 (0.3%)
胃腸音異常 Gastrointestinal sounds abnormal	0	0	0	1 (0.6%)	0	1 (0.3%)
裂孔ヘルニア Hiatus hernia	0	0	0	1 (0.6%)	0	1 (0.3%)
口の感覚鈍麻 Hypoaesthesia oral	0	0	0	0	1 (0.5%)	1 (0.3%)
下部消化管出血 Lower gastrointestinal haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)
口腔内出血 Mouth haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)
食道静脈瘤出血 Oesophageal varices haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)
口腔粘膜血腫 Oral mucosa haematoma	0	0	0	1 (0.6%)	0	1 (0.3%)
歯周病 Periodontal disease	0	0	0	0	1 (0.5%)	1 (0.3%)
咳嗽後嘔吐 Post-tussive vomiting	0	0	0	0	1 (0.5%)	1 (0.3%)
小腸出血 Small intestinal haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
血液およびリンパ系障害 Blood and lymphatic system disorders	75 (35.0%)	122 (56.5%)	197 (45.8%)	34 (19.9%)	57 (28.9%)	91 (24.7%)
貧血 Anaemia	31 (14.5%)	81 (37.5%)	112 (26.0%)	14 (8.2%)	21 (10.7%)	35 (9.5%)
血小板減少症 Thrombocytopenia	40 (18.7%)	63 (29.2%)	103 (24.0%)	16 (9.4%)	28 (14.2%)	44 (12.0%)
好中球減少症 Neutropenia	9 (4.2%)	14 (6.5%)	23 (5.3%)	5 (2.9%)	4 (2.0%)	9 (2.4%)
白血球減少症 Leukopenia	5 (2.3%)	4 (1.9%)	9 (2.1%)	3 (1.8%)	4 (2.0%)	7 (1.9%)
血小板増加症 Thrombocytosis	5 (2.3%)	2 (0.9%)	7 (1.6%)	0	4 (2.0%)	4 (1.1%)
白血球増加症 Leukocytosis	4 (1.9%)	0	4 (0.9%)	1 (0.6%)	3 (1.5%)	4 (1.1%)
発熱性好中球減少症 Febrile neutropenia	1 (0.5%)	2 (0.9%)	3 (0.7%)	2 (1.2%)	0	2 (0.5%)
リンパ球減少症 Lymphopenia	2 (0.9%)	1 (0.5%)	3 (0.7%)	0	2 (1.0%)	2 (0.5%)
脾腫 Splenomegaly	1 (0.5%)	0	1 (0.2%)	2 (1.2%)	1 (0.5%)	3 (0.8%)
内出血発生の増加傾向 Increased tendency to bruise	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
凝血異常 Coagulopathy	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
赤血球増加症 Polycythaemia	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
脾臓梗塞 Splenic infarction	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
失血性貧血 Blood loss anaemia	0	1 (0.5%)	1 (0.2%)	0	0	0
低プロトロンビン血症 Hypoprothrombinaemia	1 (0.5%)	0	1 (0.2%)	0	0	0
リンパ節石灰化 Lymph node calcification	1 (0.5%)	0	1 (0.2%)	0	0	0
リンパ節症 Lymphadenopathy	1 (0.5%)	0	1 (0.2%)	0	0	0
リンパ球増加症 Lymphocytosis	1 (0.5%)	0	1 (0.2%)	0	0	0
微小血管症性溶血性貧血 Microangiopathic haemolytic anaemia	1 (0.5%)	0	1 (0.2%)	0	0	0
脾血腫 Splenic haematoma	0	0	0	0	2 (1.0%)	2 (0.5%)
過粘稠度症候群 Hyperviscosity syndrome	0	0	0	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
肥満細胞症 Mastocytosis	0	0	0	1 (0.6%)	0	1 (0.3%)
好中球増加症 Neutrophilia	0	0	0	0	1 (0.5%)	1 (0.3%)
特発性血腫 Spontaneous haematoma	0	0	0	0	1 (0.5%)	1 (0.3%)
感染症および寄生虫症 Infections and infestations	77 (36.0%)	92 (42.6%)	169 (39.3%)	51 (29.8%)	70 (35.5%)	121 (32.9%)
上気道感染 Upper respiratory tract infection	12 (5.6%)	14 (6.5%)	26 (6.0%)	8 (4.7%)	12 (6.1%)	20 (5.4%)
上咽頭炎 Nasopharyngitis	9 (4.2%)	16 (7.4%)	25 (5.8%)	5 (2.9%)	8 (4.1%)	13 (3.5%)
尿路感染 Urinary tract infection	10 (4.7%)	11 (5.1%)	21 (4.9%)	8 (4.7%)	11 (5.6%)	19 (5.2%)
帯状疱疹 Herpes zoster	4 (1.9%)	9 (4.2%)	13 (3.0%)	4 (2.3%)	0	4 (1.1%)
肺炎 Pneumonia	5 (2.3%)	6 (2.8%)	11 (2.6%)	5 (2.9%)	7 (3.6%)	12 (3.3%)
気道感染 Respiratory tract infection	3 (1.4%)	8 (3.7%)	11 (2.6%)	2 (1.2%)	4 (2.0%)	6 (1.6%)
口腔ヘルペス Oral herpes	3 (1.4%)	8 (3.7%)	11 (2.6%)	2 (1.2%)	3 (1.5%)	5 (1.4%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
気管支炎 Bronchitis	4 (1.9%)	5 (2.3%)	9 (2.1%)	3 (1.8%)	11 (5.6%)	14 (3.8%)
膀胱炎 Cystitis	7 (3.3%)	0	7 (1.6%)	4 (2.3%)	3 (1.5%)	7 (1.9%)
インフルエンザ Influenza	1 (0.5%)	6 (2.8%)	7 (1.6%)	1 (0.6%)	4 (2.0%)	5 (1.4%)
鼻炎 Rhinitis	2 (0.9%)	4 (1.9%)	6 (1.4%)	0	1 (0.5%)	1 (0.3%)
胃腸炎 Gastroenteritis	3 (1.4%)	2 (0.9%)	5 (1.2%)	1 (0.6%)	4 (2.0%)	5 (1.4%)
皮膚感染 Skin infection	4 (1.9%)	1 (0.5%)	5 (1.2%)	1 (0.6%)	0	1 (0.3%)
下気道感染 Lower respiratory tract infection	3 (1.4%)	1 (0.5%)	4 (0.9%)	2 (1.2%)	3 (1.5%)	5 (1.4%)
敗血症 Sepsis	3 (1.4%)	1 (0.5%)	4 (0.9%)	2 (1.2%)	0	2 (0.5%)
副鼻腔炎 Sinusitis	0	3 (1.4%)	3 (0.7%)	0	4 (2.0%)	4 (1.1%)
蜂巣炎 Cellulitis	3 (1.4%)	0	3 (0.7%)	2 (1.2%)	0	2 (0.5%)
ウイルス感染 Viral infection	1 (0.5%)	2 (0.9%)	3 (0.7%)	1 (0.6%)	1 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
術後創感染 Postoperative wound infection	1 (0.5%)	2 (0.9%)	3 (0.7%)	1 (0.6%)	0	1 (0.3%)
結膜炎 Conjunctivitis	0	3 (1.4%)	3 (0.7%)	0	0	0
癜風 Tinea versicolour	3 (1.4%)	0	3 (0.7%)	0	0	0
皮膚真菌感染 Fungal skin infection	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
消化管感染 Gastrointestinal infection	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
限局性感染 Localised infection	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
口腔カンジダ症 Oral candidiasis	2 (0.9%)	0	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
毛包炎 Folliculitis	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
歯肉炎 Gingivitis	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
感染 Infection	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
歯周炎 Periodontitis	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
咽頭炎 Pharyngitis	0	2 (0.9%)	2 (0.5%)	0	0	0
気管気管支炎 Tracheobronchitis	0	2 (0.9%)	2 (0.5%)	0	0	0
腟感染 Vaginal infection	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
陰部ヘルペス Genital herpes	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
クロストリジウム・ディフィシレ大腸炎 Clostridium difficile colitis	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
大腸菌性尿路感染 Escherichia urinary tract infection	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
真菌感染 Fungal infection	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
肺感染 Lung infection	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
外耳炎 Otitis externa	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
赤痢菌感染 Shigella infection	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
肛門膿瘍 Anal abscess	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
憩室炎 Diverticulitis	1 (0.5%)	0	1 (0.2%)	0	0	0
大腸菌性敗血症 Escherichia sepsis	1 (0.5%)	0	1 (0.2%)	0	0	0
真菌性食道炎 Fungal oesophagitis	0	1 (0.5%)	1 (0.2%)	0	0	0
せつ Furuncle	0	1 (0.5%)	1 (0.2%)	0	0	0
ウイルス性消化管感染 Gastrointestinal viral infection	0	1 (0.5%)	1 (0.2%)	0	0	0
麦粒腫 Hordeolum	0	1 (0.5%)	1 (0.2%)	0	0	0
膿痂疹 Impetigo	0	1 (0.5%)	1 (0.2%)	0	0	0
喉頭炎 Laryngitis	1 (0.5%)	0	1 (0.2%)	0	0	0
口唇感染 Lip infection	1 (0.5%)	0	1 (0.2%)	0	0	0
ライム病 Lyme disease	1 (0.5%)	0	1 (0.2%)	0	0	0
爪真菌症 Onychomycosis	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
爪囲炎 Paronychia	0	1 (0.5%)	1 (0.2%)	0	0	0
腹膜炎 Peritonitis	0	1 (0.5%)	1 (0.2%)	0	0	0
細菌性肺炎 Pneumonia bacterial	1 (0.5%)	0	1 (0.2%)	0	0	0
処置後感染 Post procedural infection	1 (0.5%)	0	1 (0.2%)	0	0	0
肺敗血症 Pulmonary sepsis	0	1 (0.5%)	1 (0.2%)	0	0	0
腎盂膀胱炎 Pyelocystitis	1 (0.5%)	0	1 (0.2%)	0	0	0
腎盂腎炎 Pyelonephritis	1 (0.5%)	0	1 (0.2%)	0	0	0
陰嚢膿瘍 Scrotal abscess	1 (0.5%)	0	1 (0.2%)	0	0	0
皮膚細菌感染 Skin bacterial infection	1 (0.5%)	0	1 (0.2%)	0	0	0
ブドウ球菌感染 Staphylococcal infection	1 (0.5%)	0	1 (0.2%)	0	0	0
レンサ球菌性敗血症 Streptococcal sepsis	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
気管炎 Tracheitis	0	1 (0.5%)	1 (0.2%)	0	0	0
ウイルス性上気道感染 Viral upper respiratory tract infection	0	1 (0.5%)	1 (0.2%)	0	0	0
外陰部腟カンジダ症 Vulvovaginal candidiasis	0	1 (0.5%)	1 (0.2%)	0	0	0
外陰腟真菌感染 Vulvovaginal mycotic infection	0	1 (0.5%)	1 (0.2%)	0	0	0
創傷感染 Wound infection	0	1 (0.5%)	1 (0.2%)	0	0	0
クロストリジウム・ディフィシレ感染 Clostridium difficile infection	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
耳感染 Ear infection	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
単純ヘルペス Herpes simplex	0	0	0	0	2 (1.0%)	2 (0.5%)
中耳炎 Otitis media	0	0	0	2 (1.2%)	0	2 (0.5%)
扁桃炎 Tonsillitis	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
ボレリア感染 Borrelia infection	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
丹毒 Erysipelas	0	0	0	0	1 (0.5%)	1 (0.3%)
壊疽 Gangrene	0	0	0	1 (0.6%)	0	1 (0.3%)
サルモネラ菌性胃腸炎 Gastroenteritis salmonella	0	0	0	0	1 (0.5%)	1 (0.3%)
消化器カンジダ症 Gastrointestinal candidiasis	0	0	0	0	1 (0.5%)	1 (0.3%)
ヘルペス性皮膚炎 Herpes dermatitis	0	0	0	0	1 (0.5%)	1 (0.3%)
感染性皮膚潰瘍 Infected skin ulcer	0	0	0	1 (0.6%)	0	1 (0.3%)
迷路炎 Labyrinthitis	0	0	0	1 (0.6%)	0	1 (0.3%)
鼻ヘルペス Nasal herpes	0	0	0	1 (0.6%)	0	1 (0.3%)
百日咳 Pertussis	0	0	0	0	1 (0.5%)	1 (0.3%)
ピコルナウイルス感染 Picornavirus infection	0	0	0	1 (0.6%)	0	1 (0.3%)
歯膿瘍 Tooth abscess	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
水痘帯状疱疹ウイルス感染 Varicella zoster virus infection	0	0	0	0	1 (0.5%)	1 (0.3%)
ウイルス性ぶどう膜炎 Viral uveitis	0	0	0	0	1 (0.5%)	1 (0.3%)
神経系障害 Nervous system disorders	93 (43.5%)	76 (35.2%)	169 (39.3%)	35 (20.5%)	52 (26.4%)	87 (23.6%)
頭痛 Headache	38 (17.8%)	43 (19.9%)	81 (18.8%)	4 (2.3%)	13 (6.6%)	17 (4.6%)
浮動性めまい Dizziness	34 (15.9%)	25 (11.6%)	59 (13.7%)	11 (6.4%)	13 (6.6%)	24 (6.5%)
末梢性感覚ニューロパチー Peripheral sensory neuropathy	20 (9.3%)	12 (5.6%)	32 (7.4%)	7 (4.1%)	15 (7.6%)	22 (6.0%)
錯感覚 Paraesthesia	15 (7.0%)	7 (3.2%)	22 (5.1%)	5 (2.9%)	6 (3.0%)	11 (3.0%)
失神寸前の状態 Presyncope	6 (2.8%)	0	6 (1.4%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
嗜眠 Lethargy	2 (0.9%)	3 (1.4%)	5 (1.2%)	3 (1.8%)	1 (0.5%)	4 (1.1%)
感覚鈍麻 Hypoaesthesia	2 (0.9%)	2 (0.9%)	4 (0.9%)	4 (2.3%)	2 (1.0%)	6 (1.6%)
振戦 Tremor	3 (1.4%)	1 (0.5%)	4 (0.9%)	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
記憶障害 Memory impairment	2 (0.9%)	2 (0.9%)	4 (0.9%)	0	0	0
坐骨神経痛 Sciatica	0	3 (1.4%)	3 (0.7%)	1 (0.6%)	4 (2.0%)	5 (1.4%)
失神 Syncope	3 (1.4%)	0	3 (0.7%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
味覚障害 Taste disorder	2 (0.9%)	1 (0.5%)	3 (0.7%)	0	0	0
平衡障害 Balance disorder	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
健忘 Amnesia	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
片頭痛 Migraine	0	2 (0.9%)	2 (0.5%)	0	0	0
味覚異常 Dysgeusia	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
一過性脳虚血発作 Transient ischaemic attack	0	1 (0.5%)	1 (0.2%)	0	2 (1.0%)	2 (0.5%)
異常感覚 Dysaesthesia	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
前頭側頭型認知症 Frontotemporal dementia	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
神経痛 Neuralgia	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
末梢性ニューロパチー Neuropathy peripheral	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
傾眠 Somnolence	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
失語症 Aphasia	0	1 (0.5%)	1 (0.2%)	0	0	0
手根管症候群 Carpal tunnel syndrome	0	1 (0.5%)	1 (0.2%)	0	0	0
脳虚血 Cerebral ischaemia	1 (0.5%)	0	1 (0.2%)	0	0	0
頚髄神経根障害 Cervical radiculopathy	0	1 (0.5%)	1 (0.2%)	0	0	0
頚腕症候群 Cervicobrachial syndrome	1 (0.5%)	0	1 (0.2%)	0	0	0
昏睡 Coma	0	1 (0.5%)	1 (0.2%)	0	0	0
注意力障害 Disturbance in attention	1 (0.5%)	0	1 (0.2%)	0	0	0
体位性めまい Dizziness postural	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
脳症 Encephalopathy	0	1 (0.5%)	1 (0.2%)	0	0	0
蟻走感 Formication	1 (0.5%)	0	1 (0.2%)	0	0	0
前兆を伴う片頭痛 Migraine with aura	1 (0.5%)	0	1 (0.2%)	0	0	0
神経系障害 Nervous system disorder	1 (0.5%)	0	1 (0.2%)	0	0	0
末梢性運動ニューロパチー Peripheral motor neuropathy	1 (0.5%)	0	1 (0.2%)	0	0	0
ヘルペス後神経痛 Post herpetic neuralgia	0	1 (0.5%)	1 (0.2%)	0	0	0
血管性脳症 Vascular encephalopathy	0	1 (0.5%)	1 (0.2%)	0	0	0
脳血管発作 Cerebrovascular accident	0	0	0	2 (1.2%)	0	2 (0.5%)
味覚消失 Ageusia	0	0	0	0	1 (0.5%)	1 (0.3%)
運動失調 Ataxia	0	0	0	0	1 (0.5%)	1 (0.3%)
脳微小血管症 Cerebral microangiopathy	0	0	0	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
脱髄 Demyelination	0	0	0	0	1 (0.5%)	1 (0.3%)
意識消失 Loss of consciousness	0	0	0	0	1 (0.5%)	1 (0.3%)
末梢性感覚運動ニューロパチー Peripheral sensorimotor neuropathy	0	0	0	1 (0.6%)	0	1 (0.3%)
副鼻腔炎に伴う頭痛 Sinus headache	0	0	0	0	1 (0.5%)	1 (0.3%)
くも膜下出血 Subarachnoid haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)
声帯麻痺 Vocal cord paralysis	0	0	0	1 (0.6%)	0	1 (0.3%)
一般・全身障害および投与部位の状態 General disorders and administration site conditions	80 (37.4%)	83 (38.4%)	163 (37.9%)	42 (24.6%)	58 (29.4%)	100 (27.2%)
疲労 Fatigue	31 (14.5%)	26 (12.0%)	57 (13.3%)	11 (6.4%)	26 (13.2%)	37 (10.1%)
発熱 Pyrexia	14 (6.5%)	17 (7.9%)	31 (7.2%)	7 (4.1%)	5 (2.5%)	12 (3.3%)
無力症 Asthenia	12 (5.6%)	16 (7.4%)	28 (6.5%)	6 (3.5%)	6 (3.0%)	12 (3.3%)
末梢性浮腫 Oedema peripheral	10 (4.7%)	14 (6.5%)	24 (5.6%)	8 (4.7%)	3 (1.5%)	11 (3.0%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
胸痛 Chest pain	7 (3.3%)	5 (2.3%)	12 (2.8%)	2 (1.2%)	6 (3.0%)	8 (2.2%)
インフルエンザ様疾患 Influenza like illness	4 (1.9%)	8 (3.7%)	12 (2.8%)	2 (1.2%)	5 (2.5%)	7 (1.9%)
倦怠感 Malaise	4 (1.9%)	4 (1.9%)	8 (1.9%)	0	2 (1.0%)	2 (0.5%)
悪寒 Chills	1 (0.5%)	5 (2.3%)	6 (1.4%)	0	2 (1.0%)	2 (0.5%)
末梢腫脹 Peripheral swelling	4 (1.9%)	1 (0.5%)	5 (1.2%)	3 (1.8%)	0	3 (0.8%)
早期満腹 Early satiety	2 (0.9%)	2 (0.9%)	4 (0.9%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
疼痛 Pain	2 (0.9%)	2 (0.9%)	4 (0.9%)	0	1 (0.5%)	1 (0.3%)
浮腫 Oedema	1 (0.5%)	2 (0.9%)	3 (0.7%)	0	2 (1.0%)	2 (0.5%)
胸部不快感 Chest discomfort	1 (0.5%)	2 (0.9%)	3 (0.7%)	0	1 (0.5%)	1 (0.3%)
非心臓性胸痛 Non-cardiac chest pain	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
乾燥症 Xerosis	0	2 (0.9%)	2 (0.5%)	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
顔面痛 Facial pain	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
重力性浮腫 Gravitational oedema	2 (0.9%)	0	2 (0.5%)	0	0	0
炎症 Inflammation	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
粘膜の炎症 Mucosal inflammation	2 (0.9%)	0	2 (0.5%)	0	0	0
死亡 Death	1 (0.5%)	0	1 (0.2%)	0	2 (1.0%)	2 (0.5%)
全身健康状態悪化 General physical health deterioration	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
全身性浮腫 Generalised oedema	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
カテーテル留置部位出血 Catheter site haemorrhage	0	1 (0.5%)	1 (0.2%)	0	0	0
捻髪音 Crepitations	1 (0.5%)	0	1 (0.2%)	0	0	0
異常感 Feeling abnormal	0	1 (0.5%)	1 (0.2%)	0	0	0
冷感 Feeling cold	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
歩行障害 Gait disturbance	1 (0.5%)	0	1 (0.2%)	0	0	0
硬結 Induration	1 (0.5%)	0	1 (0.2%)	0	0	0
粘膜出血 Mucosal haemorrhage	0	1 (0.5%)	1 (0.2%)	0	0	0
突然死 Sudden death	1 (0.5%)	0	1 (0.2%)	0	0	0
腫脹 Swelling	0	1 (0.5%)	1 (0.2%)	0	0	0
熱感 Feeling hot	0	0	0	1 (0.6%)	2 (1.0%)	3 (0.8%)
カテーテル留置部位疼痛 Catheter site pain	0	0	0	0	1 (0.5%)	1 (0.3%)
不快感 Discomfort	0	0	0	0	1 (0.5%)	1 (0.3%)
薬剤離脱症候群 Drug withdrawal syndrome	0	0	0	0	1 (0.5%)	1 (0.3%)
高熱 Hyperthermia	0	0	0	1 (0.6%)	0	1 (0.3%)
治癒不良 Impaired healing	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
注射部位出血 Injection site haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)
口渇 Thirst	0	0	0	0	1 (0.5%)	1 (0.3%)
呼吸器、胸郭および縦隔障害 Respiratory, thoracic and mediastinal disorders	61 (28.5%)	67 (31.0%)	128 (29.8%)	31 (18.1%)	43 (21.8%)	74 (20.1%)
呼吸困難 Dyspnoea	19 (8.9%)	17 (7.9%)	36 (8.4%)	3 (1.8%)	9 (4.6%)	12 (3.3%)
咳嗽 Cough	18 (8.4%)	17 (7.9%)	35 (8.1%)	12 (7.0%)	22 (11.2%)	34 (9.2%)
鼻出血 Epistaxis	9 (4.2%)	15 (6.9%)	24 (5.6%)	7 (4.1%)	7 (3.6%)	14 (3.8%)
労作性呼吸困難 Dyspnoea exertional	7 (3.3%)	7 (3.2%)	14 (3.3%)	0	2 (1.0%)	2 (0.5%)
口腔咽頭痛 Oropharyngeal pain	2 (0.9%)	9 (4.2%)	11 (2.6%)	2 (1.2%)	1 (0.5%)	3 (0.8%)
鼻漏 Rhinorrhoea	3 (1.4%)	3 (1.4%)	6 (1.4%)	2 (1.2%)	0	2 (0.5%)
湿性咳嗽 Productive cough	4 (1.9%)	1 (0.5%)	5 (1.2%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
低酸素症 Hypoxia	2 (0.9%)	1 (0.5%)	3 (0.7%)	1 (0.6%)	2 (1.0%)	3 (0.8%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
慢性閉塞性肺疾患 Chronic obstructive pulmonary disease	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
発声障害 Dysphonia	2 (0.9%)	0	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
しゃっくり Hiccups	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
カタル Catarrh	0	2 (0.9%)	2 (0.5%)	0	0	0
ラ音 Rales	2 (0.9%)	0	2 (0.5%)	0	0	0
呼吸不全 Respiratory failure	1 (0.5%)	0	1 (0.2%)	0	2 (1.0%)	2 (0.5%)
喀血 Haemoptysis	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
鼻閉 Nasal congestion	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
肺水腫 Pulmonary oedema	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
上気道咳症候群 Upper-airway cough syndrome	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
急性呼吸不全 Acute respiratory failure	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
咽喉乾燥 Dry throat	1 (0.5%)	0	1 (0.2%)	0	0	0
発作性夜間呼吸困難 Dyspnoea paroxysmal nocturnal	1 (0.5%)	0	1 (0.2%)	0	0	0
肺浸潤 Lung infiltration	0	1 (0.5%)	1 (0.2%)	0	0	0
呼吸時疼痛 Painful respiration	1 (0.5%)	0	1 (0.2%)	0	0	0
咽頭潰瘍 Pharyngeal ulceration	1 (0.5%)	0	1 (0.2%)	0	0	0
胸膜痛 Pleuritic pain	0	1 (0.5%)	1 (0.2%)	0	0	0
誤嚥性肺炎 Pneumonia aspiration	1 (0.5%)	0	1 (0.2%)	0	0	0
肺線維症 Pulmonary fibrosis	1 (0.5%)	0	1 (0.2%)	0	0	0
肺肉芽腫 Pulmonary granuloma	1 (0.5%)	0	1 (0.2%)	0	0	0
肺出血 Pulmonary haemorrhage	0	1 (0.5%)	1 (0.2%)	0	0	0
肺高血圧症 Pulmonary hypertension	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
逆流性喉頭炎 Reflux laryngitis	1 (0.5%)	0	1 (0.2%)	0	0	0
睡眠時無呼吸症候群 Sleep apnoea syndrome	0	1 (0.5%)	1 (0.2%)	0	0	0
痰貯留 Sputum retention	0	1 (0.5%)	1 (0.2%)	0	0	0
咽喉刺激感 Throat irritation	0	1 (0.5%)	1 (0.2%)	0	0	0
咽喉絞扼感 Throat tightness	1 (0.5%)	0	1 (0.2%)	0	0	0
胸水 Pleural effusion	0	0	0	0	3 (1.5%)	3 (0.8%)
喘息 Asthma	0	0	0	0	2 (1.0%)	2 (0.5%)
肺塞栓症 Pulmonary embolism	0	0	0	2 (1.2%)	0	2 (0.5%)
気管支拡張症 Bronchiectasis	0	0	0	0	1 (0.5%)	1 (0.3%)
慢性気管支炎 Bronchitis chronic	0	0	0	1 (0.6%)	0	1 (0.3%)
肺気腫 Emphysema	0	0	0	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
喉頭の炎症 Laryngeal inflammation	0	0	0	0	1 (0.5%)	1 (0.3%)
肺硬化 Lung consolidation	0	0	0	0	1 (0.5%)	1 (0.3%)
肺障害 Lung disorder	0	0	0	0	1 (0.5%)	1 (0.3%)
起坐呼吸 Orthopnoea	0	0	0	0	1 (0.5%)	1 (0.3%)
胸膜炎 Pleurisy	0	0	0	0	1 (0.5%)	1 (0.3%)
肺腫瘤 Pulmonary mass	0	0	0	1 (0.6%)	0	1 (0.3%)
副鼻腔痛 Sinus pain	0	0	0	1 (0.6%)	0	1 (0.3%)
喘鳴 Wheezing	0	0	0	1 (0.6%)	0	1 (0.3%)
筋骨格系および結合組織障害 Musculoskeletal and connective tissue disorders	58 (27.1%)	67 (31.0%)	125 (29.1%)	25 (14.6%)	48 (24.4%)	73 (19.8%)
四肢痛 Pain in extremity	14 (6.5%)	18 (8.3%)	32 (7.4%)	6 (3.5%)	12 (6.1%)	18 (4.9%)
関節痛 Arthralgia	15 (7.0%)	10 (4.6%)	25 (5.8%)	4 (2.3%)	5 (2.5%)	9 (2.4%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
背部痛 Back pain	10 (4.7%)	10 (4.6%)	20 (4.7%)	3 (1.8%)	12 (6.1%)	15 (4.1%)
筋痙縮 Muscle spasms	8 (3.7%)	11 (5.1%)	19 (4.4%)	0	4 (2.0%)	4 (1.1%)
骨痛 Bone pain	3 (1.4%)	15 (6.9%)	18 (4.2%)	3 (1.8%)	7 (3.6%)	10 (2.7%)
筋骨格痛 Musculoskeletal pain	8 (3.7%)	3 (1.4%)	11 (2.6%)	3 (1.8%)	3 (1.5%)	6 (1.6%)
筋肉痛 Myalgia	5 (2.3%)	6 (2.8%)	11 (2.6%)	1 (0.6%)	4 (2.0%)	5 (1.4%)
筋力低下 Muscular weakness	2 (0.9%)	4 (1.9%)	6 (1.4%)	2 (1.2%)	1 (0.5%)	3 (0.8%)
鼠径部痛 Groin pain	2 (0.9%)	2 (0.9%)	4 (0.9%)	0	1 (0.5%)	1 (0.3%)
筋骨格系胸痛 Musculoskeletal chest pain	1 (0.5%)	3 (1.4%)	4 (0.9%)	1 (0.6%)	0	1 (0.3%)
関節炎 Arthritis	1 (0.5%)	3 (1.4%)	4 (0.9%)	0	0	0
脊椎痛 Spinal pain	3 (1.4%)	0	3 (0.7%)	0	2 (1.0%)	2 (0.5%)
側腹部痛 Flank pain	2 (0.9%)	1 (0.5%)	3 (0.7%)	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
筋肉疲労 Muscle fatigue	0	2 (0.9%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
顎痛 Pain in jaw	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
変形性関節症 Osteoarthritis	0	2 (0.9%)	2 (0.5%)	0	0	0
腱炎 Tendonitis	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
滑液包炎 Bursitis	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
筋骨格硬直 Musculoskeletal stiffness	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
滑液貯留 Bursal fluid accumulation	1 (0.5%)	0	1 (0.2%)	0	0	0
足変形 Foot deformity	1 (0.5%)	0	1 (0.2%)	0	0	0
痛風性関節炎 Gouty arthritis	1 (0.5%)	0	1 (0.2%)	0	0	0
骨減少症 Osteopenia	1 (0.5%)	0	1 (0.2%)	0	0	0
シェーグレン症候群 Sjogren's syndrome	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
変形性脊椎症 Spinal osteoarthritis	1 (0.5%)	0	1 (0.2%)	0	0	0
開口障害 Trismus	0	1 (0.5%)	1 (0.2%)	0	0	0
頚部痛 Neck pain	0	0	0	0	2 (1.0%)	2 (0.5%)
反応性関節炎 Arthritis reactive	0	0	0	1 (0.6%)	0	1 (0.3%)
骨病変 Bone lesion	0	0	0	0	1 (0.5%)	1 (0.3%)
胸壁血腫 Chest wall haematoma	0	0	0	1 (0.6%)	0	1 (0.3%)
筋膜炎 Fasciitis	0	0	0	0	1 (0.5%)	1 (0.3%)
関節滲出液 Joint effusion	0	0	0	0	1 (0.5%)	1 (0.3%)
四肢不快感 Limb discomfort	0	0	0	0	1 (0.5%)	1 (0.3%)
骨溶解 Osteolysis	0	0	0	0	1 (0.5%)	1 (0.3%)
骨硬化症 Osteosclerosis	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
関節周囲炎 Periarthritis	0	0	0	0	1 (0.5%)	1 (0.3%)
腱痛 Tendon pain	0	0	0	1 (0.6%)	0	1 (0.3%)
皮膚および皮下組織障害 Skin and subcutaneous tissue disorders	51 (23.8%)	46 (21.3%)	97 (22.6%)	33 (19.3%)	50 (25.4%)	83 (22.6%)
そう痒症 Pruritus	10 (4.7%)	11 (5.1%)	21 (4.9%)	6 (3.5%)	17 (8.6%)	23 (6.3%)
寝汗 Night sweats	8 (3.7%)	9 (4.2%)	17 (4.0%)	7 (4.1%)	11 (5.6%)	18 (4.9%)
発疹 Rash	9 (4.2%)	5 (2.3%)	14 (3.3%)	4 (2.3%)	10 (5.1%)	14 (3.8%)
紅斑 Erythema	7 (3.3%)	0	7 (1.6%)	3 (1.8%)	1 (0.5%)	4 (1.1%)
斑状出血 Ecchymosis	4 (1.9%)	3 (1.4%)	7 (1.6%)	1 (0.6%)	0	1 (0.3%)
脱毛症 Alopecia	3 (1.4%)	2 (0.9%)	5 (1.2%)	1 (0.6%)	0	1 (0.3%)
皮膚潰瘍 Skin ulcer	2 (0.9%)	3 (1.4%)	5 (1.2%)	1 (0.6%)	0	1 (0.3%)
斑状丘疹状皮疹 Rash maculo-papular	3 (1.4%)	1 (0.5%)	4 (0.9%)	1 (0.6%)	2 (1.0%)	3 (0.8%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
点状出血 Petechiae	3 (1.4%)	1 (0.5%)	4 (0.9%)	0	2 (1.0%)	2 (0.5%)
多汗症 Hyperhidrosis	0	3 (1.4%)	3 (0.7%)	2 (1.2%)	7 (3.6%)	9 (2.4%)
皮膚病変 Skin lesion	2 (0.9%)	1 (0.5%)	3 (0.7%)	1 (0.6%)	0	1 (0.3%)
皮膚乾燥 Dry skin	2 (0.9%)	1 (0.5%)	3 (0.7%)	0	0	0
紅斑性皮疹 Rash erythematous	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
接触皮膚炎 Dermatitis contact	2 (0.9%)	0	2 (0.5%)	0	0	0
湿疹 Eczema	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
過角化 Hyperkeratosis	2 (0.9%)	0	2 (0.5%)	0	0	0
皮膚疼痛 Pain of skin	0	2 (0.9%)	2 (0.5%)	0	0	0
皮膚出血 Skin haemorrhage	2 (0.9%)	0	2 (0.5%)	0	0	0
毛細血管拡張症 Telangiectasia	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
全身性そう痒症 Pruritus generalised	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	3 (1.5%)	4 (1.1%)
光線角化症 Actinic keratosis	0	1 (0.5%)	1 (0.2%)	3 (1.8%)	0	3 (0.8%)
アレルギー性皮膚炎 Dermatitis allergic	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
全身性皮疹 Rash generalised	1 (0.5%)	0	1 (0.2%)	0	2 (1.0%)	2 (0.5%)
斑状皮疹 Rash macular	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
丘疹性皮疹 Rash papular	0	1 (0.5%)	1 (0.2%)	0	2 (1.0%)	2 (0.5%)
薬疹 Drug eruption	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
嵌入爪 Ingrowing nail	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
乾癬 Psoriasis	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
紫斑 Purpura	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
水原性そう痒症 Aquagenic pruritus	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
水疱 Blister	1 (0.5%)	0	1 (0.2%)	0	0	0
血性水疱 Blood blister	1 (0.5%)	0	1 (0.2%)	0	0	0
紅色症 Erythrosis	1 (0.5%)	0	1 (0.2%)	0	0	0
間擦疹 Intertrigo	0	1 (0.5%)	1 (0.2%)	0	0	0
手掌・足底発赤知覚不全症候群 Palmar-plantar erythrodysaesthesia syndrome	0	1 (0.5%)	1 (0.2%)	0	0	0
口囲皮膚炎 Perioral dermatitis	0	1 (0.5%)	1 (0.2%)	0	0	0
毛孔性皮疹 Rash follicular	1 (0.5%)	0	1 (0.2%)	0	0	0
そう痒性皮疹 Rash pruritic	0	1 (0.5%)	1 (0.2%)	0	0	0
脂腺過形成 Sebaceous hyperplasia	0	1 (0.5%)	1 (0.2%)	0	0	0
中毒性皮疹 Toxic skin eruption	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
冷汗 Cold sweat	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
皮膚嚢腫 Dermal cyst	0	0	0	1 (0.6%)	0	1 (0.3%)
全身性剥脱性皮膚炎 Dermatitis exfoliative generalised	0	0	0	0	1 (0.5%)	1 (0.3%)
皮膚症 Dermatosis	0	0	0	1 (0.6%)	0	1 (0.3%)
酒さ Rosacea	0	0	0	1 (0.6%)	0	1 (0.3%)
皮膚剥脱 Skin exfoliation	0	0	0	1 (0.6%)	0	1 (0.3%)
皮膚脆弱性 Skin fragility	0	0	0	1 (0.6%)	0	1 (0.3%)
顔面腫脹 Swelling face	0	0	0	0	1 (0.5%)	1 (0.3%)
蕁麻疹 Urticaria	0	0	0	0	1 (0.5%)	1 (0.3%)
代謝および栄養障害 Metabolism and nutrition disorders	48 (22.4%)	43 (19.9%)	91 (21.2%)	29 (17.0%)	45 (22.8%)	74 (20.1%)
食欲減退 Decreased appetite	11 (5.1%)	13 (6.0%)	24 (5.6%)	7 (4.1%)	11 (5.6%)	18 (4.9%)
ビタミンＢ１欠乏 Vitamin B1 deficiency	7 (3.3%)	12 (5.6%)	19 (4.4%)	5 (2.9%)	8 (4.1%)	13 (3.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
高尿酸血症 Hyperuricaemia	10 (4.7%)	7 (3.2%)	17 (4.0%)	5 (2.9%)	7 (3.6%)	12 (3.3%)
高カリウム血症 Hyperkalaemia	7 (3.3%)	5 (2.3%)	12 (2.8%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
低カリウム血症 Hypokalaemia	4 (1.9%)	4 (1.9%)	8 (1.9%)	0	5 (2.5%)	5 (1.4%)
低マグネシウム血症 Hypomagnesaemia	6 (2.8%)	1 (0.5%)	7 (1.6%)	0	1 (0.5%)	1 (0.3%)
低カルシウム血症 Hypocalcaemia	3 (1.4%)	3 (1.4%)	6 (1.4%)	1 (0.6%)	4 (2.0%)	5 (1.4%)
脱水 Dehydration	2 (0.9%)	2 (0.9%)	4 (0.9%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
ビタミンD欠乏 Vitamin D deficiency	3 (1.4%)	1 (0.5%)	4 (0.9%)	0	1 (0.5%)	1 (0.3%)
痛風 Gout	3 (1.4%)	0	3 (0.7%)	2 (1.2%)	0	2 (0.5%)
糖尿病 Diabetes mellitus	0	2 (0.9%)	2 (0.5%)	2 (1.2%)	4 (2.0%)	6 (1.6%)
低ナトリウム血症 Hyponatraemia	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	3 (1.5%)	4 (1.1%)
低血糖 Hypoglycaemia	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	2 (1.0%)	3 (0.8%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
高血糖 Hyperglycaemia	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	2 (1.0%)	2 (0.5%)
ビタミンB群欠乏 Vitamin B complex deficiency	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
鉄欠乏 Iron deficiency	2 (0.9%)	0	2 (0.5%)	0	0	0
鉄過剰 Iron overload	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
体液貯留 Fluid retention	0	1 (0.5%)	1 (0.2%)	2 (1.2%)	1 (0.5%)	3 (0.8%)
高カルシウム血症 Hypercalcaemia	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
高マグネシウム血症 Hypermagnesaemia	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
低アルブミン血症 Hypoalbuminaemia	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
低リン酸血症 Hypophosphataemia	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
葉酸欠乏 Folate deficiency	0	1 (0.5%)	1 (0.2%)	0	0	0
ヘモジデリン沈着症 Haemosiderosis	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
血液量増加症 Hypervolaemia	0	1 (0.5%)	1 (0.2%)	0	0	0
栄養障害 Malnutrition	1 (0.5%)	0	1 (0.2%)	0	0	0
多飲症 Polydipsia	0	1 (0.5%)	1 (0.2%)	0	0	0
腫瘍崩壊症候群 Tumour lysis syndrome	0	1 (0.5%)	1 (0.2%)	0	0	0
ビタミンK欠乏 Vitamin K deficiency	1 (0.5%)	0	1 (0.2%)	0	0	0
高トリグリセリド血症 Hypertriglyceridaemia	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
異常体重減少 Abnormal loss of weight	0	0	0	0	1 (0.5%)	1 (0.3%)
電解質失調 Electrolyte imbalance	0	0	0	0	1 (0.5%)	1 (0.3%)
高コレステロール血症 Hypercholesterolaemia	0	0	0	0	1 (0.5%)	1 (0.3%)
高フェリチン血症 Hyperferritinaemia	0	0	0	1 (0.6%)	0	1 (0.3%)
ビタミンＢ６欠乏 Vitamin B6 deficiency	0	0	0	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
血管障害 Vascular disorders	49 (22.9%)	29 (13.4%)	78 (18.1%)	19 (11.1%)	32 (16.2%)	51 (13.9%)
高血圧 Hypertension	9 (4.2%)	20 (9.3%)	29 (6.7%)	7 (4.1%)	13 (6.6%)	20 (5.4%)
低血圧 Hypotension	19 (8.9%)	1 (0.5%)	20 (4.7%)	3 (1.8%)	7 (3.6%)	10 (2.7%)
潮紅 Flushing	13 (6.1%)	1 (0.5%)	14 (3.3%)	1 (0.6%)	3 (1.5%)	4 (1.1%)
血腫 Haematoma	6 (2.8%)	3 (1.4%)	9 (2.1%)	4 (2.3%)	2 (1.0%)	6 (1.6%)
ほてり Hot flush	3 (1.4%)	4 (1.9%)	7 (1.6%)	1 (0.6%)	3 (1.5%)	4 (1.1%)
静脈炎 Phlebitis	2 (0.9%)	0	2 (0.5%)	0	0	0
出血 Haemorrhage	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
起立性低血圧 Orthostatic hypotension	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
末梢動脈閉塞性疾患 Peripheral arterial occlusive disease	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
表在性血栓性静脈炎 Thrombophlebitis superficial	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
四肢静脈血栓症 Venous thrombosis limb	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
大動脈硬化症 Aortic arteriosclerosis	1 (0.5%)	0	1 (0.2%)	0	0	0
大動脈解離 Aortic dissection	1 (0.5%)	0	1 (0.2%)	0	0	0
大動脈血栓症 Aortic thrombosis	1 (0.5%)	0	1 (0.2%)	0	0	0
本態性高血圧症 Essential hypertension	1 (0.5%)	0	1 (0.2%)	0	0	0
高血圧クリーゼ Hypertensive crisis	0	1 (0.5%)	1 (0.2%)	0	0	0
末梢冷感 Peripheral coldness	1 (0.5%)	0	1 (0.2%)	0	0	0
末梢性虚血 Peripheral ischaemia	0	1 (0.5%)	1 (0.2%)	0	0	0
末梢静脈疾患 Peripheral venous disease	0	1 (0.5%)	1 (0.2%)	0	0	0
静脈穿刺不良 Poor venous access	1 (0.5%)	0	1 (0.2%)	0	0	0
血栓性静脈炎 Thrombophlebitis	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
大動脈狭窄 Aortic stenosis	0	0	0	0	1 (0.5%)	1 (0.3%)
動脈硬化症 Arteriosclerosis	0	0	0	0	1 (0.5%)	1 (0.3%)
末梢循環不良 Poor peripheral circulation	0	0	0	0	1 (0.5%)	1 (0.3%)
静脈瘤 Varicose vein	0	0	0	0	1 (0.5%)	1 (0.3%)
血管拡張 Vasodilatation	0	0	0	1 (0.6%)	0	1 (0.3%)
臨床検査 Investigations	40 (18.7%)	37 (17.1%)	77 (17.9%)	25 (14.6%)	30 (15.2%)	55 (14.9%)
アラニンアミノトランスフェラーゼ増加 Alanine aminotransferase increased	10 (4.7%)	10 (4.6%)	20 (4.7%)	2 (1.2%)	7 (3.6%)	9 (2.4%)
γ－グルタミルトランスフェラーゼ増加 Gamma-glutamyltransferase increased	6 (2.8%)	7 (3.2%)	13 (3.0%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
アスパラギン酸アミノトランスフェラーゼ増加 Aspartate aminotransferase increased	7 (3.3%)	5 (2.3%)	12 (2.8%)	1 (0.6%)	6 (3.0%)	7 (1.9%)
血中クレアチニン増加 Blood creatinine increased	9 (4.2%)	2 (0.9%)	11 (2.6%)	4 (2.3%)	7 (3.6%)	11 (3.0%)
血中アルカリホスファターゼ増加 Blood alkaline phosphatase increased	3 (1.4%)	5 (2.3%)	8 (1.9%)	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
体重減少 Weight decreased	6 (2.8%)	1 (0.5%)	7 (1.6%)	6 (3.5%)	3 (1.5%)	9 (2.4%)
体重増加 Weight increased	2 (0.9%)	5 (2.3%)	7 (1.6%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
血中ビリルビン増加 Blood bilirubin increased	2 (0.9%)	4 (1.9%)	6 (1.4%)	4 (2.3%)	3 (1.5%)	7 (1.9%)
心電図ＱＴ延長 Electrocardiogram QT prolonged	1 (0.5%)	4 (1.9%)	5 (1.2%)	0	0	0
活性化部分トロンボプラスチン時間延長 Activated partial thromboplastin time prolonged	1 (0.5%)	2 (0.9%)	3 (0.7%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
心雑音 Cardiac murmur	2 (0.9%)	1 (0.5%)	3 (0.7%)	0	0	0
腎クレアチニン・クリアランス減少 Creatinine renal clearance decreased	2 (0.9%)	0	2 (0.5%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
総蛋白増加 Protein total increased	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
リパーゼ増加 Lipase increased	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
トランスアミナーゼ上昇 Transaminases increased	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
国際標準比増加 International normalised ratio increased	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
血中鉄減少 Blood iron decreased	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
ヘマトクリット増加 Haematocrit increased	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
出血時間延長 Bleeding time prolonged	0	1 (0.5%)	1 (0.2%)	0	0	0
血中重炭酸塩減少 Blood bicarbonate decreased	1 (0.5%)	0	1 (0.2%)	0	0	0
血中クレアチンホスホキナーゼ増加 Blood creatine phosphokinase increased	0	1 (0.5%)	1 (0.2%)	0	0	0
血中乳酸増加 Blood lactic acid increased	1 (0.5%)	0	1 (0.2%)	0	0	0
体温上昇 Body temperature increased	0	1 (0.5%)	1 (0.2%)	0	0	0
心電図ＳＴ部分下降 Electrocardiogram ST segment depression	1 (0.5%)	0	1 (0.2%)	0	0	0
心電図異常 Electrocardiogram abnormal	1 (0.5%)	0	1 (0.2%)	0	0	0
ヘモグロビン増加 Haemoglobin increased	0	1 (0.5%)	1 (0.2%)	0	0	0
ヘプシジン減少 Hepcidin decreased	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
リンパ節触知 Lymph node palpable	1 (0.5%)	0	1 (0.2%)	0	0	0
好中球数増加 Neutrophil count increased	1 (0.5%)	0	1 (0.2%)	0	0	0
脈拍欠損 Pulse absent	0	1 (0.5%)	1 (0.2%)	0	0	0
血中乳酸脱水素酵素増加 Blood lactate dehydrogenase increased	0	0	0	1 (0.6%)	2 (1.0%)	3 (0.8%)
プロトロンビン時間延長 Prothrombin time prolonged	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
抗リン脂質抗体陽性 Antiphospholipid antibodies positive	0	0	0	1 (0.6%)	0	1 (0.3%)
血中葉酸減少 Blood folate decreased	0	0	0	1 (0.6%)	0	1 (0.3%)
血中尿素増加 Blood urea increased	0	0	0	1 (0.6%)	0	1 (0.3%)
胸部X線異常 Chest X-ray abnormal	0	0	0	0	1 (0.5%)	1 (0.3%)
骨盤コンピュータ断層撮影異常 Computerised tomogram pelvis abnormal	0	0	0	0	1 (0.5%)	1 (0.3%)
肝酵素上昇 Hepatic enzyme increased	0	0	0	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
肝機能検査異常 Liver function test abnormal	0	0	0	1 (0.6%)	0	1 (0.3%)
平均赤血球容積減少 Mean cell volume decreased	0	0	0	0	1 (0.5%)	1 (0.3%)
血清フェリチン増加 Serum ferritin increased	0	0	0	0	1 (0.5%)	1 (0.3%)
傷害、中毒および処置合併症 Injury, poisoning and procedural complications	26 (12.1%)	29 (13.4%)	55 (12.8%)	14 (8.2%)	16 (8.1%)	30 (8.2%)
挫傷 Contusion	16 (7.5%)	10 (4.6%)	26 (6.0%)	4 (2.3%)	4 (2.0%)	8 (2.2%)
転倒 Fall	6 (2.8%)	4 (1.9%)	10 (2.3%)	5 (2.9%)	5 (2.5%)	10 (2.7%)
皮膚擦過傷 Skin abrasion	1 (0.5%)	3 (1.4%)	4 (0.9%)	0	2 (1.0%)	2 (0.5%)
皮膚裂傷 Skin laceration	2 (0.9%)	2 (0.9%)	4 (0.9%)	0	2 (1.0%)	2 (0.5%)
四肢損傷 Limb injury	2 (0.9%)	1 (0.5%)	3 (0.7%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
処置による疼痛 Procedural pain	1 (0.5%)	2 (0.9%)	3 (0.7%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
処置後出血 Post procedural haemorrhage	0	2 (0.9%)	2 (0.5%)	2 (1.2%)	1 (0.5%)	3 (0.8%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
創傷 Wound	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
靱帯捻挫 Ligament sprain	0	2 (0.9%)	2 (0.5%)	0	0	0
眼窩周囲血腫 Periorbital haematoma	2 (0.9%)	0	2 (0.5%)	0	0	0
頭部損傷 Head injury	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
過量投与 Overdose	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
膝蓋骨骨折 Patella fracture	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
腱断裂 Tendon rupture	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
腹部損傷 Abdominal injury	0	1 (0.5%)	1 (0.2%)	0	0	0
節足動物咬傷 Arthropod bite	1 (0.5%)	0	1 (0.2%)	0	0	0
眼挫傷 Eye contusion	0	1 (0.5%)	1 (0.2%)	0	0	0
大腿骨骨折 Femur fracture	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
手骨折 Hand fracture	0	1 (0.5%)	1 (0.2%)	0	0	0
低圧症 Hypobarism	0	1 (0.5%)	1 (0.2%)	0	0	0
靱帯断裂 Ligament rupture	0	1 (0.5%)	1 (0.2%)	0	0	0
四肢圧挫損傷 Limb crushing injury	1 (0.5%)	0	1 (0.2%)	0	0	0
口腔内損傷 Mouth injury	0	1 (0.5%)	1 (0.2%)	0	0	0
処置後合併症 Post procedural complication	1 (0.5%)	0	1 (0.2%)	0	0	0
処置後挫傷 Post procedural contusion	1 (0.5%)	0	1 (0.2%)	0	0	0
術後譫妄 Postoperative delirium	1 (0.5%)	0	1 (0.2%)	0	0	0
肋骨骨折 Rib fracture	0	1 (0.5%)	1 (0.2%)	0	0	0
引っかき傷 Scratch	1 (0.5%)	0	1 (0.2%)	0	0	0
漿液腫 Seroma	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
脊椎圧迫骨折 Spinal compression fracture	1 (0.5%)	0	1 (0.2%)	0	0	0
輸血反応 Transfusion reaction	0	1 (0.5%)	1 (0.2%)	0	0	0
輸血関連合併症 Transfusion related complication	0	1 (0.5%)	1 (0.2%)	0	0	0
外傷性血腫 Traumatic haematoma	1 (0.5%)	0	1 (0.2%)	0	0	0
創合併症 Wound complication	1 (0.5%)	0	1 (0.2%)	0	0	0
足骨折 Foot fracture	0	0	0	0	2 (1.0%)	2 (0.5%)
吻合部狭窄 Anastomotic stenosis	0	0	0	1 (0.6%)	0	1 (0.3%)
顔面骨骨折 Facial bones fracture	0	0	0	0	1 (0.5%)	1 (0.3%)
筋損傷 Muscle injury	0	0	0	1 (0.6%)	0	1 (0.3%)
処置による悪心 Procedural nausea	0	0	0	0	1 (0.5%)	1 (0.3%)
骨格損傷 Skeletal injury	0	0	0	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
外傷性血胸 Traumatic haemothorax	0	0	0	0	1 (0.5%)	1 (0.3%)
腎および尿路障害 Renal and urinary disorders	24 (11.2%)	19 (8.8%)	43 (10.0%)	13 (7.6%)	19 (9.6%)	32 (8.7%)
腎不全 Renal failure	3 (1.4%)	4 (1.9%)	7 (1.6%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
排尿困難 Dysuria	3 (1.4%)	3 (1.4%)	6 (1.4%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
頻尿 Pollakiuria	3 (1.4%)	2 (0.9%)	5 (1.2%)	1 (0.6%)	3 (1.5%)	4 (1.1%)
急性腎障害 Acute kidney injury	3 (1.4%)	1 (0.5%)	4 (0.9%)	2 (1.2%)	4 (2.0%)	6 (1.6%)
血尿 Haematuria	3 (1.4%)	1 (0.5%)	4 (0.9%)	0	2 (1.0%)	2 (0.5%)
腎結石症 Nephrolithiasis	2 (0.9%)	2 (0.9%)	4 (0.9%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
腎仙痛 Renal colic	0	4 (1.9%)	4 (0.9%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
慢性腎臓病 Chronic kidney disease	2 (0.9%)	1 (0.5%)	3 (0.7%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
腎機能障害 Renal impairment	2 (0.9%)	0	2 (0.5%)	2 (1.2%)	2 (1.0%)	4 (1.1%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
夜間頻尿 Nocturia	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
尿失禁 Urinary incontinence	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	2 (1.0%)	2 (0.5%)
着色尿 Chromaturia	2 (0.9%)	0	2 (0.5%)	0	0	0
多尿 Polyuria	2 (0.9%)	0	2 (0.5%)	0	0	0
蛋白尿 Proteinuria	1 (0.5%)	0	1 (0.2%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
白血球尿 Leukocyturia	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
出血性膀胱炎 Cystitis haemorrhagic	0	1 (0.5%)	1 (0.2%)	0	0	0
中毒性ネフロパシー Nephropathy toxic	0	1 (0.5%)	1 (0.2%)	0	0	0
腎動脈狭窄症 Renal artery stenosis	0	1 (0.5%)	1 (0.2%)	0	0	0
膀胱ポリープ Urinary bladder polyp	1 (0.5%)	0	1 (0.2%)	0	0	0
尿閉 Urinary retention	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
尿路痛 Urinary tract pain	1 (0.5%)	0	1 (0.2%)	0	0	0
尿管結石症 Ureterolithiasis	0	0	0	1 (0.6%)	0	1 (0.3%)
眼障害 Eye disorders	24 (11.2%)	17 (7.9%)	41 (9.5%)	18 (10.5%)	17 (8.6%)	35 (9.5%)
霧視 Vision blurred	5 (2.3%)	3 (1.4%)	8 (1.9%)	2 (1.2%)	1 (0.5%)	3 (0.8%)
皮質白内障 Cataract cortical	3 (1.4%)	3 (1.4%)	6 (1.4%)	2 (1.2%)	4 (2.0%)	6 (1.6%)
核性白内障 Cataract nuclear	4 (1.9%)	1 (0.5%)	5 (1.2%)	4 (2.3%)	5 (2.5%)	9 (2.4%)
ドライアイ Dry eye	0	3 (1.4%)	3 (0.7%)	0	3 (1.5%)	3 (0.8%)
視力低下 Visual acuity reduced	1 (0.5%)	2 (0.9%)	3 (0.7%)	0	2 (1.0%)	2 (0.5%)
嚢下白内障 Cataract subcapsular	1 (0.5%)	1 (0.5%)	2 (0.5%)	3 (1.8%)	0	3 (0.8%)
眼痛 Eye pain	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
流涙増加 Lacrimation increased	2 (0.9%)	0	2 (0.5%)	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
視力障害 Visual impairment	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
白内障 Cataract	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
角膜炎 Keratitis	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
複視 Diplopia	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
眼出血 Eye haemorrhage	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
眼刺激 Eye irritation	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
眼瞼浮腫 Eyelid oedema	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
黄斑変性 Macular degeneration	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
網膜出血 Retinal haemorrhage	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
結膜上皮侵入 Conjunctivalisation	0	1 (0.5%)	1 (0.2%)	0	0	0
眼球浮腫 Eye oedema	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
眼部腫脹 Eye swelling	1 (0.5%)	0	1 (0.2%)	0	0	0
星状硝子体症 Hyalosis asteroid	1 (0.5%)	0	1 (0.2%)	0	0	0
眼窩浮腫 Orbital oedema	1 (0.5%)	0	1 (0.2%)	0	0	0
眼窩周囲浮腫 Periorbital oedema	1 (0.5%)	0	1 (0.2%)	0	0	0
光視症 Photopsia	1 (0.5%)	0	1 (0.2%)	0	0	0
眼瞼腫脹 Swelling of eyelid	1 (0.5%)	0	1 (0.2%)	0	0	0
硝子体浮遊物 Vitreous floaters	1 (0.5%)	0	1 (0.2%)	0	0	0
結膜出血 Conjunctival haemorrhage	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
糖尿病網膜症 Diabetic retinopathy	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
眼充血 Ocular hyperaemia	0	0	0	0	2 (1.0%)	2 (0.5%)
眼瞼炎 Blepharitis	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
眼瞼下垂 Eyelid ptosis	0	0	0	1 (0.6%)	0	1 (0.3%)
緑内障 Glaucoma	0	0	0	1 (0.6%)	0	1 (0.3%)
睫毛の成長 Growth of eyelashes	0	0	0	0	1 (0.5%)	1 (0.3%)
マイボーム腺機能不全 Meibomian gland dysfunction	0	0	0	0	1 (0.5%)	1 (0.3%)
網膜瘢痕 Retinal scar	0	0	0	1 (0.6%)	0	1 (0.3%)
硝子体変性 Vitreous degeneration	0	0	0	1 (0.6%)	0	1 (0.3%)
精神障害 Psychiatric disorders	20 (9.3%)	17 (7.9%)	37 (8.6%)	13 (7.6%)	15 (7.6%)	28 (7.6%)
不安 Anxiety	7 (3.3%)	6 (2.8%)	13 (3.0%)	3 (1.8%)	1 (0.5%)	4 (1.1%)
不眠症 Insomnia	4 (1.9%)	6 (2.8%)	10 (2.3%)	5 (2.9%)	6 (3.0%)	11 (3.0%)
うつ病 Depression	6 (2.8%)	3 (1.4%)	9 (2.1%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
錯乱状態 Confusional state	1 (0.5%)	1 (0.5%)	2 (0.5%)	1 (0.6%)	1 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
精神状態変化 Mental status changes	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
神経過敏 Nervousness	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
激越 Agitation	1 (0.5%)	0	1 (0.2%)	0	0	0
不安障害 Anxiety disorder	0	1 (0.5%)	1 (0.2%)	0	0	0
精神緩慢 Bradyphrenia	0	1 (0.5%)	1 (0.2%)	0	0	0
幻覚 Hallucination	1 (0.5%)	0	1 (0.2%)	0	0	0
初期不眠症 Initial insomnia	0	1 (0.5%)	1 (0.2%)	0	0	0
悪夢 Nightmare	0	1 (0.5%)	1 (0.2%)	0	0	0
リビドー減退 Libido decreased	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
感情障害 Affective disorder	0	0	0	0	1 (0.5%)	1 (0.3%)
抑うつ気分 Depressed mood	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
失見当識 Disorientation	0	0	0	1 (0.6%)	0	1 (0.3%)
睡眠障害 Sleep disorder	0	0	0	0	1 (0.5%)	1 (0.3%)
自殺念慮 Suicidal ideation	0	0	0	1 (0.6%)	0	1 (0.3%)
心臓障害 Cardiac disorders	20 (9.3%)	15 (6.9%)	35 (8.1%)	7 (4.1%)	11 (5.6%)	18 (4.9%)
心房細動 Atrial fibrillation	8 (3.7%)	2 (0.9%)	10 (2.3%)	2 (1.2%)	2 (1.0%)	4 (1.1%)
狭心症 Angina pectoris	4 (1.9%)	1 (0.5%)	5 (1.2%)	0	2 (1.0%)	2 (0.5%)
心不全 Cardiac failure	2 (0.9%)	3 (1.4%)	5 (1.2%)	0	2 (1.0%)	2 (0.5%)
動悸 Palpitations	2 (0.9%)	3 (1.4%)	5 (1.2%)	0	2 (1.0%)	2 (0.5%)
頻脈 Tachycardia	2 (0.9%)	2 (0.9%)	4 (0.9%)	1 (0.6%)	0	1 (0.3%)
急性心筋梗塞 Acute myocardial infarction	3 (1.4%)	0	3 (0.7%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
うっ血性心不全 Cardiac failure congestive	1 (0.5%)	2 (0.9%)	3 (0.7%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
急性心不全 Cardiac failure acute	0	2 (0.9%)	2 (0.5%)	0	0	0
心拡大 Cardiomegaly	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
左室不全 Left ventricular failure	0	2 (0.9%)	2 (0.5%)	0	0	0
心房粗動 Atrial flutter	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
洞性徐脈 Sinus bradycardia	0	1 (0.5%)	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
不安定狭心症 Angina unstable	1 (0.5%)	0	1 (0.2%)	0	0	0
完全房室ブロック Atrioventricular block complete	1 (0.5%)	0	1 (0.2%)	0	0	0
徐脈 Bradycardia	0	1 (0.5%)	1 (0.2%)	0	0	0
期外収縮 Extrasystoles	1 (0.5%)	0	1 (0.2%)	0	0	0
高血圧性心疾患 Hypertensive heart disease	0	1 (0.5%)	1 (0.2%)	0	0	0
左室機能不全 Left ventricular dysfunction	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
僧帽弁閉鎖不全症 Mitral valve incompetence	0	1 (0.5%)	1 (0.2%)	0	0	0
心嚢液貯留 Pericardial effusion	1 (0.5%)	0	1 (0.2%)	0	0	0
上室性頻脈 Supraventricular tachycardia	1 (0.5%)	0	1 (0.2%)	0	0	0
三尖弁閉鎖不全症 Tricuspid valve incompetence	1 (0.5%)	0	1 (0.2%)	0	0	0
第一度房室ブロック Atrioventricular block first degree	0	0	0	1 (0.6%)	0	1 (0.3%)
心停止 Cardiac arrest	0	0	0	0	1 (0.5%)	1 (0.3%)
慢性心不全 Cardiac failure chronic	0	0	0	0	1 (0.5%)	1 (0.3%)
心臓弁膜疾患 Cardiac valve disease	0	0	0	0	1 (0.5%)	1 (0.3%)
拡張機能障害 Diastolic dysfunction	0	0	0	0	1 (0.5%)	1 (0.3%)
心筋虚血 Myocardial ischaemia	0	0	0	1 (0.6%)	0	1 (0.3%)
耳および迷路障害 Ear and labyrinth disorders	13 (6.1%)	13 (6.0%)	26 (6.0%)	7 (4.1%)	7 (3.6%)	14 (3.8%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
回転性めまい Vertigo	8 (3.7%)	7 (3.2%)	15 (3.5%)	3 (1.8%)	5 (2.5%)	8 (2.2%)
耳鳴 Tinnitus	2 (0.9%)	2 (0.9%)	4 (0.9%)	0	0	0
耳痛 Ear pain	1 (0.5%)	2 (0.9%)	3 (0.7%)	0	0	0
耳不快感 Ear discomfort	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
聴力低下 Hypoacusis	1 (0.5%)	0	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
耳閉 Ear congestion	0	1 (0.5%)	1 (0.2%)	0	0	0
難聴 Deafness	0	0	0	1 (0.6%)	0	1 (0.3%)
耳出血 Ear haemorrhage	0	0	0	0	1 (0.5%)	1 (0.3%)
乗物酔い Motion sickness	0	0	0	1 (0.6%)	0	1 (0.3%)
突発性難聴 Sudden hearing loss	0	0	0	1 (0.6%)	0	1 (0.3%)
鼓膜穿孔 Tympanic membrane perforation	0	0	0	1 (0.6%)	0	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
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） Neoplasms benign, malignant and unspecified (incl cysts and polyps)	11 (5.1%)	14 (6.5%)	25 (5.8%)	10 (5.8%)	14 (7.1%)	24 (6.5%)
皮膚有棘細胞癌 Squamous cell carcinoma of skin	3 (1.4%)	4 (1.9%)	7 (1.6%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
基底細胞癌 Basal cell carcinoma	2 (0.9%)	3 (1.4%)	5 (1.2%)	3 (1.8%)	2 (1.0%)	5 (1.4%)
急性骨髄性白血病 Acute myeloid leukaemia	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	2 (1.0%)	2 (0.5%)
膵管内乳頭粘液性腫瘍 Intraductal papillary mucinous neoplasm	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	0	0
骨髄線維症 Myelofibrosis	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	2 (1.0%)	3 (0.8%)
悪性黒色腫 Malignant melanoma	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
メラノサイト性母斑 Melanocytic naevus	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	0	1 (0.3%)
膀胱移行上皮癌 Bladder transitional cell carcinoma	1 (0.5%)	0	1 (0.2%)	0	0	0
再発マントル細胞リンパ腫 Mantle cell lymphoma recurrent	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
鼻の良性新生物 Nasal neoplasm benign	0	1 (0.5%)	1 (0.2%)	0	0	0
食道扁平上皮癌 Oesophageal squamous cell carcinoma	1 (0.5%)	0	1 (0.2%)	0	0	0
卵巣明細胞癌 Ovarian clear cell carcinoma	1 (0.5%)	0	1 (0.2%)	0	0	0
再発前立腺癌 Prostate cancer recurrent	0	1 (0.5%)	1 (0.2%)	0	0	0
脾臓辺縁帯リンパ腫 Splenic marginal zone lymphoma	1 (0.5%)	0	1 (0.2%)	0	0	0
急性骨髄性白血病への転化 Transformation to acute myeloid leukaemia	0	1 (0.5%)	1 (0.2%)	0	0	0
子宮癌 Uterine cancer	1 (0.5%)	0	1 (0.2%)	0	0	0
脂漏性角化症 Seborrhoeic keratosis	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
子宮平滑筋腫 Uterine leiomyoma	0	0	0	0	2 (1.0%)	2 (0.5%)
乳腺線維腺腫 Fibroadenoma of breast	0	0	0	1 (0.6%)	0	1 (0.3%)
骨血管腫 Haemangioma of bone	0	0	0	0	1 (0.5%)	1 (0.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
白赤芽球症 Leukoerythroblastosis	0	0	0	1 (0.6%)	0	1 (0.3%)
遠隔転移を伴う扁平上皮癌 Metastatic squamous cell carcinoma	0	0	0	0	1 (0.5%)	1 (0.3%)
前立腺癌 Prostate cancer	0	0	0	0	1 (0.5%)	1 (0.3%)
直腸癌 Rectal cancer	0	0	0	1 (0.6%)	0	1 (0.3%)
鼻副鼻腔乳頭腫 Sinonasal papilloma	0	0	0	0	1 (0.5%)	1 (0.3%)
生殖系および乳房障害 Reproductive system and breast disorders	5 (2.3%)	7 (3.2%)	12 (2.8%)	2 (1.2%)	4 (2.0%)	6 (1.6%)
良性前立腺肥大症 Benign prostatic hyperplasia	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
膣出血 Vaginal haemorrhage	1 (0.5%)	1 (0.5%)	2 (0.5%)	0	1 (0.5%)	1 (0.3%)
膣分泌物 Vaginal discharge	0	1 (0.5%)	1 (0.2%)	0	1 (0.5%)	1 (0.3%)
月経過多 Menorrhagia	0	1 (0.5%)	1 (0.2%)	0	0	0
会陰痛 Perineal pain	1 (0.5%)	0	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
陰嚢浮腫 Scrotal oedema	0	1 (0.5%)	1 (0.2%)	0	0	0
自発陰茎勃起 Spontaneous penile erection	0	1 (0.5%)	1 (0.2%)	0	0	0
腟ポリープ Vaginal polyp	0	1 (0.5%)	1 (0.2%)	0	0	0
外陰腟の炎症 Vulvovaginal inflammation	1 (0.5%)	0	1 (0.2%)	0	0	0
外陰腟痛 Vulvovaginal pain	1 (0.5%)	0	1 (0.2%)	0	0	0
精巣上体嚢胞 Epididymal cyst	0	0	0	1 (0.6%)	0	1 (0.3%)
子宮頚部びらん Uterine cervical erosion	0	0	0	0	1 (0.5%)	1 (0.3%)
腟脱 Vaginal prolapse	0	0	0	1 (0.6%)	0	1 (0.3%)
肝胆道系障害 Hepatobiliary disorders	1 (0.5%)	5 (2.3%)	6 (1.4%)	2 (1.2%)	5 (2.5%)	7 (1.9%)
胆道仙痛 Biliary colic	0	2 (0.9%)	2 (0.5%)	0	0	0
胆石症 Cholelithiasis	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
肝機能異常 Hepatic function abnormal	0	1 (0.5%)	1 (0.2%)	0	0	0
肝細胞損傷 Hepatocellular injury	0	1 (0.5%)	1 (0.2%)	0	0	0
過形成性胆嚢症 Hyperplastic cholecystopathy	1 (0.5%)	0	1 (0.2%)	0	0	0
黄疸眼 Ocular icterus	0	0	0	1 (0.6%)	1 (0.5%)	2 (0.5%)
急性胆嚢炎 Cholecystitis acute	0	0	0	0	1 (0.5%)	1 (0.3%)
胆汁うっ滞 Cholestasis	0	0	0	1 (0.6%)	0	1 (0.3%)
肝硬変 Hepatic cirrhosis	0	0	0	0	1 (0.5%)	1 (0.3%)
肝不全 Hepatic failure	0	0	0	0	1 (0.5%)	1 (0.3%)
門脈圧亢進症 Portal hypertension	0	0	0	0	1 (0.5%)	1 (0.3%)
先天性、家族性および遺伝性障害 Congenital, familial and genetic disorders	0	3 (1.4%)	3 (0.7%)	0	0	0
ジルベール症候群 Gilbert's syndrome	0	1 (0.5%)	1 (0.2%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（全体）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=214)	RUX (N=216)	Total (N=430)	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)
陰嚢水瘤 Hydrocele	0	1 (0.5%)	1 (0.2%)	0	0	0
包茎 Phimosis	0	1 (0.5%)	1 (0.2%)	0	0	0
内分泌障害 Endocrine disorders	2 (0.9%)	0	2 (0.5%)	1 (0.6%)	0	1 (0.3%)
低アルドステロン症 Hypoaldosteronism	1 (0.5%)	0	1 (0.2%)	0	0	0
甲状腺機能低下症 Hypothyroidism	1 (0.5%)	0	1 (0.2%)	0	0	0
甲状腺腫瘤 Thyroid mass	0	0	0	1 (0.6%)	0	1 (0.3%)
外科および内科処置 Surgical and medical procedures	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)
抜歯 Tooth extraction	1 (0.5%)	0	1 (0.2%)	1 (0.6%)	1 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
有害事象発現例数 ANY EVENT	5 (83.3%)	8 (88.9%)	13 (86.7%)	4 (66.7%)	9 (100.0%)	13 (86.7%)
胃腸障害 Gastrointestinal disorders	1 (16.7%)	5 (55.6%)	6 (40.0%)	1 (16.7%)	5 (55.6%)	6 (40.0%)
下痢 Diarrhoea	0	1 (11.1%)	1 (6.7%)	0	2 (22.2%)	2 (13.3%)
腹痛 Abdominal pain	0	0	0	0	0	0
悪心 Nausea	0	0	0	0	3 (33.3%)	3 (20.0%)
便秘 Constipation	1 (16.7%)	0	1 (6.7%)	1 (16.7%)	1 (11.1%)	2 (13.3%)
嘔吐 Vomiting	0	1 (11.1%)	1 (6.7%)	0	0	0
上腹部痛 Abdominal pain upper	0	0	0	0	0	0
腹部膨満 Abdominal distension	0	0	0	0	0	0
消化不良 Dyspepsia	1 (16.7%)	0	1 (6.7%)	0	0	0
腹部不快感 Abdominal discomfort	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
胃食道逆流性疾患 Gastrooesophageal reflux disease	0	0	0	0	0	0
鼓腸 Flatulence	0	0	0	0	0	0
口内乾燥 Dry mouth	0	0	0	0	0	0
歯痛 Toothache	0	0	0	0	0	0
口腔内潰瘍形成 Mouth ulceration	0	0	0	0	0	0
痔核 Haemorrhoids	0	0	0	0	0	0
歯肉出血 Gingival bleeding	0	1 (11.1%)	1 (6.7%)	0	0	0
鼠径ヘルニア Inguinal hernia	0	0	0	0	0	0
口内炎 Stomatitis	0	2 (22.2%)	2 (13.3%)	0	1 (11.1%)	1 (6.7%)
小腸炎 Enteritis	0	0	0	0	0	0
腹水 Ascites	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
直腸出血 Rectal haemorrhage	0	0	0	0	0	0
口唇炎 Cheilitis	0	1 (11.1%)	1 (6.7%)	0	1 (11.1%)	1 (6.7%)
アフタ性潰瘍 Aphthous ulcer	0	0	0	0	0	0
腸炎 Enterocolitis	0	1 (11.1%)	1 (6.7%)	0	0	0
肛門周囲痛 Proctalgia	0	0	0	0	0	0
胃炎 Gastritis	0	0	0	0	0	0
食道静脈瘤 Varices oesophageal	0	0	0	0	0	0
嚥下障害 Dysphagia	0	0	0	0	0	0
レッチング Retching	0	0	0	0	0	0
小腸閉塞 Small intestinal obstruction	0	0	0	0	0	0
下腹部痛 Abdominal pain lower	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
肛門出血 Anal haemorrhage	0	0	0	0	0	0
憩室穿孔 Diverticular perforation	0	0	0	0	0	0
びらん性食道炎 Erosive oesophagitis	0	0	0	0	0	0
変色便 Faeces discoloured	0	0	0	0	0	0
軟便 Faeces soft	0	0	0	0	0	0
胃ポリープ Gastric polyps	0	0	0	0	0	0
胃潰瘍 Gastric ulcer	0	0	0	0	0	0
血便排泄 Haematochezia	0	0	0	0	0	0
痔出血 Haemorrhoidal haemorrhage	0	0	0	0	0	0
イレウス Ileus	0	0	0	0	0	0
口唇痛 Lip pain	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
メレナ Melaena	0	0	0	0	0	0
腸間膜静脈血栓症 Mesenteric vein thrombosis	0	0	0	0	0	0
嚥下痛 Odynophagia	0	0	0	0	0	0
食道痛 Oesophageal pain	0	0	0	0	0	0
食道炎 Oesophagitis	0	0	0	0	0	0
消化性潰瘍 Peptic ulcer	0	0	0	0	0	0
腹膜出血 Peritoneal haemorrhage	0	0	0	0	0	0
亜イレウス Subileus	0	0	0	0	0	0
舌紅斑 Tongue erythema	0	0	0	0	0	0
肛門失禁 Anal incontinence	0	0	0	0	0	0
口角口唇炎 Angular cheilitis	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
心窩部不快感 Epigastric discomfort	0	0	0	0	0	0
口腔内痛 Oral pain	0	0	0	0	0	0
腹部硬直 Abdominal rigidity	0	0	0	0	0	0
便意切迫 Defaecation urgency	0	0	0	0	0	0
齲歯 Dental caries	0	0	0	0	1 (11.1%)	1 (6.7%)
出血性十二指腸潰瘍 Duodenal ulcer haemorrhage	0	0	0	0	0	0
食中毒 Food poisoning	0	0	0	0	0	0
胃出血 Gastric haemorrhage	0	0	0	0	0	0
出血性胃潰瘍 Gastric ulcer haemorrhage	0	0	0	1 (16.7%)	0	1 (6.7%)
びらん性胃炎 Gastritis erosive	0	0	0	0	0	0
胃腸出血 Gastrointestinal haemorrhage	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
消化器痛 Gastrointestinal pain	0	0	0	0	0	0
胃腸音異常 Gastrointestinal sounds abnormal	0	0	0	0	0	0
裂孔ヘルニア Hiatus hernia	0	0	0	0	0	0
口の感覚鈍麻 Hypoaesthesia oral	0	0	0	0	0	0
下部消化管出血 Lower gastrointestinal haemorrhage	0	0	0	0	0	0
口腔内出血 Mouth haemorrhage	0	0	0	0	0	0
食道静脈瘤出血 Oesophageal varices haemorrhage	0	0	0	0	0	0
口腔粘膜血腫 Oral mucosa haematoma	0	0	0	0	0	0
歯周病 Periodontal disease	0	0	0	0	1 (11.1%)	1 (6.7%)
咳嗽後嘔吐 Post-tussive vomiting	0	0	0	0	0	0
小腸出血 Small intestinal haemorrhage	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
血液およびリンパ系障害 Blood and lymphatic system disorders	1 (16.7%)	7 (77.8%)	8 (53.3%)	1 (16.7%)	2 (22.2%)	3 (20.0%)
貧血 Anaemia	0	6 (66.7%)	6 (40.0%)	1 (16.7%)	0	1 (6.7%)
血小板減少症 Thrombocytopenia	1 (16.7%)	3 (33.3%)	4 (26.7%)	0	1 (11.1%)	1 (6.7%)
好中球減少症 Neutropenia	0	2 (22.2%)	2 (13.3%)	0	0	0
白血球減少症 Leukopenia	0	1 (11.1%)	1 (6.7%)	0	0	0
血小板増加症 Thrombocytosis	0	0	0	0	0	0
白血球増加症 Leukocytosis	0	0	0	0	0	0
発熱性好中球減少症 Febrile neutropenia	0	0	0	0	0	0
リンパ球減少症 Lymphopenia	0	1 (11.1%)	1 (6.7%)	0	1 (11.1%)	1 (6.7%)
脾腫 Splenomegaly	0	0	0	0	0	0
内出血発生の増加傾向 Increased tendency to bruise	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
凝血異常 Coagulopathy	0	0	0	0	0	0
赤血球増加症 Polycythaemia	0	0	0	0	0	0
脾臓梗塞 Splenic infarction	0	0	0	0	0	0
失血性貧血 Blood loss anaemia	0	0	0	0	0	0
低プロトロンビン血症 Hypoprothrombinaemia	0	0	0	0	0	0
リンパ節石灰化 Lymph node calcification	0	0	0	0	0	0
リンパ節症 Lymphadenopathy	0	0	0	0	0	0
リンパ球増加症 Lymphocytosis	0	0	0	0	0	0
微小血管症性溶血性貧血 Microangiopathic haemolytic anaemia	0	0	0	0	0	0
脾血腫 Splenic haematoma	0	0	0	0	0	0
過粘稠度症候群 Hyperviscosity syndrome	0	0	0	1 (16.7%)	0	1 (6.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
肥満細胞症 Mastocytosis	0	0	0	0	0	0
好中球増加症 Neutrophilia	0	0	0	0	0	0
特発性血腫 Spontaneous haematoma	0	0	0	0	0	0
感染症および寄生虫症 Infections and infestations	1 (16.7%)	4 (44.4%)	5 (33.3%)	2 (33.3%)	3 (33.3%)	5 (33.3%)
上気道感染 Upper respiratory tract infection	0	1 (11.1%)	1 (6.7%)	0	0	0
上咽頭炎 Nasopharyngitis	1 (16.7%)	2 (22.2%)	3 (20.0%)	2 (33.3%)	0	2 (13.3%)
尿路感染 Urinary tract infection	0	0	0	1 (16.7%)	0	1 (6.7%)
帯状疱疹 Herpes zoster	0	0	0	0	0	0
肺炎 Pneumonia	0	0	0	0	0	0
気道感染 Respiratory tract infection	0	0	0	0	0	0
口腔ヘルペス Oral herpes	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
気管支炎 Bronchitis	0	0	0	0	1 (11.1%)	1 (6.7%)
膀胱炎 Cystitis	0	0	0	0	1 (11.1%)	1 (6.7%)
インフルエンザ Influenza	0	0	0	0	0	0
鼻炎 Rhinitis	0	0	0	0	0	0
胃腸炎 Gastroenteritis	0	0	0	0	1 (11.1%)	1 (6.7%)
皮膚感染 Skin infection	0	0	0	0	0	0
下気道感染 Lower respiratory tract infection	0	0	0	0	0	0
敗血症 Sepsis	0	0	0	0	0	0
副鼻腔炎 Sinusitis	0	0	0	0	0	0
蜂巣炎 Cellulitis	0	0	0	0	0	0
ウイルス感染 Viral infection	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
術後創感染 Postoperative wound infection	0	0	0	0	0	0
結膜炎 Conjunctivitis	0	0	0	0	0	0
癜風 Tinea versicolour	0	0	0	0	0	0
皮膚真菌感染 Fungal skin infection	0	0	0	0	0	0
消化管感染 Gastrointestinal infection	0	0	0	0	0	0
限局性感染 Localised infection	0	0	0	0	0	0
口腔カンジダ症 Oral candidiasis	0	0	0	0	0	0
毛包炎 Folliculitis	0	0	0	0	0	0
歯肉炎 Gingivitis	0	0	0	0	0	0
感染 Infection	0	1 (11.1%)	1 (6.7%)	0	0	0
歯周炎 Periodontitis	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
咽頭炎 Pharyngitis	0	0	0	0	0	0
気管気管支炎 Tracheobronchitis	0	0	0	0	0	0
腟感染 Vaginal infection	0	0	0	0	0	0
陰部ヘルペス Genital herpes	0	0	0	0	0	0
クロストリジウム・ディフィシレ大腸炎 Clostridium difficile colitis	0	0	0	0	0	0
大腸菌性尿路感染 Escherichia urinary tract infection	0	0	0	0	0	0
真菌感染 Fungal infection	0	0	0	0	0	0
肺感染 Lung infection	0	0	0	0	0	0
外耳炎 Otitis externa	0	0	0	0	0	0
赤痢菌感染 Shigella infection	0	0	0	0	0	0
肛門膿瘍 Anal abscess	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
憩室炎 Diverticulitis	1 (16.7%)	0	1 (6.7%)	0	0	0
大腸菌性敗血症 Escherichia sepsis	0	0	0	0	0	0
真菌性食道炎 Fungal oesophagitis	0	0	0	0	0	0
せつ Furuncle	0	0	0	0	0	0
ウイルス性消化管感染 Gastrointestinal viral infection	0	0	0	0	0	0
麦粒腫 Hordeolum	0	0	0	0	0	0
膿痂疹 Impetigo	0	0	0	0	0	0
喉頭炎 Laryngitis	0	0	0	0	0	0
口唇感染 Lip infection	0	0	0	0	0	0
ライム病 Lyme disease	0	0	0	0	0	0
爪真菌症 Onychomycosis	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
爪囲炎 Paronychia	0	0	0	0	0	0
腹膜炎 Peritonitis	0	0	0	0	0	0
細菌性肺炎 Pneumonia bacterial	0	0	0	0	0	0
処置後感染 Post procedural infection	0	0	0	0	0	0
肺敗血症 Pulmonary sepsis	0	0	0	0	0	0
腎盂膀胱炎 Pyelocystitis	0	0	0	0	0	0
腎盂腎炎 Pyelonephritis	0	0	0	0	0	0
陰嚢膿瘍 Scrotal abscess	0	0	0	0	0	0
皮膚細菌感染 Skin bacterial infection	0	0	0	0	0	0
ブドウ球菌感染 Staphylococcal infection	0	0	0	0	0	0
レンサ球菌性敗血症 Streptococcal sepsis	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
気管炎 Tracheitis	0	0	0	0	0	0
ウイルス性上気道感染 Viral upper respiratory tract infection	0	0	0	0	0	0
外陰部腟カンジダ症 Vulvovaginal candidiasis	0	0	0	0	0	0
外陰腟真菌感染 Vulvovaginal mycotic infection	0	0	0	0	0	0
創傷感染 Wound infection	0	0	0	0	0	0
クロストリジウム・ディフィシレ感染 Clostridium difficile infection	0	0	0	0	0	0
耳感染 Ear infection	0	0	0	0	0	0
単純ヘルペス Herpes simplex	0	0	0	0	0	0
中耳炎 Otitis media	0	0	0	0	0	0
扁桃炎 Tonsillitis	0	0	0	0	0	0
ボレリア感染 Borrelia infection	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
丹毒 Erysipelas	0	0	0	0	0	0
壊疽 Gangrene	0	0	0	0	0	0
サルモネラ菌性胃腸炎 Gastroenteritis salmonella	0	0	0	0	0	0
消化器カンジダ症 Gastrointestinal candidiasis	0	0	0	0	0	0
ヘルペス性皮膚炎 Herpes dermatitis	0	0	0	0	0	0
感染性皮膚潰瘍 Infected skin ulcer	0	0	0	0	0	0
迷路炎 Labyrinthitis	0	0	0	0	0	0
鼻ヘルペス Nasal herpes	0	0	0	0	0	0
百日咳 Pertussis	0	0	0	0	0	0
ピコルナウイルス感染 Picornavirus infection	0	0	0	0	0	0
歯膿瘍 Tooth abscess	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
水痘帯状疱疹ウイルス感染 Varicella zoster virus infection	0	0	0	0	0	0
ウイルス性ぶどう膜炎 Viral uveitis	0	0	0	0	0	0
神経系障害 Nervous system disorders	2 (33.3%)	2 (22.2%)	4 (26.7%)	1 (16.7%)	2 (22.2%)	3 (20.0%)
頭痛 Headache	1 (16.7%)	1 (11.1%)	2 (13.3%)	1 (16.7%)	0	1 (6.7%)
浮動性めまい Dizziness	0	0	0	0	1 (11.1%)	1 (6.7%)
末梢性感覚ニューロパチー Peripheral sensory neuropathy	1 (16.7%)	1 (11.1%)	2 (13.3%)	0	1 (11.1%)	1 (6.7%)
錯感覚 Paraesthesia	0	0	0	0	0	0
失神寸前の状態 Presyncope	0	0	0	0	0	0
嗜眠 Lethargy	0	0	0	0	0	0
感覚鈍麻 Hypoaesthesia	0	0	0	0	0	0
振戦 Tremor	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
記憶障害 Memory impairment	0	0	0	0	0	0
坐骨神経痛 Sciatica	0	0	0	0	0	0
失神 Syncope	0	0	0	0	0	0
味覚障害 Taste disorder	0	0	0	0	0	0
平衡障害 Balance disorder	0	0	0	0	0	0
健忘 Amnesia	0	0	0	0	0	0
片頭痛 Migraine	0	0	0	0	0	0
味覚異常 Dysgeusia	0	0	0	0	0	0
一過性脳虚血発作 Transient ischaemic attack	0	0	0	0	0	0
異常感覚 Dysaesthesia	0	0	0	0	0	0
前頭側頭型認知症 Frontotemporal dementia	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
神経痛 Neuralgia	0	0	0	0	0	0
末梢性ニューロパチー Neuropathy peripheral	0	0	0	0	0	0
傾眠 Somnolence	0	0	0	0	1 (11.1%)	1 (6.7%)
失語症 Aphasia	0	0	0	0	0	0
手根管症候群 Carpal tunnel syndrome	0	0	0	0	0	0
脳虚血 Cerebral ischaemia	0	0	0	0	0	0
頚髄神経根障害 Cervical radiculopathy	0	0	0	0	0	0
頚腕症候群 Cervicobrachial syndrome	0	0	0	0	0	0
昏睡 Coma	0	0	0	0	0	0
注意力障害 Disturbance in attention	0	0	0	0	0	0
体位性めまい Dizziness postural	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
脳症 Encephalopathy	0	0	0	0	0	0
蟻走感 Formication	0	0	0	0	0	0
前兆を伴う片頭痛 Migraine with aura	0	0	0	0	0	0
神経系障害 Nervous system disorder	0	0	0	0	0	0
末梢性運動ニューロパチー Peripheral motor neuropathy	0	0	0	0	0	0
ヘルペス後神経痛 Post herpetic neuralgia	0	0	0	0	0	0
血管性脳症 Vascular encephalopathy	0	0	0	0	0	0
脳血管発作 Cerebrovascular accident	0	0	0	0	0	0
味覚消失 Ageusia	0	0	0	0	0	0
運動失調 Ataxia	0	0	0	0	0	0
脳微小血管症 Cerebral microangiopathy	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
脱髄 Demyelination	0	0	0	0	0	0
意識消失 Loss of consciousness	0	0	0	0	0	0
末梢性感覚運動ニューロパチー Peripheral sensorimotor neuropathy	0	0	0	0	0	0
副鼻腔炎に伴う頭痛 Sinus headache	0	0	0	0	0	0
くも膜下出血 Subarachnoid haemorrhage	0	0	0	0	0	0
声帯麻痺 Vocal cord paralysis	0	0	0	0	0	0
一般・全身障害および投与部位の状態 General disorders and administration site conditions	1 (16.7%)	2 (22.2%)	3 (20.0%)	1 (16.7%)	1 (11.1%)	2 (13.3%)
疲労 Fatigue	0	0	0	0	0	0
発熱 Pyrexia	0	1 (11.1%)	1 (6.7%)	1 (16.7%)	0	1 (6.7%)
無力症 Asthenia	0	0	0	0	0	0
末梢性浮腫 Oedema peripheral	0	1 (11.1%)	1 (6.7%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
胸痛 Chest pain	0	0	0	0	1 (11.1%)	1 (6.7%)
インフルエンザ様疾患 Influenza like illness	0	0	0	0	0	0
倦怠感 Malaise	0	0	0	0	0	0
悪寒 Chills	0	0	0	0	0	0
末梢腫脹 Peripheral swelling	0	0	0	0	0	0
早期満腹 Early satiety	0	0	0	0	0	0
疼痛 Pain	0	0	0	0	0	0
浮腫 Oedema	1 (16.7%)	0	1 (6.7%)	0	0	0
胸部不快感 Chest discomfort	0	0	0	0	0	0
非心臓性胸痛 Non-cardiac chest pain	0	0	0	0	0	0
乾燥症 Xerosis	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
顔面痛 Facial pain	0	0	0	0	0	0
重力性浮腫 Gravitational oedema	0	0	0	0	0	0
炎症 Inflammation	0	0	0	0	0	0
粘膜の炎症 Mucosal inflammation	0	0	0	0	0	0
死亡 Death	0	0	0	0	0	0
全身健康状態悪化 General physical health deterioration	0	0	0	0	0	0
全身性浮腫 Generalised oedema	0	0	0	0	0	0
カテーテル留置部位出血 Catheter site haemorrhage	0	0	0	0	0	0
捻髪音 Crepitations	0	0	0	0	0	0
異常感 Feeling abnormal	0	0	0	0	0	0
冷感 Feeling cold	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
歩行障害 Gait disturbance	0	0	0	0	0	0
硬結 Induration	0	0	0	0	0	0
粘膜出血 Mucosal haemorrhage	0	0	0	0	0	0
突然死 Sudden death	0	0	0	0	0	0
腫脹 Swelling	0	0	0	0	0	0
熱感 Feeling hot	0	0	0	0	0	0
カテーテル留置部位疼痛 Catheter site pain	0	0	0	0	0	0
不快感 Discomfort	0	0	0	0	0	0
薬剤離脱症候群 Drug withdrawal syndrome	0	0	0	0	0	0
高熱 Hyperthermia	0	0	0	0	0	0
治癒不良 Impaired healing	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
注射部位出血 Injection site haemorrhage	0	0	0	0	0	0
口渇 Thirst	0	0	0	0	0	0
呼吸器、胸郭および縦隔障害 Respiratory, thoracic and mediastinal disorders	0	3 (33.3%)	3 (20.0%)	0	0	0
呼吸困難 Dyspnoea	0	0	0	0	0	0
咳嗽 Cough	0	1 (11.1%)	1 (6.7%)	0	0	0
鼻出血 Epistaxis	0	0	0	0	0	0
労作性呼吸困難 Dyspnoea exertional	0	0	0	0	0	0
口腔咽頭痛 Oropharyngeal pain	0	2 (22.2%)	2 (13.3%)	0	0	0
鼻漏 Rhinorrhoea	0	0	0	0	0	0
湿性咳嗽 Productive cough	0	0	0	0	0	0
低酸素症 Hypoxia	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
慢性閉塞性肺疾患 Chronic obstructive pulmonary disease	0	0	0	0	0	0
発声障害 Dysphonia	0	0	0	0	0	0
しゃっくり Hiccups	0	0	0	0	0	0
カタル Catarrh	0	0	0	0	0	0
ラ音 Rales	0	0	0	0	0	0
呼吸不全 Respiratory failure	0	0	0	0	0	0
喀血 Haemoptysis	0	0	0	0	0	0
鼻閉 Nasal congestion	0	0	0	0	0	0
肺水腫 Pulmonary oedema	0	0	0	0	0	0
上気道咳症候群 Upper-airway cough syndrome	0	0	0	0	0	0
急性呼吸不全 Acute respiratory failure	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
咽喉乾燥 Dry throat	0	0	0	0	0	0
発作性夜間呼吸困難 Dyspnoea paroxysmal nocturnal	0	0	0	0	0	0
肺浸潤 Lung infiltration	0	0	0	0	0	0
呼吸時疼痛 Painful respiration	0	0	0	0	0	0
咽頭潰瘍 Pharyngeal ulceration	0	0	0	0	0	0
胸膜痛 Pleuritic pain	0	0	0	0	0	0
誤嚥性肺炎 Pneumonia aspiration	0	0	0	0	0	0
肺線維症 Pulmonary fibrosis	0	0	0	0	0	0
肺肉芽腫 Pulmonary granuloma	0	0	0	0	0	0
肺出血 Pulmonary haemorrhage	0	0	0	0	0	0
肺高血圧症 Pulmonary hypertension	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
逆流性喉頭炎 Reflux laryngitis	0	0	0	0	0	0
睡眠時無呼吸症候群 Sleep apnoea syndrome	0	0	0	0	0	0
痰貯留 Sputum retention	0	1 (11.1%)	1 (6.7%)	0	0	0
咽喉刺激感 Throat irritation	0	0	0	0	0	0
咽喉絞扼感 Throat tightness	0	0	0	0	0	0
胸水 Pleural effusion	0	0	0	0	0	0
喘息 Asthma	0	0	0	0	0	0
肺塞栓症 Pulmonary embolism	0	0	0	0	0	0
気管支拡張症 Bronchiectasis	0	0	0	0	0	0
慢性気管支炎 Bronchitis chronic	0	0	0	0	0	0
肺気腫 Emphysema	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
喉頭の炎症 Laryngeal inflammation	0	0	0	0	0	0
肺硬化 Lung consolidation	0	0	0	0	0	0
肺障害 Lung disorder	0	0	0	0	0	0
起坐呼吸 Orthopnoea	0	0	0	0	0	0
胸膜炎 Pleurisy	0	0	0	0	0	0
肺腫瘤 Pulmonary mass	0	0	0	0	0	0
副鼻腔痛 Sinus pain	0	0	0	0	0	0
喘鳴 Wheezing	0	0	0	0	0	0
筋骨格系および結合組織障害 Musculoskeletal and connective tissue disorders	0	3 (33.3%)	3 (20.0%)	0	0	0
四肢痛 Pain in extremity	0	1 (11.1%)	1 (6.7%)	0	0	0
関節痛 Arthralgia	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
背部痛 Back pain	0	1 (11.1%)	1 (6.7%)	0	0	0
筋痙縮 Muscle spasms	0	1 (11.1%)	1 (6.7%)	0	0	0
骨痛 Bone pain	0	0	0	0	0	0
筋骨格痛 Musculoskeletal pain	0	0	0	0	0	0
筋肉痛 Myalgia	0	0	0	0	0	0
筋力低下 Muscular weakness	0	0	0	0	0	0
鼠径部痛 Groin pain	0	0	0	0	0	0
筋骨格系胸痛 Musculoskeletal chest pain	0	0	0	0	0	0
関節炎 Arthritis	0	0	0	0	0	0
脊椎痛 Spinal pain	0	0	0	0	0	0
側腹部痛 Flank pain	0	1 (11.1%)	1 (6.7%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
筋肉疲労 Muscle fatigue	0	0	0	0	0	0
顎痛 Pain in jaw	0	0	0	0	0	0
変形性関節症 Osteoarthritis	0	0	0	0	0	0
腱炎 Tendonitis	0	0	0	0	0	0
滑液包炎 Bursitis	0	0	0	0	0	0
筋骨格硬直 Musculoskeletal stiffness	0	1 (11.1%)	1 (6.7%)	0	0	0
滑液貯留 Bursal fluid accumulation	0	0	0	0	0	0
足変形 Foot deformity	0	0	0	0	0	0
痛風性関節炎 Gouty arthritis	0	0	0	0	0	0
骨減少症 Osteopenia	0	0	0	0	0	0
シェーグレン症候群 Sjogren's syndrome	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
変形性脊椎症 Spinal osteoarthritis	0	0	0	0	0	0
開口障害 Trismus	0	0	0	0	0	0
頚部痛 Neck pain	0	0	0	0	0	0
反応性関節炎 Arthritis reactive	0	0	0	0	0	0
骨病変 Bone lesion	0	0	0	0	0	0
胸壁血腫 Chest wall haematoma	0	0	0	0	0	0
筋膜炎 Fasciitis	0	0	0	0	0	0
関節滲出液 Joint effusion	0	0	0	0	0	0
四肢不快感 Limb discomfort	0	0	0	0	0	0
骨溶解 Osteolysis	0	0	0	0	0	0
骨硬化症 Osteosclerosis	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
関節周囲炎 Periarthritis	0	0	0	0	0	0
腱痛 Tendon pain	0	0	0	0	0	0
皮膚および皮下組織障害 Skin and subcutaneous tissue disorders	0	2 (22.2%)	2 (13.3%)	0	3 (33.3%)	3 (20.0%)
そう痒症 Pruritus	0	1 (11.1%)	1 (6.7%)	0	1 (11.1%)	1 (6.7%)
寝汗 Night sweats	0	0	0	0	0	0
発疹 Rash	0	1 (11.1%)	1 (6.7%)	0	2 (22.2%)	2 (13.3%)
紅斑 Erythema	0	0	0	0	0	0
斑状出血 Ecchymosis	0	0	0	0	0	0
脱毛症 Alopecia	0	0	0	0	0	0
皮膚潰瘍 Skin ulcer	0	0	0	0	0	0
斑状丘疹状皮疹 Rash maculo-papular	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
点状出血 Petechiae	0	0	0	0	0	0
多汗症 Hyperhidrosis	0	0	0	0	0	0
皮膚病変 Skin lesion	0	0	0	0	0	0
皮膚乾燥 Dry skin	0	0	0	0	0	0
紅斑性皮疹 Rash erythematous	0	0	0	0	0	0
接触皮膚炎 Dermatitis contact	0	0	0	0	0	0
湿疹 Eczema	0	0	0	0	0	0
過角化 Hyperkeratosis	0	0	0	0	0	0
皮膚疼痛 Pain of skin	0	0	0	0	0	0
皮膚出血 Skin haemorrhage	0	0	0	0	0	0
毛細血管拡張症 Telangiectasia	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
全身性そう痒症 Pruritus generalised	0	0	0	0	0	0
光線角化症 Actinic keratosis	0	0	0	0	0	0
アレルギー性皮膚炎 Dermatitis allergic	0	0	0	0	0	0
全身性皮疹 Rash generalised	0	0	0	0	0	0
斑状皮疹 Rash macular	0	0	0	0	0	0
丘疹性皮疹 Rash papular	0	0	0	0	0	0
薬疹 Drug eruption	0	0	0	0	1 (11.1%)	1 (6.7%)
嵌入爪 Ingrowing nail	0	0	0	0	0	0
乾癬 Psoriasis	0	0	0	0	0	0
紫斑 Purpura	0	0	0	0	0	0
水原性そう痒症 Aquagenic pruritus	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
水疱 Blister	0	0	0	0	0	0
血性水疱 Blood blister	0	0	0	0	0	0
紅色症 Erythrosis	0	0	0	0	0	0
間擦疹 Intertrigo	0	0	0	0	0	0
手掌・足底発赤知覚不全症候群 Palmar-plantar erythrodysaesthesia syndrome	0	0	0	0	0	0
口囲皮膚炎 Perioral dermatitis	0	0	0	0	0	0
毛孔性皮疹 Rash follicular	0	0	0	0	0	0
そう痒性皮疹 Rash pruritic	0	0	0	0	0	0
脂腺過形成 Sebaceous hyperplasia	0	0	0	0	0	0
中毒性皮疹 Toxic skin eruption	0	0	0	0	0	0
冷汗 Cold sweat	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
皮膚嚢腫 Dermal cyst	0	0	0	0	0	0
全身性剥脱性皮膚炎 Dermatitis exfoliative generalised	0	0	0	0	0	0
皮膚症 Dermatosis	0	0	0	0	0	0
酒さ Rosacea	0	0	0	0	0	0
皮膚剥脱 Skin exfoliation	0	0	0	0	0	0
皮膚脆弱性 Skin fragility	0	0	0	0	0	0
顔面腫脹 Swelling face	0	0	0	0	0	0
蕁麻疹 Urticaria	0	0	0	0	0	0
代謝および栄養障害 Metabolism and nutrition disorders	1 (16.7%)	2 (22.2%)	3 (20.0%)	2 (33.3%)	2 (22.2%)	4 (26.7%)
食欲減退 Decreased appetite	0	1 (11.1%)	1 (6.7%)	0	0	0
ビタミンＢ１欠乏 Vitamin B1 deficiency	0	0	0	0	1 (11.1%)	1 (6.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
高尿酸血症 Hyperuricaemia	1 (16.7%)	0	1 (6.7%)	1 (16.7%)	0	1 (6.7%)
高カリウム血症 Hyperkalaemia	0	0	0	0	0	0
低カリウム血症 Hypokalaemia	0	1 (11.1%)	1 (6.7%)	0	0	0
低マグネシウム血症 Hypomagnesaemia	0	0	0	0	0	0
低カルシウム血症 Hypocalcaemia	0	1 (11.1%)	1 (6.7%)	0	1 (11.1%)	1 (6.7%)
脱水 Dehydration	0	0	0	1 (16.7%)	0	1 (6.7%)
ビタミンD欠乏 Vitamin D deficiency	0	0	0	0	0	0
痛風 Gout	0	0	0	1 (16.7%)	0	1 (6.7%)
糖尿病 Diabetes mellitus	0	0	0	1 (16.7%)	0	1 (6.7%)
低ナトリウム血症 Hyponatraemia	0	0	0	0	0	0
低血糖 Hypoglycaemia	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
高血糖 Hyperglycaemia	0	0	0	0	0	0
ビタミンB群欠乏 Vitamin B complex deficiency	0	0	0	0	0	0
鉄欠乏 Iron deficiency	0	0	0	0	0	0
鉄過剰 Iron overload	0	0	0	0	0	0
体液貯留 Fluid retention	0	0	0	0	0	0
高カルシウム血症 Hypercalcaemia	0	0	0	0	0	0
高マグネシウム血症 Hypermagnesaemia	0	1 (11.1%)	1 (6.7%)	0	1 (11.1%)	1 (6.7%)
低アルブミン血症 Hypoalbuminaemia	0	0	0	0	0	0
低リン酸血症 Hypophosphataemia	0	0	0	0	0	0
葉酸欠乏 Folate deficiency	0	0	0	0	0	0
ヘモジデリン沈着症 Haemosiderosis	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
血液量増加症 Hypervolaemia	0	0	0	0	0	0
栄養障害 Malnutrition	0	0	0	0	0	0
多飲症 Polydipsia	0	0	0	0	0	0
腫瘍崩壊症候群 Tumour lysis syndrome	0	0	0	0	0	0
ビタミンＫ欠乏 Vitamin K deficiency	0	0	0	0	0	0
高トリグリセリド血症 Hypertriglyceridaemia	0	0	0	0	0	0
異常体重減少 Abnormal loss of weight	0	0	0	0	0	0
電解質失調 Electrolyte imbalance	0	0	0	0	0	0
高コレステロール血症 Hypercholesterolaemia	0	0	0	0	0	0
高フェリチン血症 Hyperferritinaemia	0	0	0	0	0	0
ビタミンＢ６欠乏 Vitamin B6 deficiency	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
血管障害 Vascular disorders	0	1 (11.1%)	1 (6.7%)	0	2 (22.2%)	2 (13.3%)
高血圧 Hypertension	0	1 (11.1%)	1 (6.7%)	0	0	0
低血圧 Hypotension	0	0	0	0	1 (11.1%)	1 (6.7%)
潮紅 Flushing	0	0	0	0	1 (11.1%)	1 (6.7%)
血腫 Haematoma	0	0	0	0	0	0
ほてり Hot flush	0	0	0	0	1 (11.1%)	1 (6.7%)
静脈炎 Phlebitis	0	0	0	0	0	0
出血 Haemorrhage	0	0	0	0	0	0
起立性低血圧 Orthostatic hypotension	0	0	0	0	0	0
末梢動脈閉塞性疾患 Peripheral arterial occlusive disease	0	0	0	0	0	0
表在性血栓性静脈炎 Thrombophlebitis superficial	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
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GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
四肢静脈血栓症 Venous thrombosis limb	0	0	0	0	0	0
大動脈硬化症 Aortic arteriosclerosis	0	0	0	0	0	0
大動脈解離 Aortic dissection	0	0	0	0	0	0
大動脈血栓症 Aortic thrombosis	0	0	0	0	0	0
本態性高血圧症 Essential hypertension	0	0	0	0	0	0
高血圧クリーゼ Hypertensive crisis	0	0	0	0	0	0
末梢冷感 Peripheral coldness	0	0	0	0	0	0
末梢性虚血 Peripheral ischaemia	0	0	0	0	0	0
末梢静脈疾患 Peripheral venous disease	0	0	0	0	0	0
静脈穿刺不良 Poor venous access	0	0	0	0	0	0
血栓性静脈炎 Thrombophlebitis	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
大動脈狭窄 Aortic stenosis	0	0	0	0	0	0
動脈硬化症 Arteriosclerosis	0	0	0	0	0	0
末梢循環不良 Poor peripheral circulation	0	0	0	0	0	0
静脈瘤 Varicose vein	0	0	0	0	0	0
血管拡張 Vasodilatation	0	0	0	0	0	0
臨床検査 Investigations	2 (33.3%)	2 (22.2%)	4 (26.7%)	1 (16.7%)	1 (11.1%)	2 (13.3%)
アラニンアミノトランスフェラーゼ増加 Alanine aminotransferase increased	0	1 (11.1%)	1 (6.7%)	0	1 (11.1%)	1 (6.7%)
γ－グルタミルトランスフェラーゼ増加 Gamma-glutamyltransferase increased	0	0	0	0	0	0
アスパラギン酸アミノトランスフェラーゼ増加 Aspartate aminotransferase increased	0	0	0	0	1 (11.1%)	1 (6.7%)
血中クレアチニン増加 Blood creatinine increased	0	0	0	0	0	0
血中アルカリホスファターゼ増加 Blood alkaline phosphatase increased	0	1 (11.1%)	1 (6.7%)	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
体重減少 Weight decreased	1 (16.7%)	0	1 (6.7%)	1 (16.7%)	0	1 (6.7%)
体重増加 Weight increased	1 (16.7%)	1 (11.1%)	2 (13.3%)	0	0	0
血中ビリルビン増加 Blood bilirubin increased	0	0	0	0	0	0
心電図ＱＴ延長 Electrocardiogram QT prolonged	0	0	0	0	0	0
活性化部分トロンボプラスチン時間延長 Activated partial thromboplastin time prolonged	0	0	0	0	0	0
心雑音 Cardiac murmur	0	0	0	0	0	0
腎クレアチニン・クリアランス減少 Creatinine renal clearance decreased	0	0	0	0	0	0
総蛋白増加 Protein total increased	0	0	0	0	0	0
リパーゼ増加 Lipase increased	0	0	0	0	0	0
トランスアミナーゼ上昇 Transaminases increased	0	0	0	0	0	0
国際標準比増加 International normalised ratio increased	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
血中鉄減少 Blood iron decreased	0	0	0	0	0	0
ヘマトクリット増加 Haematocrit increased	0	0	0	0	0	0
出血時間延長 Bleeding time prolonged	0	0	0	0	0	0
血中重炭酸塩減少 Blood bicarbonate decreased	0	0	0	0	0	0
血中クレアチンホスホキナーゼ増加 Blood creatine phosphokinase increased	0	1 (11.1%)	1 (6.7%)	0	0	0
血中乳酸増加 Blood lactic acid increased	0	0	0	0	0	0
体温上昇 Body temperature increased	0	0	0	0	0	0
心電図ＳＴ部分下降 Electrocardiogram ST segment depression	0	0	0	0	0	0
心電図異常 Electrocardiogram abnormal	0	0	0	0	0	0
ヘモグロビン増加 Haemoglobin increased	0	0	0	0	0	0
ヘプシジン減少 Hepcidin decreased	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
リンパ節触知 Lymph node palpable	0	0	0	0	0	0
好中球数増加 Neutrophil count increased	0	0	0	0	0	0
脈拍欠損 Pulse absent	0	0	0	0	0	0
血中乳酸脱水素酵素増加 Blood lactate dehydrogenase increased	0	0	0	0	0	0
プロトロンビン時間延長 Prothrombin time prolonged	0	0	0	0	0	0
抗リン脂質抗体陽性 Antiphospholipid antibodies positive	0	0	0	0	0	0
血中葉酸減少 Blood folate decreased	0	0	0	0	0	0
血中尿素増加 Blood urea increased	0	0	0	0	0	0
胸部X線異常 Chest X-ray abnormal	0	0	0	0	0	0
骨盤コンピュータ断層撮影異常 Computerised tomogram pelvis abnormal	0	0	0	0	0	0
肝酵素上昇 Hepatic enzyme increased	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
肝機能検査異常 Liver function test abnormal	0	0	0	0	0	0
平均赤血球容積減少 Mean cell volume decreased	0	0	0	0	0	0
血清フェリチン増加 Serum ferritin increased	0	0	0	0	0	0
傷害、中毒および処置合併症 Injury, poisoning and procedural complications	0	0	0	0	0	0
挫傷 Contusion	0	0	0	0	0	0
転倒 Fall	0	0	0	0	0	0
皮膚擦過傷 Skin abrasion	0	0	0	0	0	0
皮膚裂傷 Skin laceration	0	0	0	0	0	0
四肢損傷 Limb injury	0	0	0	0	0	0
処置による疼痛 Procedural pain	0	0	0	0	0	0
処置後出血 Post procedural haemorrhage	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
創傷 Wound	0	0	0	0	0	0
靱帯捻挫 Ligament sprain	0	0	0	0	0	0
眼窩周囲血腫 Periorbital haematoma	0	0	0	0	0	0
頭部損傷 Head injury	0	0	0	0	0	0
過量投与 Overdose	0	0	0	0	0	0
膝蓋骨骨折 Patella fracture	0	0	0	0	0	0
腱断裂 Tendon rupture	0	0	0	0	0	0
腹部損傷 Abdominal injury	0	0	0	0	0	0
節足動物咬傷 Arthropod bite	0	0	0	0	0	0
眼挫傷 Eye contusion	0	0	0	0	0	0
大腿骨骨折 Femur fracture	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
手骨折 Hand fracture	0	0	0	0	0	0
低圧症 Hypobarism	0	0	0	0	0	0
靱帯断裂 Ligament rupture	0	0	0	0	0	0
四肢圧挫損傷 Limb crushing injury	0	0	0	0	0	0
口腔内損傷 Mouth injury	0	0	0	0	0	0
処置後合併症 Post procedural complication	0	0	0	0	0	0
処置後挫傷 Post procedural contusion	0	0	0	0	0	0
術後譫妄 Postoperative delirium	0	0	0	0	0	0
肋骨骨折 Rib fracture	0	0	0	0	0	0
引っかき傷 Scratch	0	0	0	0	0	0
漿液腫 Seroma	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
脊椎圧迫骨折 Spinal compression fracture	0	0	0	0	0	0
輸血反応 Transfusion reaction	0	0	0	0	0	0
輸血関連合併症 Transfusion related complication	0	0	0	0	0	0
外傷性血腫 Traumatic haematoma	0	0	0	0	0	0
創合併症 Wound complication	0	0	0	0	0	0
足骨折 Foot fracture	0	0	0	0	0	0
吻合部狭窄 Anastomotic stenosis	0	0	0	0	0	0
顔面骨骨折 Facial bones fracture	0	0	0	0	0	0
筋損傷 Muscle injury	0	0	0	0	0	0
処置による悪心 Procedural nausea	0	0	0	0	0	0
骨格損傷 Skeletal injury	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
外傷性血胸 Traumatic haemothorax	0	0	0	0	0	0
腎および尿路障害 Renal and urinary disorders	1 (16.7%)	0	1 (6.7%)	1 (16.7%)	0	1 (6.7%)
腎不全 Renal failure	0	0	0	0	0	0
排尿困難 Dysuria	0	0	0	0	0	0
頻尿 Pollakiuria	0	0	0	0	0	0
急性腎障害 Acute kidney injury	0	0	0	0	0	0
血尿 Haematuria	1 (16.7%)	0	1 (6.7%)	0	0	0
腎結石症 Nephrolithiasis	0	0	0	0	0	0
腎仙痛 Renal colic	0	0	0	0	0	0
慢性腎臓病 Chronic kidney disease	0	0	0	0	0	0
腎機能障害 Renal impairment	0	0	0	1 (16.7%)	0	1 (6.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
夜間頻尿 Nocturia	0	0	0	0	0	0
尿失禁 Urinary incontinence	0	0	0	0	0	0
着色尿 Chromaturia	0	0	0	0	0	0
多尿 Polyuria	0	0	0	0	0	0
蛋白尿 Proteinuria	0	0	0	0	0	0
白血球尿 Leukocyturia	0	0	0	0	0	0
出血性膀胱炎 Cystitis haemorrhagic	0	0	0	0	0	0
中毒性ネフロパシー Nephropathy toxic	0	0	0	0	0	0
腎動脈狭窄症 Renal artery stenosis	0	0	0	0	0	0
膀胱ポリープ Urinary bladder polyp	0	0	0	0	0	0
尿閉 Urinary retention	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
尿路痛 Urinary tract pain	0	0	0	0	0	0
尿管結石症 Ureterolithiasis	0	0	0	0	0	0
眼障害 Eye disorders	1 (16.7%)	0	1 (6.7%)	1 (16.7%)	1 (11.1%)	2 (13.3%)
霧視 Vision blurred	0	0	0	0	0	0
皮質白内障 Cataract cortical	0	0	0	0	0	0
核性白内障 Cataract nuclear	0	0	0	0	0	0
ドライアイ Dry eye	0	0	0	0	0	0
視力低下 Visual acuity reduced	0	0	0	0	0	0
嚢下白内障 Cataract subcapsular	0	0	0	0	0	0
眼痛 Eye pain	0	0	0	0	0	0
流涙増加 Lacrimation increased	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
視力障害 Visual impairment	0	0	0	0	0	0
白内障 Cataract	0	0	0	0	0	0
角膜炎 Keratitis	1 (16.7%)	0	1 (6.7%)	0	0	0
複視 Diplopia	0	0	0	0	0	0
眼出血 Eye haemorrhage	0	0	0	0	0	0
眼刺激 Eye irritation	0	0	0	0	0	0
眼瞼浮腫 Eyelid oedema	0	0	0	0	1 (11.1%)	1 (6.7%)
黄斑変性 Macular degeneration	0	0	0	0	0	0
網膜出血 Retinal haemorrhage	0	0	0	1 (16.7%)	0	1 (6.7%)
結膜上皮侵入 Conjunctivalisation	0	0	0	0	0	0
眼球浮腫 Eye oedema	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
眼部腫脹 Eye swelling	0	0	0	0	0	0
星状硝子体症 Hyalosis asteroid	1 (16.7%)	0	1 (6.7%)	0	0	0
眼窩浮腫 Orbital oedema	0	0	0	0	0	0
眼窩周囲浮腫 Periorbital oedema	0	0	0	0	0	0
光視症 Photopsia	0	0	0	0	0	0
眼瞼腫脹 Swelling of eyelid	0	0	0	0	0	0
硝子体浮遊物 Vitreous floaters	0	0	0	0	0	0
結膜出血 Conjunctival haemorrhage	0	0	0	0	0	0
糖尿病網膜症 Diabetic retinopathy	0	0	0	0	0	0
眼充血 Ocular hyperaemia	0	0	0	0	0	0
眼瞼炎 Blepharitis	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
眼瞼下垂 Eyelid ptosis	0	0	0	0	0	0
緑内障 Glaucoma	0	0	0	0	0	0
睫毛の成長 Growth of eyelashes	0	0	0	0	0	0
マイボーム腺機能不全 Meibomian gland dysfunction	0	0	0	0	0	0
網膜瘢痕 Retinal scar	0	0	0	0	0	0
硝子体変性 Vitreous degeneration	0	0	0	0	0	0
精神障害 Psychiatric disorders	0	0	0	1 (16.7%)	0	1 (6.7%)
不安 Anxiety	0	0	0	0	0	0
不眠症 Insomnia	0	0	0	1 (16.7%)	0	1 (6.7%)
うつ病 Depression	0	0	0	0	0	0
錯乱状態 Confusional state	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
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表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
精神状態変化 Mental status changes	0	0	0	0	0	0
神経過敏 Nervousness	0	0	0	0	0	0
激越 Agitation	0	0	0	0	0	0
不安障害 Anxiety disorder	0	0	0	0	0	0
精神緩慢 Bradyphrenia	0	0	0	0	0	0
幻覚 Hallucination	0	0	0	0	0	0
初期不眠症 Initial insomnia	0	0	0	0	0	0
悪夢 Nightmare	0	0	0	0	0	0
リビドー減退 Libido decreased	0	0	0	0	0	0
感情障害 Affective disorder	0	0	0	0	0	0
抑うつ気分 Depressed mood	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
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GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
失見当識 Disorientation	0	0	0	0	0	0
睡眠障害 Sleep disorder	0	0	0	0	0	0
自殺念慮 Suicidal ideation	0	0	0	0	0	0
心臓障害 Cardiac disorders	0	0	0	0	0	0
心房細動 Atrial fibrillation	0	0	0	0	0	0
狭心症 Angina pectoris	0	0	0	0	0	0
心不全 Cardiac failure	0	0	0	0	0	0
動悸 Palpitations	0	0	0	0	0	0
頻脈 Tachycardia	0	0	0	0	0	0
急性心筋梗塞 Acute myocardial infarction	0	0	0	0	0	0
うっ血性心不全 Cardiac failure congestive	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
急性心不全 Cardiac failure acute	0	0	0	0	0	0
心拡大 Cardiomegaly	0	0	0	0	0	0
左室不全 Left ventricular failure	0	0	0	0	0	0
心房粗動 Atrial flutter	0	0	0	0	0	0
洞性徐脈 Sinus bradycardia	0	0	0	0	0	0
不安定狭心症 Angina unstable	0	0	0	0	0	0
完全房室ブロック Atrioventricular block complete	0	0	0	0	0	0
徐脈 Bradycardia	0	0	0	0	0	0
期外収縮 Extrasystoles	0	0	0	0	0	0
高血圧性心疾患 Hypertensive heart disease	0	0	0	0	0	0
左室機能不全 Left ventricular dysfunction	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
僧帽弁閉鎖不全症 Mitral valve incompetence	0	0	0	0	0	0
心嚢液貯留 Pericardial effusion	0	0	0	0	0	0
上室性頻脈 Supraventricular tachycardia	0	0	0	0	0	0
三尖弁閉鎖不全症 Tricuspid valve incompetence	0	0	0	0	0	0
第一度房室ブロック Atrioventricular block first degree	0	0	0	0	0	0
心停止 Cardiac arrest	0	0	0	0	0	0
慢性心不全 Cardiac failure chronic	0	0	0	0	0	0
心臓弁膜疾患 Cardiac valve disease	0	0	0	0	0	0
拡張機能障害 Diastolic dysfunction	0	0	0	0	0	0
心筋虚血 Myocardial ischaemia	0	0	0	0	0	0
耳および迷路障害 Ear and labyrinth disorders	0	1 (11.1%)	1 (6.7%)	0	1 (11.1%)	1 (6.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
回転性めまい Vertigo	0	1 (11.1%)	1 (6.7%)	0	1 (11.1%)	1 (6.7%)
耳鳴 Tinnitus	0	0	0	0	0	0
耳痛 Ear pain	0	0	0	0	0	0
耳不快感 Ear discomfort	0	0	0	0	0	0
聴力低下 Hypoacusis	0	0	0	0	0	0
耳閉 Ear congestion	0	0	0	0	0	0
難聴 Deafness	0	0	0	0	0	0
耳出血 Ear haemorrhage	0	0	0	0	0	0
乗物酔い Motion sickness	0	0	0	0	0	0
突発性難聴 Sudden hearing loss	0	0	0	0	0	0
鼓膜穿孔 Tympanic membrane perforation	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
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） Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (16.7%)	0	1 (6.7%)	0	1 (11.1%)	1 (6.7%)
皮膚有棘細胞癌 Squamous cell carcinoma of skin	0	0	0	0	0	0
基底細胞癌 Basal cell carcinoma	0	0	0	0	0	0
急性骨髄性白血病 Acute myeloid leukaemia	0	0	0	0	1 (11.1%)	1 (6.7%)
膵管内乳頭粘液性腫瘍 Intraductal papillary mucinous neoplasm	1 (16.7%)	0	1 (6.7%)	0	0	0
骨髄線維症 Myelofibrosis	0	0	0	0	0	0
悪性黒色腫 Malignant melanoma	0	0	0	0	0	0
メラノサイト性母斑 Melanocytic naevus	0	0	0	0	0	0
膀胱移行上皮癌 Bladder transitional cell carcinoma	0	0	0	0	0	0
再発マントル細胞リンパ腫 Mantle cell lymphoma recurrent	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
鼻の良性新生物 Nasal neoplasm benign	0	0	0	0	0	0
食道扁平上皮癌 Oesophageal squamous cell carcinoma	0	0	0	0	0	0
卵巣明細胞癌 Ovarian clear cell carcinoma	0	0	0	0	0	0
再発前立腺癌 Prostate cancer recurrent	0	0	0	0	0	0
脾臓辺縁帯リンパ腫 Splenic marginal zone lymphoma	0	0	0	0	0	0
急性骨髄性白血病への転化 Transformation to acute myeloid leukaemia	0	0	0	0	0	0
子宮癌 Uterine cancer	0	0	0	0	0	0
脂漏性角化症 Seborrhoeic keratosis	0	0	0	0	0	0
子宮平滑筋腫 Uterine leiomyoma	0	0	0	0	0	0
乳腺線維腺腫 Fibroadenoma of breast	0	0	0	0	0	0
骨血管腫 Haemangioma of bone	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
白赤芽球症 Leukoerythroblastosis	0	0	0	0	0	0
遠隔転移を伴う扁平上皮癌 Metastatic squamous cell carcinoma	0	0	0	0	0	0
前立腺癌 Prostate cancer	0	0	0	0	0	0
直腸癌 Rectal cancer	0	0	0	0	0	0
鼻副鼻腔乳頭腫 Sinonasal papilloma	0	0	0	0	0	0
生殖系および乳房障害 Reproductive system and breast disorders	0	0	0	0	0	0
良性前立腺肥大症 Benign prostatic hyperplasia	0	0	0	0	0	0
膣出血 Vaginal haemorrhage	0	0	0	0	0	0
膣分泌物 Vaginal discharge	0	0	0	0	0	0
月経過多 Menorrhagia	0	0	0	0	0	0
会陰痛 Perineal pain	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
陰嚢浮腫 Scrotal oedema	0	0	0	0	0	0
自発陰茎勃起 Spontaneous penile erection	0	0	0	0	0	0
腟ポリープ Vaginal polyp	0	0	0	0	0	0
外陰腟の炎症 Vulvovaginal inflammation	0	0	0	0	0	0
外陰腟痛 Vulvovaginal pain	0	0	0	0	0	0
精巣上体嚢胞 Epididymal cyst	0	0	0	0	0	0
子宮頚部びらん Uterine cervical erosion	0	0	0	0	0	0
腟脱 Vaginal prolapse	0	0	0	0	0	0
肝胆道系障害 Hepatobiliary disorders	1 (16.7%)	0	1 (6.7%)	0	0	0
胆道仙痛 Biliary colic	0	0	0	0	0	0
胆石症 Cholelithiasis	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
肝機能異常 Hepatic function abnormal	0	0	0	0	0	0
肝細胞損傷 Hepatocellular injury	0	0	0	0	0	0
過形成性胆嚢症 Hyperplastic cholecystopathy	1 (16.7%)	0	1 (6.7%)	0	0	0
黄疸眼 Ocular icterus	0	0	0	0	0	0
急性胆嚢炎 Cholecystitis acute	0	0	0	0	0	0
胆汁うっ滞 Cholestasis	0	0	0	0	0	0
肝硬変 Hepatic cirrhosis	0	0	0	0	0	0
肝不全 Hepatic failure	0	0	0	0	0	0
門脈圧亢進症 Portal hypertension	0	0	0	0	0	0
先天性、家族性および遺伝性障害 Congenital, familial and genetic disorders	0	0	0	0	0	0
ジルベール症候群 Gilbert's syndrome	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-3 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Double-Blind Phase, and First 24 Weeks in Open-Label Phase）

	有害事象（日本人）					
	DB Phase			OL Phase (Week 24 - Week 48)		
System Organ Class Preferred Term	MMB (N=6)	RUX (N=9)	Total (N=15)	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)
陰嚢水瘤 Hydrocele	0	0	0	0	0	0
包茎 Phimosis	0	0	0	0	0	0
内分泌障害 Endocrine disorders	0	0	0	0	0	0
低アルドステロン症 Hypoaldosteronism	0	0	0	0	0	0
甲状腺機能低下症 Hypothyroidism	0	0	0	0	0	0
甲状腺腫瘤 Thyroid mass	0	0	0	0	0	0
外科および内科処置 Surgical and medical procedures	0	0	0	0	0	0
抜歯 Tooth extraction	0	0	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.1, 5.3.5.1 Japanese Table 1.3071
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_DB.sas 2.003.651.700

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
有害事象発現例数 ANY EVENT	157 (91.8%)	190 (96.4%)	347 (94.3%)	397 (96.6%)
感染症および寄生虫症 Infections and infestations	88 (51.5%)	111 (56.3%)	199 (54.1%)	237 (57.7%)
尿路感染 Urinary tract infection	20 (11.7%)	23 (11.7%)	43 (11.7%)	49 (11.9%)
肺炎 Pneumonia	20 (11.7%)	19 (9.6%)	39 (10.6%)	43 (10.5%)
上気道感染 Upper respiratory tract infection	18 (10.5%)	18 (9.1%)	36 (9.8%)	47 (11.4%)
上咽頭炎 Nasopharyngitis	7 (4.1%)	14 (7.1%)	21 (5.7%)	28 (6.8%)
気管支炎 Bronchitis	8 (4.7%)	12 (6.1%)	20 (5.4%)	22 (5.4%)
胃腸炎 Gastroenteritis	5 (2.9%)	8 (4.1%)	13 (3.5%)	15 (3.6%)
気道感染 Respiratory tract infection	4 (2.3%)	9 (4.6%)	13 (3.5%)	15 (3.6%)
帯状疱疹 Herpes zoster	8 (4.7%)	3 (1.5%)	11 (3.0%)	14 (3.4%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
膀胱炎 Cystitis	6 (3.5%)	4 (2.0%)	10 (2.7%)	14 (3.4%)
口腔ヘルペス Oral herpes	4 (2.3%)	6 (3.0%)	10 (2.7%)	13 (3.2%)
インフルエンザ Influenza	2 (1.2%)	8 (4.1%)	10 (2.7%)	11 (2.7%)
副鼻腔炎 Sinusitis	3 (1.8%)	7 (3.6%)	10 (2.7%)	10 (2.4%)
下気道感染 Lower respiratory tract infection	4 (2.3%)	4 (2.0%)	8 (2.2%)	11 (2.7%)
敗血症 Sepsis	6 (3.5%)	2 (1.0%)	8 (2.2%)	10 (2.4%)
蜂巣炎 Cellulitis	4 (2.3%)	2 (1.0%)	6 (1.6%)	9 (2.2%)
大腸菌性尿路感染 Escherichia urinary tract infection	2 (1.2%)	2 (1.0%)	4 (1.1%)	5 (1.2%)
肺感染 Lung infection	4 (2.3%)	0	4 (1.1%)	5 (1.2%)
口腔カンジダ症 Oral candidiasis	2 (1.2%)	1 (0.5%)	3 (0.8%)	5 (1.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
憩室炎 Diverticulitis	1 (0.6%)	2 (1.0%)	3 (0.8%)	4 (1.0%)
ウイルス感染 Viral infection	1 (0.6%)	2 (1.0%)	3 (0.8%)	4 (1.0%)
クロストリジウム・ディフィシレ大腸炎 Clostridium difficile colitis	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
結膜炎 Conjunctivitis	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
耳感染 Ear infection	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
せつ Furuncle	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
単純ヘルペス Herpes simplex	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
中耳炎 Otitis media	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
真菌感染 Fungal infection	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
皮膚真菌感染 Fungal skin infection	2 (1.2%)	0	2 (0.5%)	3 (0.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
消化管感染 Gastrointestinal infection	2 (1.2%)	0	2 (0.5%)	3 (0.7%)
限局性感染 Localised infection	2 (1.2%)	0	2 (0.5%)	3 (0.7%)
外耳炎 Otitis externa	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
細菌性肺炎 Pneumonia bacterial	2 (1.2%)	0	2 (0.5%)	3 (0.7%)
腎盂腎炎 Pyelonephritis	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
ボレリア感染 Borrelia infection	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
クロストリジウム・ディフィシレ感染 Clostridium difficile infection	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
丹毒 Erysipelas	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
サルモネラ菌性胃腸炎 Gastroenteritis salmonella	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
ウイルス性胃腸炎 Gastroenteritis viral	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
陰部ヘルペス Genital herpes	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
咽頭炎 Pharyngitis	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
ウイルス性肺炎 Pneumonia viral	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
扁桃炎 Tonsillitis	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
水痘帯状疱疹ウイルス感染 Varicella zoster virus infection	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
創傷感染 Wound infection	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
皮膚感染 Skin infection	1 (0.6%)	0	1 (0.3%)	5 (1.2%)
鼻炎 Rhinitis	0	1 (0.5%)	1 (0.3%)	3 (0.7%)
毛包炎 Folliculitis	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
歯肉炎 Gingivitis	0	1 (0.5%)	1 (0.3%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
喉頭炎 Laryngitis	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
歯周炎 Periodontitis	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
腹部敗血症 Abdominal sepsis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
四肢膿瘍 Abscess limb	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
菌血症 Bacteraemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
気管支肺アスペルギルス症 Bronchopulmonary aspergillosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
カンジダ感染 Candida infection	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
医療機器関連感染 Device related infection	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
感染性腸炎 Enteritis infectious	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
感染性小腸結腸炎 Enterocolitis infectious	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
大腸菌感染 Escherichia infection	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
眼感染 Eye infection	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
真菌性食道炎 Fungal oesophagitis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
壊疽 Gangrene	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
消化器カンジダ症 Gastrointestinal candidiasis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
ヘルペス性皮膚炎 Herpes dermatitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
感染性皮膚嚢腫 Infected dermal cyst	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
感染性皮膚潰瘍 Infected skin ulcer	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
迷路炎 Labyrinthitis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
筋膿瘍 Muscle abscess	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
鼻ヘルペス Nasal herpes	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
神経ボレリア症 Neuroborreliosis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
百日咳 Pertussis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
ピコルナウイルス感染 Picornavirus infection	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ＲＳウイルス肺炎 Pneumonia respiratory syncytial viral	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
術後創感染 Postoperative wound infection	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肺敗血症 Pulmonary sepsis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肺結核 Pulmonary tuberculosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
敗血症性ショック Septic shock	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
セラチア性菌血症 Serratia bacteraemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
赤痢菌感染 Shigella infection	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
唾液腺炎 Sialoadenitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
皮下組織膿瘍 Subcutaneous abscess	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
破傷風 Tetanus	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
歯膿瘍 Tooth abscess	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
歯感染 Tooth infection	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
結核 Tuberculosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
前庭神経炎 Vestibular neuronitis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ウイルス性ぶどう膜炎 Viral uveitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
癬風 Tinea versicolour	0	0	0	3 (0.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
肛門膿瘍 Anal abscess	0	0	0	1 (0.2%)
大腸菌性敗血症 Escherichia sepsis	0	0	0	1 (0.2%)
感染 Infection	0	0	0	1 (0.2%)
口唇感染 Lip infection	0	0	0	1 (0.2%)
ライム病 Lyme disease	0	0	0	1 (0.2%)
処置後感染 Post procedural infection	0	0	0	1 (0.2%)
腎盂膀胱炎 Pyelocystitis	0	0	0	1 (0.2%)
陰嚢膿瘍 Scrotal abscess	0	0	0	1 (0.2%)
皮膚細菌感染 Skin bacterial infection	0	0	0	1 (0.2%)
ブドウ球菌感染 Staphylococcal infection	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
レンサ球菌性敗血症 Streptococcal sepsis	0	0	0	1 (0.2%)
腟感染 Vaginal infection	0	0	0	1 (0.2%)
胃腸障害 Gastrointestinal disorders	70 (40.9%)	105 (53.3%)	175 (47.6%)	233 (56.7%)
下痢 Diarrhoea	30 (17.5%)	39 (19.8%)	69 (18.8%)	99 (24.1%)
悪心 Nausea	16 (9.4%)	39 (19.8%)	55 (14.9%)	85 (20.7%)
腹痛 Abdominal pain	13 (7.6%)	27 (13.7%)	40 (10.9%)	61 (14.8%)
便秘 Constipation	13 (7.6%)	19 (9.6%)	32 (8.7%)	51 (12.4%)
嘔吐 Vomiting	8 (4.7%)	12 (6.1%)	20 (5.4%)	37 (9.0%)
胃食道逆流性疾患 Gastrooesophageal reflux disease	4 (2.3%)	11 (5.6%)	15 (4.1%)	21 (5.1%)
消化不良 Dyspepsia	6 (3.5%)	9 (4.6%)	15 (4.1%)	18 (4.4%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
上腹部痛 Abdominal pain upper	6 (3.5%)	7 (3.6%)	13 (3.5%)	22 (5.4%)
腹部膨満 Abdominal distension	4 (2.3%)	8 (4.1%)	12 (3.3%)	19 (4.6%)
腹水 Ascites	3 (1.8%)	4 (2.0%)	7 (1.9%)	8 (1.9%)
腹部不快感 Abdominal discomfort	3 (1.8%)	3 (1.5%)	6 (1.6%)	14 (3.4%)
胃炎 Gastritis	3 (1.8%)	2 (1.0%)	5 (1.4%)	6 (1.5%)
食道静脈瘤 Varices oesophageal	2 (1.2%)	3 (1.5%)	5 (1.4%)	6 (1.5%)
口内乾燥 Dry mouth	2 (1.2%)	2 (1.0%)	4 (1.1%)	10 (2.4%)
歯痛 Toothache	1 (0.6%)	3 (1.5%)	4 (1.1%)	7 (1.7%)
痔核 Haemorrhoids	0	4 (2.0%)	4 (1.1%)	6 (1.5%)
直腸出血 Rectal haemorrhage	0	4 (2.0%)	4 (1.1%)	6 (1.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
鼠径ヘルニア Inguinal hernia	4 (2.3%)	0	4 (1.1%)	5 (1.2%)
下腹部痛 Abdominal pain lower	1 (0.6%)	3 (1.5%)	4 (1.1%)	4 (1.0%)
びらん性胃炎 Gastritis erosive	2 (1.2%)	2 (1.0%)	4 (1.1%)	4 (1.0%)
大腸炎 Colitis	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
心窩部不快感 Epigastric discomfort	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
裂孔ヘルニア Hiatus hernia	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
口腔内出血 Mouth haemorrhage	0	3 (1.5%)	3 (0.8%)	3 (0.7%)
口内炎 Stomatitis	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
鼓腸 Flatulence	1 (0.6%)	1 (0.5%)	2 (0.5%)	5 (1.2%)
歯肉出血 Gingival bleeding	0	2 (1.0%)	2 (0.5%)	3 (0.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
肛門失禁 Anal incontinence	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
口角口唇炎 Angular cheilitis	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
齲歯 Dental caries	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
憩室 Diverticulum	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
食道静脈瘤出血 Oesophageal varices haemorrhage	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
口腔内痛 Oral pain	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
口唇炎 Cheilitis	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
嚥下障害 Dysphagia	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
胃潰瘍 Gastric ulcer	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
口腔内潰瘍形成 Mouth ulceration	1 (0.6%)	0	1 (0.3%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
レッチング Retching	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
小腸閉塞 Small intestinal obstruction	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
腹部硬直 Abdominal rigidity	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
異常便 Abnormal faeces	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
水疱性出血性口峡炎 Angina bullosa haemorrhagica	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
アフタ性潰瘍 Aphthous ulcer	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
慢性胃炎 Chronic gastritis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
便意切迫 Defaecation urgency	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
歯組織の壊死 Dental necrosis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
出血性十二指腸潰瘍 Duodenal ulcer haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
十二指腸炎 Duodenitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
腸炎 Enterocolitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
腹膜垂炎 Epiploic appendagitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
食中毒 Food poisoning	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
胃障害 Gastric disorder	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
胃出血 Gastric haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
出血性胃潰瘍 Gastric ulcer haemorrhage	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
胃腸障害 Gastrointestinal disorder	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
胃腸出血 Gastrointestinal haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
消化管運動障害 Gastrointestinal motility disorder	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
消化器痛 Gastrointestinal pain	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
胃腸音異常 Gastrointestinal sounds abnormal	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
歯肉潰瘍 Gingival ulceration	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
舌痛 Glossodynia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
吐血 Haematemesis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
口の感覚鈍麻 Hypoaesthesia oral	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
イレウス Ileus	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
腸梗塞 Intestinal infarction	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
腹腔内血腫 Intra-abdominal haematoma	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
下部消化管出血 Lower gastrointestinal haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
メレナ Melaena	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
口腔粘膜血腫 Oral mucosa haematoma	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
膵嚢胞 Pancreatic cyst	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
膵脂肪変性 Pancreatic steatosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
膵炎 Pancreatitis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
歯周病 Periodontal disease	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
咳嗽後嘔吐 Post-tussive vomiting	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
小腸出血 Small intestinal haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
埋伏歯 Tooth impacted	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
臍ヘルニア Umbilical hernia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
上部消化管出血 Upper gastrointestinal haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
内臓静脈血栓症 Visceral venous thrombosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
小腸炎 Enteritis	0	0	0	2 (0.5%)
肛門周囲痛 Proctalgia	0	0	0	2 (0.5%)
軟便 Faeces soft	0	0	0	1 (0.2%)
胃ポリープ Gastric polyps	0	0	0	1 (0.2%)
血便排泄 Haematochezia	0	0	0	1 (0.2%)
痔出血 Haemorrhoidal haemorrhage	0	0	0	1 (0.2%)
口唇痛 Lip pain	0	0	0	1 (0.2%)
腸間膜静脈血栓症 Mesenteric vein thrombosis	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
嚥下痛 Odynophagia	0	0	0	1 (0.2%)
食道炎 Oesophagitis	0	0	0	1 (0.2%)
消化性潰瘍 Peptic ulcer	0	0	0	1 (0.2%)
舌紅斑 Tongue erythema	0	0	0	1 (0.2%)
一般・全身障害および投与部位の状態 General disorders and administration site conditions	65 (38.0%)	85 (43.1%)	150 (40.8%)	204 (49.6%)
疲労 Fatigue	17 (9.9%)	39 (19.8%)	56 (15.2%)	84 (20.4%)
発熱 Pyrexia	17 (9.9%)	14 (7.1%)	31 (8.4%)	43 (10.5%)
末梢性浮腫 Oedema peripheral	16 (9.4%)	10 (5.1%)	26 (7.1%)	32 (7.8%)
無力症 Asthenia	13 (7.6%)	12 (6.1%)	25 (6.8%)	36 (8.8%)
胸痛 Chest pain	2 (1.2%)	8 (4.1%)	10 (2.7%)	16 (3.9%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
インフルエンザ様疾患 Influenza like illness	4 (2.3%)	6 (3.0%)	10 (2.7%)	14 (3.4%)
末梢腫脹 Peripheral swelling	4 (2.3%)	1 (0.5%)	5 (1.4%)	9 (2.2%)
早期満腹 Early satiety	1 (0.6%)	3 (1.5%)	4 (1.1%)	6 (1.5%)
悪寒 Chills	1 (0.6%)	3 (1.5%)	4 (1.1%)	5 (1.2%)
倦怠感 Malaise	1 (0.6%)	2 (1.0%)	3 (0.8%)	7 (1.7%)
非心臓性胸痛 Non-cardiac chest pain	1 (0.6%)	2 (1.0%)	3 (0.8%)	5 (1.2%)
疼痛 Pain	2 (1.2%)	1 (0.5%)	3 (0.8%)	5 (1.2%)
胸部不快感 Chest discomfort	1 (0.6%)	2 (1.0%)	3 (0.8%)	4 (1.0%)
熱感 Feeling hot	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
死亡 Death	0	2 (1.0%)	2 (0.5%)	3 (0.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
歩行障害 Gait disturbance	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
全身性浮腫 Generalised oedema	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
粘膜の炎症 Mucosal inflammation	2 (1.2%)	0	2 (0.5%)	3 (0.7%)
浮腫 Oedema	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
全身健康状態悪化 General physical health deterioration	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
治癒不良 Impaired healing	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
腫脹 Swelling	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
口渇 Thirst	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
カテーテル留置部位疼痛 Catheter site pain	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
医療機器関連合併症 Complication associated with device	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
不快感 Discomfort	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
薬剤離脱症候群 Drug withdrawal syndrome	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
顔面浮腫 Face oedema	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
高熱 Hyperthermia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
注入部位疼痛 Infusion site pain	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
注射部位出血 Injection site haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
多臓器機能不全症候群 Multiple organ dysfunction syndrome	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
乾燥症 Xerosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
重力性浮腫 Gravitational oedema	0	0	0	2 (0.5%)
捻髪音 Crepitations	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
顔面痛 Facial pain	0	0	0	1 (0.2%)
硬結 Induration	0	0	0	1 (0.2%)
炎症 Inflammation	0	0	0	1 (0.2%)
突然死 Sudden death	0	0	0	1 (0.2%)
血液およびリンパ系障害 Blood and lymphatic system disorders	66 (38.6%)	84 (42.6%)	150 (40.8%)	191 (46.5%)
貧血 Anaemia	41 (24.0%)	32 (16.2%)	73 (19.8%)	93 (22.6%)
血小板減少症 Thrombocytopenia	29 (17.0%)	40 (20.3%)	69 (18.8%)	94 (22.9%)
好中球減少症 Neutropenia	7 (4.1%)	8 (4.1%)	15 (4.1%)	20 (4.9%)
白血球増加症 Leukocytosis	3 (1.8%)	9 (4.6%)	12 (3.3%)	16 (3.9%)
白血球減少症 Leukopenia	5 (2.9%)	6 (3.0%)	11 (3.0%)	13 (3.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
血小板増加症 Thrombocytosis	2 (1.2%)	6 (3.0%)	8 (2.2%)	12 (2.9%)
リンパ球減少症 Lymphopenia	2 (1.2%)	3 (1.5%)	5 (1.4%)	6 (1.5%)
脾腫 Splenomegaly	4 (2.3%)	1 (0.5%)	5 (1.4%)	6 (1.5%)
脾臓梗塞 Splenic infarction	4 (2.3%)	0	4 (1.1%)	5 (1.2%)
赤血球増加症 Polycythaemia	0	3 (1.5%)	3 (0.8%)	3 (0.7%)
発熱性好中球減少症 Febrile neutropenia	2 (1.2%)	0	2 (0.5%)	3 (0.7%)
内出血発生の増加傾向 Increased tendency to bruise	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
脾血腫 Splenic haematoma	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
骨髄毒性 Bone marrow toxicity	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
凝血異常 Coagulopathy	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
溶血 Haemolysis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
溶血性貧血 Haemolytic anaemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
過粘稠度症候群 Hyperviscosity syndrome	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
鉄欠乏性貧血 Iron deficiency anaemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肥満細胞症 Mastocytosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
好中球増加症 Neutrophilia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
脾臓障害 Spleen disorder	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
脾臓血栓症 Splenic thrombosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
特発性血腫 Spontaneous haematoma	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
低プロトロンビン血症 Hypoprothrombinaemia	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
リンパ節石灰化 Lymph node calcification	0	0	0	1 (0.2%)
リンパ節症 Lymphadenopathy	0	0	0	1 (0.2%)
リンパ球増加症 Lymphocytosis	0	0	0	1 (0.2%)
微小血管症性溶血性貧血 Microangiopathic haemolytic anaemia	0	0	0	1 (0.2%)
神経系障害 Nervous system disorders	65 (38.0%)	80 (40.6%)	145 (39.4%)	203 (49.4%)
浮動性めまい Dizziness	18 (10.5%)	25 (12.7%)	43 (11.7%)	72 (17.5%)
末梢性感覚ニューロパチー Peripheral sensory neuropathy	15 (8.8%)	28 (14.2%)	43 (11.7%)	61 (14.8%)
頭痛 Headache	13 (7.6%)	24 (12.2%)	37 (10.1%)	68 (16.5%)
錯感覚 Paraesthesia	6 (3.5%)	11 (5.6%)	17 (4.6%)	28 (6.8%)
感覚鈍麻 Hypoaesthesia	7 (4.1%)	6 (3.0%)	13 (3.5%)	15 (3.6%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
失神 Syncope	6 (3.5%)	3 (1.5%)	9 (2.4%)	12 (2.9%)
嗜眠 Lethargy	4 (2.3%)	2 (1.0%)	6 (1.6%)	7 (1.7%)
坐骨神経痛 Sciatica	1 (0.6%)	5 (2.5%)	6 (1.6%)	6 (1.5%)
平衡障害 Balance disorder	3 (1.8%)	1 (0.5%)	4 (1.1%)	6 (1.5%)
失神寸前の状態 Presyncope	2 (1.2%)	1 (0.5%)	3 (0.8%)	8 (1.9%)
健忘 Amnesia	1 (0.6%)	2 (1.0%)	3 (0.8%)	4 (1.0%)
味覚異常 Dysgeusia	2 (1.2%)	1 (0.5%)	3 (0.8%)	4 (1.0%)
末梢性ニューロパチー Neuropathy peripheral	2 (1.2%)	1 (0.5%)	3 (0.8%)	4 (1.0%)
傾眠 Somnolence	1 (0.6%)	2 (1.0%)	3 (0.8%)	4 (1.0%)
脳血管発作 Cerebrovascular accident	3 (1.8%)	0	3 (0.8%)	3 (0.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
一過性脳虚血発作 Transient ischaemic attack	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
神経痛 Neuralgia	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
灼熱感 Burning sensation	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
意識消失 Loss of consciousness	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
感覚障害 Sensory disturbance	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
声帯麻痺 Vocal cord paralysis	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
記憶障害 Memory impairment	0	1 (0.5%)	1 (0.3%)	3 (0.7%)
振戦 Tremor	1 (0.6%)	0	1 (0.3%)	3 (0.7%)
注意力障害 Disturbance in attention	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
体位性めまい Dizziness postural	1 (0.6%)	0	1 (0.3%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
異常感覚 Dysaesthesia	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
蟻走感 Formication	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
末梢性運動ニューロパチー Peripheral motor neuropathy	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
味覚消失 Ageusia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
運動失調 Ataxia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
小脳卒中 Cerebellar stroke	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
大脳萎縮 Cerebral atrophy	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
脳微小血管症 Cerebral microangiopathy	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
大脳静脈血栓症 Cerebral venous thrombosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
脳血管不全 Cerebrovascular insufficiency	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
認知障害 Cognitive disorder	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
認知症 Dementia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
脱髄 Demyelination	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
前頭側頭型認知症 Frontotemporal dementia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
出血性卒中 Haemorrhagic stroke	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
不全片麻痺 Hemiparesis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ラクナ梗塞 Lacunar infarction	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
白質脳症 Leukoencephalopathy	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ミオトニー Myotonia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
眼振 Nystagmus	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
後頭神経痛 Occipital neuralgia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
パーキンソン病 Parkinson's disease	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
末梢性感覚運動ニューロパチー Peripheral sensorimotor neuropathy	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
多発ニューロパチー Polyneuropathy	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
ヘルペス後神経痛 Post herpetic neuralgia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
下肢静止不能症候群 Restless legs syndrome	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
副鼻腔炎に伴う頭痛 Sinus headache	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
くも膜下出血 Subarachnoid haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
三叉神経痛 Trigeminal neuralgia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
味覚障害 Taste disorder	0	0	0	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
脳虚血 Cerebral ischaemia	0	0	0	1 (0.2%)
頚腕症候群 Cervicobrachial syndrome	0	0	0	1 (0.2%)
前兆を伴う片頭痛 Migraine with aura	0	0	0	1 (0.2%)
神経系障害 Nervous system disorder	0	0	0	1 (0.2%)
代謝および栄養障害 Metabolism and nutrition disorders	63 (36.8%)	70 (35.5%)	133 (36.1%)	161 (39.2%)
食欲減退 Decreased appetite	15 (8.8%)	15 (7.6%)	30 (8.2%)	40 (9.7%)
高尿酸血症 Hyperuricaemia	12 (7.0%)	14 (7.1%)	26 (7.1%)	34 (8.3%)
ビタミンＢ１欠乏 Vitamin B1 deficiency	8 (4.7%)	11 (5.6%)	19 (5.2%)	25 (6.1%)
高カリウム血症 Hyperkalaemia	10 (5.8%)	3 (1.5%)	13 (3.5%)	18 (4.4%)
低カリウム血症 Hypokalaemia	4 (2.3%)	9 (4.6%)	13 (3.5%)	17 (4.1%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
痛風 Gout	6 (3.5%)	3 (1.5%)	9 (2.4%)	12 (2.9%)
糖尿病 Diabetes mellitus	2 (1.2%)	6 (3.0%)	8 (2.2%)	8 (1.9%)
低カルシウム血症 Hypocalcaemia	3 (1.8%)	4 (2.0%)	7 (1.9%)	10 (2.4%)
低ナトリウム血症 Hyponatraemia	3 (1.8%)	4 (2.0%)	7 (1.9%)	9 (2.2%)
高血糖 Hyperglycaemia	3 (1.8%)	4 (2.0%)	7 (1.9%)	8 (1.9%)
脱水 Dehydration	2 (1.2%)	3 (1.5%)	5 (1.4%)	7 (1.7%)
低血糖 Hypoglycaemia	2 (1.2%)	3 (1.5%)	5 (1.4%)	6 (1.5%)
低マグネシウム血症 Hypomagnesaemia	2 (1.2%)	2 (1.0%)	4 (1.1%)	10 (2.4%)
鉄欠乏 Iron deficiency	2 (1.2%)	2 (1.0%)	4 (1.1%)	6 (1.5%)
低アルブミン血症 Hypoalbuminaemia	3 (1.8%)	1 (0.5%)	4 (1.1%)	5 (1.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
高コレステロール血症 Hypercholesterolaemia	1 (0.6%)	3 (1.5%)	4 (1.1%)	4 (1.0%)
高トリグリセリド血症 Hypertriglyceridaemia	2 (1.2%)	2 (1.0%)	4 (1.1%)	4 (1.0%)
ビタミンD欠乏 Vitamin D deficiency	2 (1.2%)	1 (0.5%)	3 (0.8%)	6 (1.5%)
体液貯留 Fluid retention	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
鉄過剰 Iron overload	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
ビタミンB群欠乏 Vitamin B complex deficiency	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
高カルシウム血症 Hypercalcaemia	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
高脂血症 Hyperlipidaemia	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
低リン酸血症 Hypophosphataemia	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
異常体重減少 Abnormal loss of weight	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
悪液質 Cachexia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
コントロール不良の糖尿病 Diabetes mellitus inadequate control	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
脂質異常症 Dyslipidaemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
電解質失調 Electrolyte imbalance	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
水分過負荷 Fluid overload	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
葉酸欠乏 Folate deficiency	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
高フェリチン血症 Hyperferritinaemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
高マグネシウム血症 Hypermagnesaemia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
高ナトリウム血症 Hypernatraemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
低蛋白血症 Hypoproteinaemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
代謝性アシドーシス Metabolic acidosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ビタミン群欠乏 Multi-vitamin deficiency	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
偽高カリウム血症 Pseudohyperkalaemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
腫瘍崩壊症候群 Tumour lysis syndrome	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
２型糖尿病 Type 2 diabetes mellitus	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
ビタミンＢ１２欠乏 Vitamin B12 deficiency	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ビタミンＢ６欠乏 Vitamin B6 deficiency	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ヘモジデリン沈着症 Haemosiderosis	0	0	0	1 (0.2%)
栄養障害 Malnutrition	0	0	0	1 (0.2%)
ビタミンＫ欠乏 Vitamin K deficiency	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
筋骨格系および結合組織障害 Musculoskeletal and connective tissue disorders	47 (27.5%)	82 (41.6%)	129 (35.1%)	169 (41.1%)
四肢痛 Pain in extremity	11 (6.4%)	19 (9.6%)	30 (8.2%)	43 (10.5%)
背部痛 Back pain	10 (5.8%)	19 (9.6%)	29 (7.9%)	37 (9.0%)
関節痛 Arthralgia	10 (5.8%)	13 (6.6%)	23 (6.3%)	35 (8.5%)
骨痛 Bone pain	4 (2.3%)	12 (6.1%)	16 (4.3%)	19 (4.6%)
筋骨格痛 Musculoskeletal pain	6 (3.5%)	8 (4.1%)	14 (3.8%)	21 (5.1%)
筋肉痛 Myalgia	5 (2.9%)	7 (3.6%)	12 (3.3%)	17 (4.1%)
筋力低下 Muscular weakness	6 (3.5%)	3 (1.5%)	9 (2.4%)	10 (2.4%)
筋痙縮 Muscle spasms	1 (0.6%)	5 (2.5%)	6 (1.6%)	13 (3.2%)
脊椎痛 Spinal pain	0	5 (2.5%)	5 (1.4%)	8 (1.9%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
変形性関節症 Osteoarthritis	2 (1.2%)	2 (1.0%)	4 (1.1%)	4 (1.0%)
関節炎 Arthritis	2 (1.2%)	1 (0.5%)	3 (0.8%)	4 (1.0%)
滑液包炎 Bursitis	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
筋骨格硬直 Musculoskeletal stiffness	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
肩回旋筋腱板症候群 Rotator cuff syndrome	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
側腹部痛 Flank pain	0	2 (1.0%)	2 (0.5%)	4 (1.0%)
鼠径部痛 Groin pain	0	2 (1.0%)	2 (0.5%)	4 (1.0%)
筋骨格系胸痛 Musculoskeletal chest pain	2 (1.2%)	0	2 (0.5%)	3 (0.7%)
顎痛 Pain in jaw	2 (1.2%)	0	2 (0.5%)	3 (0.7%)
反応性関節炎 Arthritis reactive	2 (1.2%)	0	2 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
椎間板突出 Intervertebral disc protrusion	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
関節滲出液 Joint effusion	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
頚部痛 Neck pain	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
痛風性関節炎 Gouty arthritis	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
骨減少症 Osteopenia	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
変形性脊椎症 Spinal osteoarthritis	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
骨病変 Bone lesion	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
胸壁血腫 Chest wall haematoma	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ピロリン酸カルシウム結晶性軟骨石灰化症 Chondrocalcinosis pyrophosphate	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肋軟骨炎 Costochondritis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
筋膜炎 Fasciitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
関節腫脹 Joint swelling	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
四肢不快感 Limb discomfort	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
運動性低下 Mobility decreased	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
筋萎縮 Muscle atrophy	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
筋肉疲労 Muscle fatigue	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
筋肉内出血 Muscle haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
骨溶解 Osteolysis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
骨粗鬆症 Osteoporosis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
骨硬化症 Osteosclerosis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
関節周囲炎 Periarthritis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
腱痛 Tendon pain	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
椎骨病変 Vertebral lesion	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
滑液貯留 Bursal fluid accumulation	0	0	0	1 (0.2%)
足変形 Foot deformity	0	0	0	1 (0.2%)
シェーグレン症候群 Sjogren's syndrome	0	0	0	1 (0.2%)
腱炎 Tendonitis	0	0	0	1 (0.2%)
呼吸器、胸郭および縦隔障害 Respiratory, thoracic and mediastinal disorders	57 (33.3%)	70 (35.5%)	127 (34.5%)	164 (39.9%)
咳嗽 Cough	23 (13.5%)	34 (17.3%)	57 (15.5%)	73 (17.8%)
呼吸困難 Dyspnoea	15 (8.8%)	19 (9.6%)	34 (9.2%)	51 (12.4%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
鼻出血 Epistaxis	8 (4.7%)	12 (6.1%)	20 (5.4%)	28 (6.8%)
胸水 Pleural effusion	1 (0.6%)	6 (3.0%)	7 (1.9%)	7 (1.7%)
口腔咽頭痛 Oropharyngeal pain	4 (2.3%)	2 (1.0%)	6 (1.6%)	8 (1.9%)
労作性呼吸困難 Dyspnoea exertional	2 (1.2%)	3 (1.5%)	5 (1.4%)	11 (2.7%)
湿性咳嗽 Productive cough	2 (1.2%)	3 (1.5%)	5 (1.4%)	8 (1.9%)
低酸素症 Hypoxia	2 (1.2%)	3 (1.5%)	5 (1.4%)	7 (1.7%)
慢性閉塞性肺疾患 Chronic obstructive pulmonary disease	3 (1.8%)	2 (1.0%)	5 (1.4%)	6 (1.5%)
呼吸不全 Respiratory failure	2 (1.2%)	3 (1.5%)	5 (1.4%)	6 (1.5%)
肺塞栓症 Pulmonary embolism	3 (1.8%)	1 (0.5%)	4 (1.1%)	4 (1.0%)
喘息 Asthma	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
胸膜炎 Pleurisy	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
発声障害 Dysphonia	1 (0.6%)	1 (0.5%)	2 (0.5%)	4 (1.0%)
鼻漏 Rhinorrhoea	2 (1.2%)	0	2 (0.5%)	4 (1.0%)
急性呼吸不全 Acute respiratory failure	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
慢性気管支炎 Bronchitis chronic	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
肺硬化 Lung consolidation	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
肺水腫 Pulmonary oedema	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
喘鳴 Wheezing	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
ラ音 Rales	1 (0.6%)	0	1 (0.3%)	3 (0.7%)
喀血 Haemoptysis	0	1 (0.5%)	1 (0.3%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
しゃっくり Hiccups	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
鼻閉 Nasal congestion	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
肺肉芽腫 Pulmonary granuloma	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
上気道咳症候群 Upper-airway cough syndrome	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
急性肺水腫 Acute pulmonary oedema	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
胞隔炎 Alveolitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
気管支拡張症 Bronchiectasis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
カタル Catarrh	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肺気腫 Emphysema	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
低換気 Hypoventilation	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
喉頭の炎症 Laryngeal inflammation	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
肺障害 Lung disorder	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
鼻乾燥 Nasal dryness	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
口腔咽頭不快感 Oropharyngeal discomfort	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
起坐呼吸 Orthopnoea	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
誤嚥性肺炎 Pneumonia aspiration	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肺高血圧症 Pulmonary hypertension	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肺腫瘤 Pulmonary mass	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
呼吸停止 Respiratory arrest	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
副鼻腔うっ血 Sinus congestion	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
副鼻腔痛 Sinus pain	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
睡眠時無呼吸症候群 Sleep apnoea syndrome	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
頻呼吸 Tachypnoea	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
咽喉乾燥 Dry throat	0	0	0	1 (0.2%)
発作性夜間呼吸困難 Dyspnoea paroxysmal nocturnal	0	0	0	1 (0.2%)
呼吸時疼痛 Painful respiration	0	0	0	1 (0.2%)
咽頭潰瘍 Pharyngeal ulceration	0	0	0	1 (0.2%)
肺線維症 Pulmonary fibrosis	0	0	0	1 (0.2%)
逆流性喉頭炎 Reflux laryngitis	0	0	0	1 (0.2%)
咽喉絞扼感 Throat tightness	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
皮膚および皮下組織障害 Skin and subcutaneous tissue disorders	55 (32.2%)	69 (35.0%)	124 (33.7%)	153 (37.2%)
そう痒症 Pruritus	12 (7.0%)	20 (10.2%)	32 (8.7%)	40 (9.7%)
寝汗 Night sweats	12 (7.0%)	17 (8.6%)	29 (7.9%)	35 (8.5%)
発疹 Rash	10 (5.8%)	12 (6.1%)	22 (6.0%)	30 (7.3%)
多汗症 Hyperhidrosis	2 (1.2%)	9 (4.6%)	11 (3.0%)	11 (2.7%)
紅斑 Erythema	4 (2.3%)	3 (1.5%)	7 (1.9%)	14 (3.4%)
点状出血 Petechiae	1 (0.6%)	3 (1.5%)	4 (1.1%)	7 (1.7%)
全身性そう痒症 Pruritus generalised	1 (0.6%)	3 (1.5%)	4 (1.1%)	5 (1.2%)
斑状丘疹状皮疹 Rash maculo-papular	1 (0.6%)	2 (1.0%)	3 (0.8%)	6 (1.5%)
全身性皮疹 Rash generalised	1 (0.6%)	2 (1.0%)	3 (0.8%)	4 (1.0%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
皮膚出血 Skin haemorrhage	2 (1.2%)	1 (0.5%)	3 (0.8%)	4 (1.0%)
光線角化症 Actinic keratosis	3 (1.8%)	0	3 (0.8%)	3 (0.7%)
脱毛症 Alopecia	1 (0.6%)	1 (0.5%)	2 (0.5%)	5 (1.2%)
斑状出血 Ecchymosis	1 (0.6%)	1 (0.5%)	2 (0.5%)	5 (1.2%)
アレルギー性皮膚炎 Dermatitis allergic	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
斑状皮疹 Rash macular	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
冷汗 Cold sweat	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
皮膚嚢腫 Dermal cyst	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
丘疹性皮疹 Rash papular	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
酒さ Rosacea	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
皮膚剥脱 Skin exfoliation	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
中毒性皮疹 Toxic skin eruption	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
紅斑性皮疹 Rash erythematous	1 (0.6%)	0	1 (0.3%)	3 (0.7%)
皮膚病変 Skin lesion	1 (0.6%)	0	1 (0.3%)	3 (0.7%)
皮膚潰瘍 Skin ulcer	1 (0.6%)	0	1 (0.3%)	3 (0.7%)
水疱 Blister	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
薬疹 Drug eruption	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
過角化 Hyperkeratosis	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
嵌入爪 Ingrowing nail	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
皮膚炎 Dermatitis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
全身性剥脱性皮膚炎 Dermatitis exfoliative generalised	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
皮膚症 Dermatosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
過敏性血管炎 Hypersensitivity vasculitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
間擦疹 Intertrigo	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
苔癬様角化症 Lichenoid keratosis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
爪変色 Nail discolouration	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
丘疹 Papule	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
乾癬 Psoriasis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
紫斑 Purpura	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
皮膚障害 Skin disorder	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
皮膚脆弱性 Skin fragility	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
顔面腫脹 Swelling face	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
蕁麻疹 Urticaria	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
接触皮膚炎 Dermatitis contact	0	0	0	2 (0.5%)
皮膚乾燥 Dry skin	0	0	0	2 (0.5%)
血性水疱 Blood blister	0	0	0	1 (0.2%)
湿疹 Eczema	0	0	0	1 (0.2%)
紅色症 Erythrosis	0	0	0	1 (0.2%)
毛孔性皮疹 Rash follicular	0	0	0	1 (0.2%)
毛細血管拡張症 Telangiectasia	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
臨床検査 Investigations	43 (25.1%)	43 (21.8%)	86 (23.4%)	112 (27.3%)
血中クレアチニン増加 Blood creatinine increased	10 (5.8%)	10 (5.1%)	20 (5.4%)	25 (6.1%)
アラニンアミノトランスフェラーゼ増加 Alanine aminotransferase increased	5 (2.9%)	11 (5.6%)	16 (4.3%)	25 (6.1%)
アスパラギン酸アミノトランスフェラーゼ増加 Aspartate aminotransferase increased	3 (1.8%)	10 (5.1%)	13 (3.5%)	19 (4.6%)
体重減少 Weight decreased	8 (4.7%)	4 (2.0%)	12 (3.3%)	16 (3.9%)
血中ビリルビン増加 Blood bilirubin increased	6 (3.5%)	6 (3.0%)	12 (3.3%)	14 (3.4%)
γ－グルタミルトランスフェラーゼ増加 Gamma-glutamyltransferase increased	3 (1.8%)	7 (3.6%)	10 (2.7%)	16 (3.9%)
活性化部分トロンボプラスチン時間延長 Activated partial thromboplastin time prolonged	2 (1.2%)	5 (2.5%)	7 (1.9%)	8 (1.9%)
体重増加 Weight increased	3 (1.8%)	2 (1.0%)	5 (1.4%)	7 (1.7%)
腎クレアチニン・クリアランス減少 Creatinine renal clearance decreased	3 (1.8%)	2 (1.0%)	5 (1.4%)	6 (1.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
血中葉酸減少 Blood folate decreased	3 (1.8%)	0	3 (0.8%)	3 (0.7%)
血中乳酸脱水素酵素増加 Blood lactate dehydrogenase increased	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
ヘマトクリット増加 Haematocrit increased	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
ヘモグロビン増加 Haemoglobin increased	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
血中アルカリホスファターゼ増加 Blood alkaline phosphatase increased	1 (0.6%)	1 (0.5%)	2 (0.5%)	4 (1.0%)
トランスアミナーゼ上昇 Transaminases increased	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
芽球細胞数増加 Blast cell count increased	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
血中クロール増加 Blood chloride increased	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
血中鉄減少 Blood iron decreased	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
国際標準比増加 International normalised ratio increased	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
プロトロンビン時間延長 Prothrombin time prolonged	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
心電図Ｑ Ｔ延長 Electrocardiogram QT prolonged	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
総蛋白増加 Protein total increased	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
抗リン脂質抗体陽性 Antiphospholipid antibodies positive	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
血中クレアチンホスホキナーゼ増加 Blood creatine phosphokinase increased	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
血中鉄増加 Blood iron increased	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
血圧上昇 Blood pressure increased	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
血中尿素増加 Blood urea increased	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
胸部Ｘ線異常 Chest X-ray abnormal	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
骨盤コンピュータ断層撮影異常 Computerised tomogram pelvis abnormal	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
大腿動脈雑音 Femoral bruit	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
糸球体濾過率減少 Glomerular filtration rate decreased	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肝酵素上昇 Hepatic enzyme increased	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
眼圧上昇 Intraocular pressure increased	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
肝機能検査異常 Liver function test abnormal	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肝機能検査値上昇 Liver function test increased	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
平均赤血球容積減少 Mean cell volume decreased	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
血清フェリチン増加 Serum ferritin increased	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
ビタミンＢ１減少 Vitamin B1 decreased	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
尿中白血球陽性 White blood cells urine positive	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
心雑音 Cardiac murmur	0	0	0	2 (0.5%)
血中重炭酸塩減少 Blood bicarbonate decreased	0	0	0	1 (0.2%)
血中乳酸増加 Blood lactic acid increased	0	0	0	1 (0.2%)
心電図ＳＴ部分下降 Electrocardiogram ST segment depression	0	0	0	1 (0.2%)
心電図異常 Electrocardiogram abnormal	0	0	0	1 (0.2%)
ヘプシジン減少 Hepcidin decreased	0	0	0	1 (0.2%)
リパーゼ増加 Lipase increased	0	0	0	1 (0.2%)
リンパ節触知 Lymph node palpable	0	0	0	1 (0.2%)
好中球数増加 Neutrophil count increased	0	0	0	1 (0.2%)
血管障害 Vascular disorders	33 (19.3%)	45 (22.8%)	78 (21.2%)	114 (27.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
高血圧 Hypertension	10 (5.8%)	19 (9.6%)	29 (7.9%)	37 (9.0%)
低血圧 Hypotension	8 (4.7%)	9 (4.6%)	17 (4.6%)	33 (8.0%)
血腫 Haematoma	5 (2.9%)	6 (3.0%)	11 (3.0%)	16 (3.9%)
ほてり Hot flush	1 (0.6%)	4 (2.0%)	5 (1.4%)	8 (1.9%)
潮紅 Flushing	1 (0.6%)	3 (1.5%)	4 (1.1%)	17 (4.1%)
静脈炎 Phlebitis	2 (1.2%)	1 (0.5%)	3 (0.8%)	5 (1.2%)
大動脈狭窄 Aortic stenosis	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
深部静脈血栓症 Deep vein thrombosis	0	3 (1.5%)	3 (0.8%)	3 (0.7%)
動脈硬化症 Arteriosclerosis	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
起立性低血圧 Orthostatic hypotension	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
表在性血栓性静脈炎 Thrombophlebitis superficial	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
静脈瘤 Varicose vein	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
大動脈硬化症 Aortic arteriosclerosis	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
出血 Haemorrhage	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
末梢動脈閉塞性疾患 Peripheral arterial occlusive disease	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
四肢静脈血栓症 Venous thrombosis limb	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
末梢動脈狭窄 Peripheral artery stenosis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
末梢循環不良 Poor peripheral circulation	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
血栓症 Thrombosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
血管拡張 Vasodilatation	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
大動脈解離 Aortic dissection	0	0	0	1 (0.2%)
大動脈血栓症 Aortic thrombosis	0	0	0	1 (0.2%)
本態性高血圧症 Essential hypertension	0	0	0	1 (0.2%)
末梢冷感 Peripheral coldness	0	0	0	1 (0.2%)
静脈穿刺不良 Poor venous access	0	0	0	1 (0.2%)
血栓性静脈炎 Thrombophlebitis	0	0	0	1 (0.2%)
腎および尿路障害 Renal and urinary disorders	39 (22.8%)	32 (16.2%)	71 (19.3%)	88 (21.4%)
急性腎障害 Acute kidney injury	5 (2.9%)	6 (3.0%)	11 (3.0%)	13 (3.2%)
腎不全 Renal failure	6 (3.5%)	4 (2.0%)	10 (2.7%)	12 (2.9%)
腎機能障害 Renal impairment	5 (2.9%)	3 (1.5%)	8 (2.2%)	10 (2.4%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
排尿困難 Dysuria	3 (1.8%)	4 (2.0%)	7 (1.9%)	10 (2.4%)
慢性腎臓病 Chronic kidney disease	5 (2.9%)	2 (1.0%)	7 (1.9%)	8 (1.9%)
血尿 Haematuria	3 (1.8%)	3 (1.5%)	6 (1.6%)	9 (2.2%)
蛋白尿 Proteinuria	4 (2.3%)	2 (1.0%)	6 (1.6%)	6 (1.5%)
頻尿 Pollakiuria	1 (0.6%)	3 (1.5%)	4 (1.1%)	7 (1.7%)
夜間頻尿 Nocturia	3 (1.8%)	1 (0.5%)	4 (1.1%)	6 (1.5%)
腎仙痛 Renal colic	2 (1.2%)	2 (1.0%)	4 (1.1%)	4 (1.0%)
腎結石症 Nephrolithiasis	1 (0.6%)	1 (0.5%)	2 (0.5%)	4 (1.0%)
尿失禁 Urinary incontinence	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
膀胱痙縮 Bladder spasm	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
尿路結石 Calculus urinary	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
高血圧性腎症 Hypertensive nephropathy	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
緊張性膀胱 Hypertonic bladder	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
白血球尿 Leukocyturia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
排尿異常 Micturition disorder	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
尿意切迫 Micturition urgency	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
腎症 Nephropathy	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
ネフローゼ症候群 Nephrotic syndrome	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
腎嚢胞 Renal cyst	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
腎障害 Renal disorder	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
腎尿細管壊死 Renal tubular necrosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
尿管結石症 Ureterolithiasis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
尿道障害 Urethral disorder	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
着色尿 Chromaturia	0	0	0	2 (0.5%)
多尿 Polyuria	0	0	0	2 (0.5%)
膀胱ポリープ Urinary bladder polyp	0	0	0	1 (0.2%)
尿閉 Urinary retention	0	0	0	1 (0.2%)
尿路痛 Urinary tract pain	0	0	0	1 (0.2%)
眼障害 Eye disorders	31 (18.1%)	28 (14.2%)	59 (16.0%)	81 (19.7%)
核性白内障 Cataract nuclear	8 (4.7%)	6 (3.0%)	14 (3.8%)	17 (4.1%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
皮質白内障 Cataract cortical	3 (1.8%)	5 (2.5%)	8 (2.2%)	11 (2.7%)
霧視 Vision blurred	5 (2.9%)	1 (0.5%)	6 (1.6%)	11 (2.7%)
視力障害 Visual impairment	2 (1.2%)	3 (1.5%)	5 (1.4%)	6 (1.5%)
ドライアイ Dry eye	1 (0.6%)	4 (2.0%)	5 (1.4%)	5 (1.2%)
結膜出血 Conjunctival haemorrhage	3 (1.8%)	1 (0.5%)	4 (1.1%)	4 (1.0%)
嚢下白内障 Cataract subcapsular	3 (1.8%)	0	3 (0.8%)	4 (1.0%)
網膜出血 Retinal haemorrhage	3 (1.8%)	0	3 (0.8%)	4 (1.0%)
糖尿病網膜症 Diabetic retinopathy	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
流涙増加 Lacrimation increased	1 (0.6%)	1 (0.5%)	2 (0.5%)	4 (1.0%)
眼痛 Eye pain	2 (1.2%)	0	2 (0.5%)	3 (0.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
視力低下 Visual acuity reduced	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
複視 Diplopia	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
眼出血 Eye haemorrhage	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
緑内障 Glaucoma	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
眼充血 Ocular hyperaemia	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
白内障 Cataract	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
眼刺激 Eye irritation	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
眼瞼浮腫 Eyelid oedema	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
角膜炎 Keratitis	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
黄斑変性 Macular degeneration	1 (0.6%)	0	1 (0.3%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
眼瞼腫脹 Swelling of eyelid	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
硝子体浮遊物 Vitreous floaters	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
眼瞼炎 Blepharitis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
眼瞼紅斑 Erythema of eyelid	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
眼瞼下垂 Eyelid ptosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
睫毛の成長 Growth of eyelashes	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
マイボーム腺機能不全 Meibomian gland dysfunction	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
網膜剥離 Retinal detachment	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
網膜瘢痕 Retinal scar	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
閃輝暗点 Scintillating scotoma	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
硝子体変性 Vitreous degeneration	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
眼部腫脹 Eye swelling	0	0	0	1 (0.2%)
星状硝子体症 Hyalosis asteroid	0	0	0	1 (0.2%)
眼窩浮腫 Orbital oedema	0	0	0	1 (0.2%)
眼窩周囲浮腫 Periorbital oedema	0	0	0	1 (0.2%)
光視症 Photopsia	0	0	0	1 (0.2%)
傷害、中毒および処置合併症 Injury, poisoning and procedural complications	30 (17.5%)	29 (14.7%)	59 (16.0%)	78 (19.0%)
転倒 Fall	9 (5.3%)	9 (4.6%)	18 (4.9%)	23 (5.6%)
挫傷 Contusion	9 (5.3%)	5 (2.5%)	14 (3.8%)	29 (7.1%)
四肢損傷 Limb injury	3 (1.8%)	2 (1.0%)	5 (1.4%)	7 (1.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
処置による疼痛 Procedural pain	2 (1.2%)	2 (1.0%)	4 (1.1%)	5 (1.2%)
処置後出血 Post procedural haemorrhage	3 (1.8%)	1 (0.5%)	4 (1.1%)	4 (1.0%)
皮膚裂傷 Skin laceration	0	3 (1.5%)	3 (0.8%)	5 (1.2%)
創傷 Wound	2 (1.2%)	0	2 (0.5%)	4 (1.0%)
皮膚擦過傷 Skin abrasion	0	2 (1.0%)	2 (0.5%)	3 (0.7%)
脊椎圧迫骨折 Spinal compression fracture	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
足骨折 Foot fracture	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
頭部損傷 Head injury	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
過量投与 Overdose	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
眼窩周囲血腫 Periorbital haematoma	0	1 (0.5%)	1 (0.3%)	3 (0.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
膝蓋骨骨折 Patella fracture	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
創合併症 Wound complication	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
吻合部狭窄 Anastomotic stenosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
背部損傷 Back injury	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
第 1 度熱傷 Burns first degree	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
一酸化炭素中毒 Carbon monoxide poisoning	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
歯科修復不成功 Dental restoration failure	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
耳部損傷 Ear injury	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
顔面骨骨折 Facial bones fracture	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
発熱性非溶血性輸血反応 Febrile nonhaemolytic transfusion reaction	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
上腕骨骨折 Humerus fracture	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
筋損傷 Muscle injury	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肉離れ Muscle strain	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
処置後炎症 Post procedural inflammation	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
処置による悪心 Procedural nausea	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
肋骨骨折 Rib fracture	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
交通事故 Road traffic accident	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
骨格損傷 Skeletal injury	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
皮膚損傷 Skin injury	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
脊椎骨折 Spinal fracture	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
脾破裂 Splenic rupture	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
皮下血腫 Subcutaneous haematoma	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
硬膜下血腫 Subdural haematoma	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
硬膜下出血 Subdural haemorrhage	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
腱断裂 Tendon rupture	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
外傷性血胸 Traumatic haemothorax	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
尺骨骨折 Ulna fracture	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
創部分泌 Wound secretion	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
節足動物咬傷 Arthropod bite	0	0	0	1 (0.2%)
四肢圧挫損傷 Limb crushing injury	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
処置後合併症 Post procedural complication	0	0	0	1 (0.2%)
処置後挫傷 Post procedural contusion	0	0	0	1 (0.2%)
術後譫妄 Postoperative delirium	0	0	0	1 (0.2%)
引っかき傷 Scratch	0	0	0	1 (0.2%)
外傷性血腫 Traumatic haematoma	0	0	0	1 (0.2%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） Neoplasms benign, malignant and unspecified (incl cysts and polyps)	32 (18.7%)	25 (12.7%)	57 (15.5%)	65 (15.8%)
基底細胞癌 Basal cell carcinoma	7 (4.1%)	4 (2.0%)	11 (3.0%)	12 (2.9%)
皮膚有棘細胞癌 Squamous cell carcinoma of skin	5 (2.9%)	4 (2.0%)	9 (2.4%)	11 (2.7%)
急性骨髄性白血病 Acute myeloid leukaemia	4 (2.3%)	3 (1.5%)	7 (1.9%)	8 (1.9%)
骨髄線維症 Myelofibrosis	3 (1.8%)	4 (2.0%)	7 (1.9%)	8 (1.9%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
悪性黒色腫 Malignant melanoma	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
メラノサイト性母斑 Melanocytic naevus	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
ボーエン病 Bowen's disease	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
脂漏性角化症 Seborrhoeic keratosis	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
子宮平滑筋腫 Uterine leiomyoma	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
子宮癌 Uterine cancer	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
良性腺腫 Adenoma benign	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
血管筋脂肪腫 Angiomyolipoma	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
再発膀胱移行上皮癌 Bladder transitional cell carcinoma recurrent	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
慢性リンパ性白血病 Chronic lymphocytic leukaemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
慢性骨髄性白血病 Chronic myeloid leukaemia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
眼瞼腫瘍 Eyelid tumour	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
乳腺線維腺腫 Fibroadenoma of breast	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
骨血管腫 Haemangioma of bone	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
ランゲルハンス細胞肉腫 Langerhans cell sarcoma	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
白赤芽球症 Leukoerythroblastosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
表皮内悪性黒色腫 Malignant melanoma in situ	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
リンパ節転移 Metastases to lymph nodes	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
遠隔転移を伴う扁平上皮癌 Metastatic squamous cell carcinoma	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
新生物 Neoplasm	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
原発性骨髄線維症 Primary myelofibrosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
前立腺癌 Prostate cancer	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
直腸癌 Rectal cancer	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
セミノーマ Seminoma	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
鼻副鼻腔乳頭腫 Sinonasal papilloma	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
皮膚癌 Skin cancer	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
皮膚乳頭腫 Skin papilloma	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
舌扁平上皮癌 Squamous cell carcinoma of the tongue	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
急性骨髄性白血病への転化 Transformation to acute myeloid leukaemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
腫瘍熱 Tumour associated fever	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
膀胱移行上皮癌 Bladder transitional cell carcinoma	0	0	0	1 (0.2%)
膵管内乳頭粘液性腫瘍 Intraductal papillary mucinous neoplasm	0	0	0	1 (0.2%)
食道扁平上皮癌 Oesophageal squamous cell carcinoma	0	0	0	1 (0.2%)
卵巣明細胞癌 Ovarian clear cell carcinoma	0	0	0	1 (0.2%)
脾臓辺縁帯リンパ腫 Splenic marginal zone lymphoma	0	0	0	1 (0.2%)
心臓障害 Cardiac disorders	28 (16.4%)	27 (13.7%)	55 (14.9%)	70 (17.0%)
心房細動 Atrial fibrillation	9 (5.3%)	9 (4.6%)	18 (4.9%)	26 (6.3%)
心不全 Cardiac failure	7 (4.1%)	4 (2.0%)	11 (3.0%)	13 (3.2%)
心房粗動 Atrial flutter	4 (2.3%)	2 (1.0%)	6 (1.6%)	7 (1.7%)
動悸 Palpitations	1 (0.6%)	4 (2.0%)	5 (1.4%)	7 (1.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
急性心筋梗塞 Acute myocardial infarction	1 (0.6%)	2 (1.0%)	3 (0.8%)	6 (1.5%)
うっ血性心不全 Cardiac failure congestive	2 (1.2%)	1 (0.5%)	3 (0.8%)	4 (1.0%)
心停止 Cardiac arrest	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
狭心症 Angina pectoris	0	2 (1.0%)	2 (0.5%)	6 (1.5%)
頻脈 Tachycardia	2 (1.2%)	0	2 (0.5%)	4 (1.0%)
大動脈弁狭窄 Aortic valve stenosis	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
徐脈 Bradycardia	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
冠動脈疾患 Coronary artery disease	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
僧帽弁閉鎖不全症 Mitral valve incompetence	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
心筋梗塞 Myocardial infarction	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
不安定狭心症 Angina unstable	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
期外収縮 Extrasystoles	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
房室ブロック Atrioventricular block	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
第一度房室ブロック Atrioventricular block first degree	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
慢性心不全 Cardiac failure chronic	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
心臓弁膜疾患 Cardiac valve disease	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
心筋症 Cardiomyopathy	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
拡張機能障害 Diastolic dysfunction	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
左室機能不全 Left ventricular dysfunction	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
左室不全 Left ventricular failure	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
心筋虚血 Myocardial ischaemia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
洞性徐脈 Sinus bradycardia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
洞性頻脈 Sinus tachycardia	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
上室性期外収縮 Supraventricular extrasystoles	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
完全房室ブロック Atrioventricular block complete	0	0	0	1 (0.2%)
心拡大 Cardiomegaly	0	0	0	1 (0.2%)
心嚢液貯留 Pericardial effusion	0	0	0	1 (0.2%)
上室性頻脈 Supraventricular tachycardia	0	0	0	1 (0.2%)
三尖弁閉鎖不全症 Tricuspid valve incompetence	0	0	0	1 (0.2%)
精神障害 Psychiatric disorders	25 (14.6%)	22 (11.2%)	47 (12.8%)	60 (14.6%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
不眠症 Insomnia	11 (6.4%)	6 (3.0%)	17 (4.6%)	21 (5.1%)
うつ病 Depression	8 (4.7%)	4 (2.0%)	12 (3.3%)	15 (3.6%)
不安 Anxiety	6 (3.5%)	2 (1.0%)	8 (2.2%)	14 (3.4%)
錯乱状態 Confusional state	3 (1.8%)	2 (1.0%)	5 (1.4%)	6 (1.5%)
リビドー減退 Libido decreased	1 (0.6%)	2 (1.0%)	3 (0.8%)	3 (0.7%)
失見当識 Disorientation	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
幻覚 Hallucination	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
精神状態変化 Mental status changes	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
神経過敏 Nervousness	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
感情障害 Affective disorder	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
譫妄 Delirium	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
妄想 Delusion	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
抑うつ気分 Depressed mood	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
睡眠障害 Sleep disorder	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
身体疾患による睡眠障害、不眠症型 Sleep disorder due to general medical condition, insomnia type	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
自殺念慮 Suicidal ideation	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
激越 Agitation	0	0	0	1 (0.2%)
耳および迷路障害 Ear and labyrinth disorders	10 (5.8%)	14 (7.1%)	24 (6.5%)	36 (8.8%)
回転性めまい Vertigo	5 (2.9%)	8 (4.1%)	13 (3.5%)	20 (4.9%)
耳鳴 Tinnitus	0	3 (1.5%)	3 (0.8%)	5 (1.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
耳痛 Ear pain	1 (0.6%)	0	1 (0.3%)	2 (0.5%)
聴力低下 Hypoacusis	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
難聴 Deafness	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
片耳難聴 Deafness unilateral	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
耳出血 Ear haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
乗物酔い Motion sickness	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
耳異常感覚 Paraesthesia ear	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
突発性難聴 Sudden hearing loss	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
鼓膜穿孔 Tympanic membrane perforation	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
耳不快感 Ear discomfort	0	0	0	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
肝胆道系障害 Hepatobiliary disorders	9 (5.3%)	10 (5.1%)	19 (5.2%)	20 (4.9%)
胆石症 Cholelithiasis	5 (2.9%)	1 (0.5%)	6 (1.6%)	6 (1.5%)
急性胆嚢炎 Cholecystitis acute	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
肝障害 Liver disorder	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
黄疸眼 Ocular icterus	1 (0.6%)	1 (0.5%)	2 (0.5%)	2 (0.5%)
門脈圧亢進症 Portal hypertension	0	2 (1.0%)	2 (0.5%)	2 (0.5%)
胆汁うっ滞 Cholestasis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肝硬変 Hepatic cirrhosis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
肝不全 Hepatic failure	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
肝機能異常 Hepatic function abnormal	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
脂肪肝 Hepatic steatosis	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
肝腫大 Hepatomegaly	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
門脈血栓症 Portal vein thrombosis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
過形成性胆嚢症 Hyperplastic cholecystopathy	0	0	0	1 (0.2%)
生殖系および乳房障害 Reproductive system and breast disorders	8 (4.7%)	9 (4.6%)	17 (4.6%)	22 (5.4%)
良性前立腺肥大症 Benign prostatic hyperplasia	3 (1.8%)	5 (2.5%)	8 (2.2%)	9 (2.2%)
腟出血 Vaginal haemorrhage	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
乳房過形成 Breast hyperplasia	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
精巣上体嚢胞 Epididymal cyst	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
勃起不全 Erectile dysfunction	0	1 (0.5%)	1 (0.3%)	1 (0.2%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
閉経後出血 Postmenopausal haemorrhage	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
精巣腫脹 Testicular swelling	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
子宮頚部びらん Uterine cervical erosion	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
子宮出血 Uterine haemorrhage	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
腟分泌物 Vaginal discharge	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
腟脱 Vaginal prolapse	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
会陰痛 Perineal pain	0	0	0	1 (0.2%)
外陰腟の炎症 Vulvovaginal inflammation	0	0	0	1 (0.2%)
外陰腟痛 Vulvovaginal pain	0	0	0	1 (0.2%)
内分泌障害 Endocrine disorders	2 (1.2%)	3 (1.5%)	5 (1.4%)	7 (1.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
甲状腺腫瘤 Thyroid mass	2 (1.2%)	0	2 (0.5%)	2 (0.5%)
甲状腺機能低下症 Hypothyroidism	0	1 (0.5%)	1 (0.3%)	2 (0.5%)
甲状腺腫 Goitre	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
甲状腺炎 Thyroiditis	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
低アルドステロン症 Hypoaldosteronism	0	0	0	1 (0.2%)
免疫系障害 Immune system disorders	2 (1.2%)	1 (0.5%)	3 (0.8%)	3 (0.7%)
薬物過敏症 Drug hypersensitivity	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
過敏症 Hypersensitivity	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
季節性アレルギー Seasonal allergy	0	1 (0.5%)	1 (0.3%)	1 (0.2%)
外科および内科処置 Surgical and medical procedures	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（全体）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=171)	Switch (RUX->MMB) (N=197)	Total (N=368)	Total (N=411)
抜歯 Tooth extraction	1 (0.6%)	1 (0.5%)	2 (0.5%)	3 (0.7%)
先天性、家族性および遺伝性障害 Congenital, familial and genetic disorders	1 (0.6%)	0	1 (0.3%)	1 (0.2%)
陰嚢水瘤 Hydrocele	1 (0.6%)	0	1 (0.3%)	1 (0.2%)

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
有害事象発現例数 ANY EVENT	5 (83.3%)	9 (100.0%)	14 (93.3%)	14 (93.3%)
感染症および寄生虫症 Infections and infestations	4 (66.7%)	4 (44.4%)	8 (53.3%)	8 (53.3%)
尿路感染 Urinary tract infection	1 (16.7%)	1 (11.1%)	2 (13.3%)	2 (13.3%)
肺炎 Pneumonia	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
上気道感染 Upper respiratory tract infection	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
上咽頭炎 Nasopharyngitis	2 (33.3%)	0	2 (13.3%)	3 (20.0%)
気管支炎 Bronchitis	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
胃腸炎 Gastroenteritis	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
気道感染 Respiratory tract infection	0	0	0	0
帯状疱疹 Herpes zoster	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
膀胱炎 Cystitis	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
口腔ヘルペス Oral herpes	0	0	0	0
インフルエンザ Influenza	0	0	0	0
副鼻腔炎 Sinusitis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
下気道感染 Lower respiratory tract infection	0	0	0	0
敗血症 Sepsis	0	0	0	0
蜂巣炎 Cellulitis	0	0	0	0
大腸菌性尿路感染 Escherichia urinary tract infection	0	0	0	0
肺感染 Lung infection	0	0	0	0
口腔カンジダ症 Oral candidiasis	0	0	0	0
憩室炎 Diverticulitis	0	0	0	1 (6.7%)
ウイルス感染 Viral infection	0	0	0	0
クロストリジウム・ディフィシレ大腸炎 Clostridium difficile colitis	0	0	0	0
結膜炎 Conjunctivitis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
耳感染 Ear infection	0	0	0	0
せつ Furuncle	0	0	0	0
単純ヘルペス Herpes simplex	0	0	0	0
中耳炎 Otitis media	0	0	0	0
真菌感染 Fungal infection	0	0	0	0
皮膚真菌感染 Fungal skin infection	0	0	0	0
消化管感染 Gastrointestinal infection	0	0	0	0
限局性感染 Localised infection	0	0	0	0
外耳炎 Otitis externa	0	0	0	0
細菌性肺炎 Pneumonia bacterial	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
腎盂腎炎 Pyelonephritis	0	0	0	0
ボレリア感染 Borrelia infection	0	0	0	0
クロストリジウム・ディフィシレ感染 Clostridium difficile infection	0	0	0	0
丹毒 Erysipelas	0	0	0	0
サルモネラ菌性胃腸炎 Gastroenteritis salmonella	0	0	0	0
ウイルス性胃腸炎 Gastroenteritis viral	0	0	0	0
陰部ヘルペス Genital herpes	0	0	0	0
咽頭炎 Pharyngitis	0	0	0	0
ウイルス性肺炎 Pneumonia viral	0	0	0	0
扁桃炎 Tonsillitis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
水痘帯状疱疹ウイルス感染 Varicella zoster virus infection	0	0	0	0
創傷感染 Wound infection	0	0	0	0
皮膚感染 Skin infection	0	0	0	0
鼻炎 Rhinitis	0	0	0	0
毛包炎 Folliculitis	0	0	0	0
歯肉炎 Gingivitis	0	0	0	0
喉頭炎 Laryngitis	0	0	0	0
歯周炎 Periodontitis	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
腹部敗血症 Abdominal sepsis	0	0	0	0
四肢膿瘍 Abscess limb	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
菌血症 Bacteraemia	0	0	0	0
気管支肺アスペルギルス症 Bronchopulmonary aspergillosis	0	0	0	0
カンジダ感染 Candida infection	0	0	0	0
医療機器関連感染 Device related infection	0	0	0	0
感染性腸炎 Enteritis infectious	0	0	0	0
感染性小腸結腸炎 Enterocolitis infectious	0	0	0	0
大腸菌感染 Escherichia infection	0	0	0	0
眼感染 Eye infection	0	0	0	0
真菌性食道炎 Fungal oesophagitis	0	0	0	0
壊疽 Gangrene	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
消化器カンジダ症 Gastrointestinal candidiasis	0	0	0	0
ヘルペス性皮膚炎 Herpes dermatitis	0	0	0	0
感染性皮膚嚢腫 Infected dermal cyst	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
感染性皮膚潰瘍 Infected skin ulcer	0	0	0	0
迷路炎 Labyrinthitis	0	0	0	0
筋膿瘍 Muscle abscess	0	0	0	0
鼻ヘルペス Nasal herpes	0	0	0	0
神経ボレリア症 Neuroborreliosis	0	0	0	0
百日咳 Pertussis	0	0	0	0
ピコルナウイルス感染 Picornavirus infection	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
ＲＳウイルス肺炎 Pneumonia respiratory syncytial viral	0	0	0	0
術後創感染 Postoperative wound infection	0	0	0	0
肺敗血症 Pulmonary sepsis	0	0	0	0
肺結核 Pulmonary tuberculosis	0	0	0	0
敗血症性ショック Septic shock	0	0	0	0
セラチア性菌血症 Serratia bacteraemia	0	0	0	0
赤痢菌感染 Shigella infection	0	0	0	0
唾液腺炎 Sialoadenitis	0	0	0	0
皮下組織膿瘍 Subcutaneous abscess	0	0	0	0
破傷風 Tetanus	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
歯膿瘍 Tooth abscess	0	0	0	0
歯感染 Tooth infection	0	0	0	0
結核 Tuberculosis	0	0	0	0
前庭神経炎 Vestibular neuronitis	0	0	0	0
ウイルス性ぶどう膜炎 Viral uveitis	0	0	0	0
癜風 Tinea versicolour	0	0	0	0
肛門膿瘍 Anal abscess	0	0	0	0
大腸菌性敗血症 Escherichia sepsis	0	0	0	0
感染 Infection	0	0	0	0
口唇感染 Lip infection	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
ライム病 Lyme disease	0	0	0	0
処置後感染 Post procedural infection	0	0	0	0
腎盂膀胱炎 Pyelocystitis	0	0	0	0
陰嚢膿瘍 Scrotal abscess	0	0	0	0
皮膚細菌感染 Skin bacterial infection	0	0	0	0
ブドウ球菌感染 Staphylococcal infection	0	0	0	0
レンサ球菌性敗血症 Streptococcal sepsis	0	0	0	0
腟感染 Vaginal infection	0	0	0	0
胃腸障害 Gastrointestinal disorders	5 (83.3%)	6 (66.7%)	11 (73.3%)	11 (73.3%)
下痢 Diarrhoea	1 (16.7%)	2 (22.2%)	3 (20.0%)	3 (20.0%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
悪心 Nausea	0	4 (44.4%)	4 (26.7%)	4 (26.7%)
腹痛 Abdominal pain	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
便秘 Constipation	3 (50.0%)	2 (22.2%)	5 (33.3%)	5 (33.3%)
嘔吐 Vomiting	0	0	0	0
胃食道逆流性疾患 Gastrooesophageal reflux disease	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
消化不良 Dyspepsia	0	0	0	1 (6.7%)
上腹部痛 Abdominal pain upper	0	0	0	0
腹部膨満 Abdominal distension	0	0	0	0
腹水 Ascites	0	0	0	0
腹部不快感 Abdominal discomfort	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
胃炎 Gastritis	0	0	0	0
食道静脈瘤 Varices oesophageal	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
口内乾燥 Dry mouth	0	0	0	0
歯痛 Toothache	0	0	0	0
痔核 Haemorrhoids	0	0	0	0
直腸出血 Rectal haemorrhage	0	0	0	0
鼠径ヘルニア Inguinal hernia	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
下腹部痛 Abdominal pain lower	0	0	0	0
びらん性胃炎 Gastritis erosive	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
大腸炎 Colitis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
心窩部不快感 Epigastric discomfort	0	0	0	0
裂孔ヘルニア Hiatus hernia	0	0	0	0
口腔内出血 Mouth haemorrhage	0	0	0	0
口内炎 Stomatitis	1 (16.7%)	1 (11.1%)	2 (13.3%)	2 (13.3%)
鼓腸 Flatulence	0	0	0	0
歯肉出血 Gingival bleeding	0	0	0	0
肛門失禁 Anal incontinence	0	0	0	0
口角口唇炎 Angular cheilitis	0	0	0	0
齲歯 Dental caries	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
憩室 Diverticulum	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
食道静脈瘤出血 Oesophageal varices haemorrhage	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
口腔内痛 Oral pain	0	0	0	0
口唇炎 Cheilitis	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
嚥下障害 Dysphagia	0	0	0	0
胃潰瘍 Gastric ulcer	0	0	0	0
口腔内潰瘍形成 Mouth ulceration	0	0	0	0
レッチング Retching	0	0	0	0
小腸閉塞 Small intestinal obstruction	0	0	0	0
腹部硬直 Abdominal rigidity	0	0	0	0
異常便 Abnormal faeces	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
水疱性出血性口峡炎 Angina bullosa haemorrhagica	0	0	0	0
アフタ性潰瘍 Aphthous ulcer	0	0	0	0
慢性胃炎 Chronic gastritis	0	0	0	0
便意切迫 Defaecation urgency	0	0	0	0
歯組織の壊死 Dental necrosis	0	0	0	0
出血性十二指腸潰瘍 Duodenal ulcer haemorrhage	0	0	0	0
十二指腸炎 Duodenitis	0	0	0	0
腸炎 Enterocolitis	0	0	0	0
腹膜垂炎 Epiploic appendagitis	0	0	0	0
食中毒 Food poisoning	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
胃障害 Gastric disorder	0	0	0	0
胃出血 Gastric haemorrhage	0	0	0	0
出血性胃潰瘍 Gastric ulcer haemorrhage	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
胃腸障害 Gastrointestinal disorder	0	0	0	0
胃腸出血 Gastrointestinal haemorrhage	0	0	0	0
消化管運動障害 Gastrointestinal motility disorder	0	0	0	0
消化器痛 Gastrointestinal pain	0	0	0	0
胃腸音異常 Gastrointestinal sounds abnormal	0	0	0	0
歯肉潰瘍 Gingival ulceration	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
舌痛 Glossodynia	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
吐血 Haematemesis	0	0	0	0
口の感覚鈍麻 Hypoaesthesia oral	0	0	0	0
イレウス Ileus	0	0	0	0
腸梗塞 Intestinal infarction	0	0	0	0
腹腔内血腫 Intra-abdominal haematoma	0	0	0	0
下部消化管出血 Lower gastrointestinal haemorrhage	0	0	0	0
メレナ Melaena	0	0	0	0
口腔粘膜血腫 Oral mucosa haematoma	0	0	0	0
膵嚢胞 Pancreatic cyst	0	0	0	0
膵脂肪変性 Pancreatic steatosis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
膵炎 Pancreatitis	0	0	0	0
歯周病 Periodontal disease	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
咳嗽後嘔吐 Post-tussive vomiting	0	0	0	0
小腸出血 Small intestinal haemorrhage	0	0	0	0
埋伏歯 Tooth impacted	0	0	0	0
臍ヘルニア Umbilical hernia	0	0	0	0
上部消化管出血 Upper gastrointestinal haemorrhage	0	0	0	0
内臓静脈血栓症 Visceral venous thrombosis	0	0	0	0
小腸炎 Enteritis	0	0	0	0
肛門周囲痛 Proctalgia	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
軟便 Faeces soft	0	0	0	0
胃ポリープ Gastric polyps	0	0	0	0
血便排泄 Haematochezia	0	0	0	0
痔出血 Haemorrhoidal haemorrhage	0	0	0	0
口唇痛 Lip pain	0	0	0	0
腸間膜静脈血栓症 Mesenteric vein thrombosis	0	0	0	0
嚥下痛 Odynophagia	0	0	0	0
食道炎 Oesophagitis	0	0	0	0
消化性潰瘍 Peptic ulcer	0	0	0	0
舌紅斑 Tongue erythema	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
一般・全身障害および投与部位の状態 General disorders and administration site conditions	2 (33.3%)	2 (22.2%)	4 (26.7%)	4 (26.7%)
疲労 Fatigue	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
発熱 Pyrexia	2 (33.3%)	1 (11.1%)	3 (20.0%)	3 (20.0%)
末梢性浮腫 Oedema peripheral	0	0	0	0
無力症 Asthenia	0	0	0	0
胸痛 Chest pain	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
インフルエンザ様疾患 Influenza like illness	0	0	0	0
末梢腫脹 Peripheral swelling	0	0	0	0
早期満腹 Early satiety	0	0	0	0
悪寒 Chills	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
倦怠感 Malaise	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
非心臓性胸痛 Non-cardiac chest pain	0	0	0	0
疼痛 Pain	0	0	0	0
胸部不快感 Chest discomfort	0	0	0	0
熱感 Feeling hot	0	0	0	0
死亡 Death	0	0	0	0
歩行障害 Gait disturbance	0	0	0	0
全身性浮腫 Generalised oedema	0	0	0	0
粘膜の炎症 Mucosal inflammation	0	0	0	0
浮腫 Oedema	0	0	0	1 (6.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
全身健康状態悪化 General physical health deterioration	0	0	0	0
治癒不良 Impaired healing	0	0	0	0
腫脹 Swelling	0	0	0	0
口渇 Thirst	0	0	0	0
カテーテル留置部位疼痛 Catheter site pain	0	0	0	0
医療機器関連合併症 Complication associated with device	0	0	0	0
不快感 Discomfort	0	0	0	0
薬剤離脱症候群 Drug withdrawal syndrome	0	0	0	0
顔面浮腫 Face oedema	0	0	0	0
高熱 Hyperthermia	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
注入部位疼痛 Infusion site pain	0	0	0	0
注射部位出血 Injection site haemorrhage	0	0	0	0
多臓器機能不全症候群 Multiple organ dysfunction syndrome	0	0	0	0
乾燥症 Xerosis	0	0	0	0
重力性浮腫 Gravitational oedema	0	0	0	0
捻髪音 Crepitations	0	0	0	0
顔面痛 Facial pain	0	0	0	0
硬結 Induration	0	0	0	0
炎症 Inflammation	0	0	0	0
突然死 Sudden death	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
血液およびリンパ系障害 Blood and lymphatic system disorders	4 (66.7%)	4 (44.4%)	8 (53.3%)	8 (53.3%)
貧血 Anaemia	4 (66.7%)	1 (11.1%)	5 (33.3%)	5 (33.3%)
血小板減少症 Thrombocytopenia	2 (33.3%)	2 (22.2%)	4 (26.7%)	4 (26.7%)
好中球減少症 Neutropenia	0	0	0	0
白血球増加症 Leukocytosis	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
白血球減少症 Leukopenia	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
血小板増加症 Thrombocytosis	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
リンパ球減少症 Lymphopenia	1 (16.7%)	1 (11.1%)	2 (13.3%)	2 (13.3%)
脾腫 Splenomegaly	0	0	0	0
脾臓梗塞 Splenic infarction	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
赤血球増加症 Polycythaemia	0	0	0	0
発熱性好中球減少症 Febrile neutropenia	0	0	0	0
内出血発生の増加傾向 Increased tendency to bruise	0	0	0	0
脾血腫 Splenic haematoma	0	0	0	0
骨髄毒性 Bone marrow toxicity	0	0	0	0
凝血異常 Coagulopathy	0	0	0	0
溶血 Haemolysis	0	0	0	0
溶血性貧血 Haemolytic anaemia	0	0	0	0
過粘稠度症候群 Hyperviscosity syndrome	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
鉄欠乏性貧血 Iron deficiency anaemia	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
肥満細胞症 Mastocytosis	0	0	0	0
好中球増加症 Neutrophilia	0	0	0	0
脾臓障害 Spleen disorder	0	0	0	0
脾臓血栓症 Splenic thrombosis	0	0	0	0
特発性血腫 Spontaneous haematoma	0	0	0	0
低プロトロンビン血症 Hypoprothrombinaemia	0	0	0	0
リンパ節石灰化 Lymph node calcification	0	0	0	0
リンパ節症 Lymphadenopathy	0	0	0	0
リンパ球増加症 Lymphocytosis	0	0	0	0
微小血管症性溶血性貧血 Microangiopathic haemolytic anaemia	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
神経系障害 Nervous system disorders	3 (50.0%)	3 (33.3%)	6 (40.0%)	7 (46.7%)
浮動性めまい Dizziness	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
末梢性感覚ニューロパチー Peripheral sensory neuropathy	0	1 (11.1%)	1 (6.7%)	2 (13.3%)
頭痛 Headache	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
錯感覚 Paraesthesia	0	0	0	0
感覚鈍麻 Hypoaesthesia	0	0	0	0
失神 Syncope	0	0	0	0
嗜眠 Lethargy	0	0	0	0
坐骨神経痛 Sciatica	0	0	0	0
平衡障害 Balance disorder	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
失神寸前の状態 Presyncope	0	0	0	0
健忘 Amnesia	0	0	0	0
味覚異常 Dysgeusia	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
末梢性ニューロパチー Neuropathy peripheral	0	0	0	0
傾眠 Somnolence	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
脳血管発作 Cerebrovascular accident	0	0	0	0
一過性脳虚血発作 Transient ischaemic attack	0	0	0	0
神経痛 Neuralgia	0	0	0	0
灼熱感 Burning sensation	0	0	0	0
意識消失 Loss of consciousness	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
感覚障害 Sensory disturbance	0	0	0	0
声帯麻痺 Vocal cord paralysis	0	0	0	0
記憶障害 Memory impairment	0	0	0	0
振戦 Tremor	0	0	0	0
注意力障害 Disturbance in attention	0	0	0	0
体位性めまい Dizziness postural	0	0	0	0
異常感覚 Dysaesthesia	0	0	0	0
蟻走感 Formication	0	0	0	0
末梢性運動ニューロパチー Peripheral motor neuropathy	0	0	0	0
味覚消失 Ageusia	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
運動失調 Ataxia	0	0	0	0
小脳卒中 Cerebellar stroke	0	0	0	0
大脳萎縮 Cerebral atrophy	0	0	0	0
脳微小血管症 Cerebral microangiopathy	0	0	0	0
大脳静脈血栓症 Cerebral venous thrombosis	0	0	0	0
脳血管不全 Cerebrovascular insufficiency	0	0	0	0
認知障害 Cognitive disorder	0	0	0	0
認知症 Dementia	0	0	0	0
脱髄 Demyelination	0	0	0	0
前頭側頭型認知症 Frontotemporal dementia	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
出血性卒中 Haemorrhagic stroke	0	0	0	0
不全片麻痺 Hemiparesis	0	0	0	0
ラクナ梗塞 Lacunar infarction	0	0	0	0
白質脳症 Leukoencephalopathy	0	0	0	0
ミオトニー Myotonia	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
眼振 Nystagmus	0	0	0	0
後頭神経痛 Occipital neuralgia	0	0	0	0
パーキンソン病 Parkinson's disease	0	0	0	0
末梢性感覚運動ニューロパチー Peripheral sensorimotor neuropathy	0	0	0	0
多発ニューロパチー Polyneuropathy	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
ヘルペス後神経痛 Post herpetic neuralgia	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
下肢静止不能症候群 Restless legs syndrome	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
副鼻腔炎に伴う頭痛 Sinus headache	0	0	0	0
くも膜下出血 Subarachnoid haemorrhage	0	0	0	0
三叉神経痛 Trigeminal neuralgia	0	0	0	0
味覚障害 Taste disorder	0	0	0	0
脳虚血 Cerebral ischaemia	0	0	0	0
頚腕症候群 Cervicobrachial syndrome	0	0	0	0
前兆を伴う片頭痛 Migraine with aura	0	0	0	0
神経系障害 Nervous system disorder	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
代謝および栄養障害 Metabolism and nutrition disorders	4 (66.7%)	2 (22.2%)	6 (40.0%)	6 (40.0%)
食欲減退 Decreased appetite	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
高尿酸血症 Hyperuricaemia	1 (16.7%)	0	1 (6.7%)	2 (13.3%)
ビタミンＢ１欠乏 Vitamin B1 deficiency	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
高カリウム血症 Hyperkalaemia	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
低カリウム血症 Hypokalaemia	0	0	0	0
痛風 Gout	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
糖尿病 Diabetes mellitus	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
低カルシウム血症 Hypocalcaemia	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
低ナトリウム血症 Hyponatraemia	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
高血糖 Hyperglycaemia	0	0	0	0
脱水 Dehydration	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
低血糖 Hypoglycaemia	0	0	0	0
低マグネシウム血症 Hypomagnesaemia	0	0	0	0
鉄欠乏 Iron deficiency	0	0	0	0
低アルブミン血症 Hypoalbuminaemia	0	0	0	0
高コレステロール血症 Hypercholesterolaemia	0	0	0	0
高トリグリセリド血症 Hypertriglyceridaemia	0	0	0	0
ビタミンD欠乏 Vitamin D deficiency	0	0	0	0
体液貯留 Fluid retention	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
鉄過剰 Iron overload	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
ビタミンＢ群欠乏 Vitamin B complex deficiency	0	0	0	0
高カルシウム血症 Hypercalcaemia	0	0	0	0
高脂血症 Hyperlipidaemia	0	0	0	0
低リン酸血症 Hypophosphataemia	0	0	0	0
異常体重減少 Abnormal loss of weight	0	0	0	0
悪液質 Cachexia	0	0	0	0
コントロール不良の糖尿病 Diabetes mellitus inadequate control	0	0	0	0
脂質異常症 Dyslipidaemia	0	0	0	0
電解質失調 Electrolyte imbalance	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
水分過負荷 Fluid overload	0	0	0	0
葉酸欠乏 Folate deficiency	0	0	0	0
高フェリチン血症 Hyperferritinaemia	0	0	0	0
高マグネシウム血症 Hypermagnesaemia	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
高ナトリウム血症 Hypernatraemia	0	0	0	0
低蛋白血症 Hypoproteinaemia	0	0	0	0
代謝性アシドーシス Metabolic acidosis	0	0	0	0
ビタミン群欠乏 Multi-vitamin deficiency	0	0	0	0
偽高カリウム血症 Pseudohyperkalaemia	0	0	0	0
腫瘍崩壊症候群 Tumour lysis syndrome	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
２型糖尿病 Type 2 diabetes mellitus	0	0	0	0
ビタミンＢ１２欠乏 Vitamin B12 deficiency	0	0	0	0
ビタミンＢ６欠乏 Vitamin B6 deficiency	0	0	0	0
ヘモジデリン沈着症 Haemosiderosis	0	0	0	0
栄養障害 Malnutrition	0	0	0	0
ビタミンＫ欠乏 Vitamin K deficiency	0	0	0	0
筋骨格系および結合組織障害 Musculoskeletal and connective tissue disorders	0	3 (33.3%)	3 (20.0%)	3 (20.0%)
四肢痛 Pain in extremity	0	0	0	0
背部痛 Back pain	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
関節痛 Arthralgia	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
骨痛 Bone pain	0	0	0	0
筋骨格痛 Musculoskeletal pain	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
筋肉痛 Myalgia	0	0	0	0
筋力低下 Muscular weakness	0	0	0	0
筋痙縮 Muscle spasms	0	0	0	0
脊椎痛 Spinal pain	0	0	0	0
変形性関節症 Osteoarthritis	0	0	0	0
関節炎 Arthritis	0	0	0	0
滑液包炎 Bursitis	0	0	0	0
筋骨格硬直 Musculoskeletal stiffness	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
肩回旋筋腱板症候群 Rotator cuff syndrome	0	0	0	0
側腹部痛 Flank pain	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
鼠径部痛 Groin pain	0	0	0	0
筋骨格系胸痛 Musculoskeletal chest pain	0	0	0	0
顎痛 Pain in jaw	0	0	0	0
反応性関節炎 Arthritis reactive	0	0	0	0
椎間板突出 Intervertebral disc protrusion	0	0	0	0
関節滲出液 Joint effusion	0	0	0	0
頚部痛 Neck pain	0	0	0	0
痛風性関節炎 Gouty arthritis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
骨減少症 Osteopenia	0	0	0	0
変形性脊椎症 Spinal osteoarthritis	0	0	0	0
骨病変 Bone lesion	0	0	0	0
胸壁血腫 Chest wall haematoma	0	0	0	0
ピロリン酸カルシウム結晶性軟骨石灰化症 Chondrocalcinosis pyrophosphate	0	0	0	0
肋軟骨炎 Costochondritis	0	0	0	0
筋膜炎 Fasciitis	0	0	0	0
関節腫脹 Joint swelling	0	0	0	0
四肢不快感 Limb discomfort	0	0	0	0
運動性低下 Mobility decreased	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
筋萎縮 Muscle atrophy	0	0	0	0
筋肉疲労 Muscle fatigue	0	0	0	0
筋肉内出血 Muscle haemorrhage	0	0	0	0
骨溶解 Osteolysis	0	0	0	0
骨粗鬆症 Osteoporosis	0	0	0	0
骨硬化症 Osteosclerosis	0	0	0	0
関節周囲炎 Periarthritis	0	0	0	0
腱痛 Tendon pain	0	0	0	0
椎骨病変 Vertebral lesion	0	0	0	0
滑液貯留 Bursal fluid accumulation	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
足変形 Foot deformity	0	0	0	0
シェーグレン症候群 Sjogren's syndrome	0	0	0	0
腱炎 Tendonitis	0	0	0	0
呼吸器、胸郭および縦隔障害 Respiratory, thoracic and mediastinal disorders	1 (16.7%)	2 (22.2%)	3 (20.0%)	3 (20.0%)
咳嗽 Cough	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
呼吸困難 Dyspnoea	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
鼻出血 Epistaxis	0	0	0	0
胸水 Pleural effusion	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
口腔咽頭痛 Oropharyngeal pain	0	0	0	0
労作性呼吸困難 Dyspnoea exertional	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
湿性咳嗽 Productive cough	0	0	0	0
低酸素症 Hypoxia	0	0	0	0
慢性閉塞性肺疾患 Chronic obstructive pulmonary disease	0	0	0	0
呼吸不全 Respiratory failure	0	0	0	0
肺塞栓症 Pulmonary embolism	0	0	0	0
喘息 Asthma	0	0	0	0
胸膜炎 Pleurisy	0	0	0	0
発声障害 Dysphonia	0	0	0	0
鼻漏 Rhinorrhoea	0	0	0	0
急性呼吸不全 Acute respiratory failure	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
慢性気管支炎 Bronchitis chronic	0	0	0	0
肺硬化 Lung consolidation	0	0	0	0
肺水腫 Pulmonary oedema	0	0	0	0
喘鳴 Wheezing	0	0	0	0
ラ音 Rales	0	0	0	0
喀血 Haemoptysis	0	0	0	0
しゃっくり Hiccups	0	0	0	0
鼻閉 Nasal congestion	0	0	0	0
肺肉芽腫 Pulmonary granuloma	0	0	0	0
上気道咳症候群 Upper-airway cough syndrome	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
急性肺水腫 Acute pulmonary oedema	0	0	0	0
胞隔炎 Alveolitis	0	0	0	0
気管支拡張症 Bronchiectasis	0	0	0	0
カタル Catarrh	0	0	0	0
肺気腫 Emphysema	0	0	0	0
低換気 Hypoventilation	0	0	0	0
喉頭の炎症 Laryngeal inflammation	0	0	0	0
肺障害 Lung disorder	0	0	0	0
鼻乾燥 Nasal dryness	0	0	0	0
口腔咽頭不快感 Oropharyngeal discomfort	0	1 (11.1%)	1 (6.7%)	1 (6.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
起坐呼吸 Orthopnoea	0	0	0	0
誤嚥性肺炎 Pneumonia aspiration	0	0	0	0
肺高血圧症 Pulmonary hypertension	0	0	0	0
肺腫瘤 Pulmonary mass	0	0	0	0
呼吸停止 Respiratory arrest	0	0	0	0
副鼻腔うっ血 Sinus congestion	0	0	0	0
副鼻腔痛 Sinus pain	0	0	0	0
睡眠時無呼吸症候群 Sleep apnoea syndrome	0	0	0	0
頻呼吸 Tachypnoea	0	0	0	0
咽喉乾燥 Dry throat	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
発作性夜間呼吸困難 Dyspnoea paroxysmal nocturnal	0	0	0	0
呼吸時疼痛 Painful respiration	0	0	0	0
咽頭潰瘍 Pharyngeal ulceration	0	0	0	0
肺線維症 Pulmonary fibrosis	0	0	0	0
逆流性喉頭炎 Reflux laryngitis	0	0	0	0
咽喉絞扼感 Throat tightness	0	0	0	0
皮膚および皮下組織障害 Skin and subcutaneous tissue disorders	2 (33.3%)	5 (55.6%)	7 (46.7%)	7 (46.7%)
そう痒症 Pruritus	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
寝汗 Night sweats	0	0	0	0
発疹 Rash	1 (16.7%)	2 (22.2%)	3 (20.0%)	3 (20.0%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
多汗症 Hyperhidrosis	0	0	0	0
紅斑 Erythema	0	0	0	0
点状出血 Petechiae	0	0	0	0
全身性そう痒症 Pruritus generalised	0	0	0	0
斑状丘疹状皮疹 Rash maculo-papular	0	0	0	0
全身性皮疹 Rash generalised	0	0	0	0
皮膚出血 Skin haemorrhage	0	0	0	0
光線角化症 Actinic keratosis	0	0	0	0
脱毛症 Alopecia	0	0	0	0
斑状出血 Ecchymosis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
アレルギー性皮膚炎 Dermatitis allergic	0	0	0	0
斑状皮疹 Rash macular	0	0	0	0
冷汗 Cold sweat	0	0	0	0
皮膚嚢腫 Dermal cyst	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
丘疹性皮疹 Rash papular	0	0	0	0
酒さ Rosacea	0	0	0	0
皮膚剥脱 Skin exfoliation	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
中毒性皮疹 Toxic skin eruption	0	0	0	0
紅斑性皮疹 Rash erythematous	0	0	0	0
皮膚病変 Skin lesion	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
皮膚潰瘍 Skin ulcer	0	0	0	0
水疱 Blister	0	0	0	0
薬疹 Drug eruption	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
過角化 Hyperkeratosis	0	0	0	0
嵌入爪 Ingrowing nail	0	0	0	0
皮膚炎 Dermatitis	0	0	0	0
全身性剥脱性皮膚炎 Dermatitis exfoliative generalised	0	0	0	0
皮膚症 Dermatosis	0	0	0	0
過敏性血管炎 Hypersensitivity vasculitis	0	0	0	0
間擦疹 Intertrigo	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
苔癬様角化症 Lichenoid keratosis	0	0	0	0
爪変色 Nail discolouration	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
丘疹 Papule	0	0	0	0
乾癬 Psoriasis	0	0	0	0
紫斑 Purpura	0	0	0	0
皮膚障害 Skin disorder	0	0	0	0
皮膚脆弱性 Skin fragility	0	0	0	0
顔面腫脹 Swelling face	0	0	0	0
蕁麻疹 Urticaria	0	0	0	0
接触皮膚炎 Dermatitis contact	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
皮膚乾燥 Dry skin	0	0	0	0
血性水疱 Blood blister	0	0	0	0
湿疹 Eczema	0	0	0	0
紅色症 Erythrosis	0	0	0	0
毛孔性皮疹 Rash follicular	0	0	0	0
毛細血管拡張症 Telangiectasia	0	0	0	0
臨床検査 Investigations	2 (33.3%)	2 (22.2%)	4 (26.7%)	5 (33.3%)
血中クレアチニン増加 Blood creatinine increased	0	0	0	0
アラニンアミノトランスフェラーゼ増加 Alanine aminotransferase increased	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
アスパラギン酸アミノトランスフェラーゼ増加 Aspartate aminotransferase increased	0	1 (11.1%)	1 (6.7%)	1 (6.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
体重減少 Weight decreased	2 (33.3%)	0	2 (13.3%)	2 (13.3%)
血中ビリルビン増加 Blood bilirubin increased	0	0	0	0
γ－グルタミルトランスフェラーゼ増加 Gamma-glutamyltransferase increased	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
活性化部分トロンボプラスチン時間延長 Activated partial thromboplastin time prolonged	0	0	0	0
体重増加 Weight increased	0	0	0	1 (6.7%)
腎クレアチニン・クリアランス減少 Creatinine renal clearance decreased	0	0	0	0
血中葉酸減少 Blood folate decreased	0	0	0	0
血中乳酸脱水素酵素増加 Blood lactate dehydrogenase increased	0	0	0	0
ヘマトクリット増加 Haematocrit increased	0	0	0	0
ヘモグロビン増加 Haemoglobin increased	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
血中アルカリホスファターゼ増加 Blood alkaline phosphatase increased	0	0	0	0
トランスアミナーゼ上昇 Transaminases increased	0	0	0	0
芽球細胞数増加 Blast cell count increased	0	0	0	0
血中クロール増加 Blood chloride increased	0	0	0	0
血中鉄減少 Blood iron decreased	0	0	0	0
国際標準比増加 International normalised ratio increased	0	0	0	0
プロトロンビン時間延長 Prothrombin time prolonged	0	0	0	0
心電図ＱＴ延長 Electrocardiogram QT prolonged	0	0	0	0
総蛋白増加 Protein total increased	0	0	0	0
抗リン脂質抗体陽性 Antiphospholipid antibodies positive	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
血中クレアチンホスホキナーゼ増加 Blood creatine phosphokinase increased	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
血中鉄増加 Blood iron increased	0	0	0	0
血圧上昇 Blood pressure increased	0	0	0	0
血中尿素増加 Blood urea increased	0	0	0	0
胸部X線異常 Chest X-ray abnormal	0	0	0	0
骨盤コンピュータ断層撮影異常 Computerised tomogram pelvis abnormal	0	0	0	0
大腿動脈雑音 Femoral bruit	0	0	0	0
糸球体濾過率減少 Glomerular filtration rate decreased	0	0	0	0
肝酵素上昇 Hepatic enzyme increased	0	0	0	0
眼圧上昇 Intraocular pressure increased	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
肝機能検査異常 Liver function test abnormal	0	0	0	0
肝機能検査値上昇 Liver function test increased	0	0	0	0
平均赤血球容積減少 Mean cell volume decreased	0	0	0	0
血清フェリチン増加 Serum ferritin increased	0	0	0	0
ビタミンＢ１減少 Vitamin B1 decreased	0	0	0	0
尿中白血球陽性 White blood cells urine positive	0	0	0	0
心雑音 Cardiac murmur	0	0	0	0
血中重炭酸塩減少 Blood bicarbonate decreased	0	0	0	0
血中乳酸増加 Blood lactic acid increased	0	0	0	0
心電図ＳＴ部分下降 Electrocardiogram ST segment depression	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
心電図異常 Electrocardiogram abnormal	0	0	0	0
ヘプシジン減少 Hepcidin decreased	0	0	0	0
リパーゼ増加 Lipase increased	0	0	0	0
リンパ節触知 Lymph node palpable	0	0	0	0
好中球数増加 Neutrophil count increased	0	0	0	0
血管障害 Vascular disorders	0	3 (33.3%)	3 (20.0%)	3 (20.0%)
高血圧 Hypertension	0	0	0	0
低血圧 Hypotension	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
血腫 Haematoma	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
ほてり Hot flush	0	1 (11.1%)	1 (6.7%)	1 (6.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
潮紅 Flushing	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
静脈炎 Phlebitis	0	0	0	0
大動脈狭窄 Aortic stenosis	0	0	0	0
深部静脈血栓症 Deep vein thrombosis	0	0	0	0
動脈硬化症 Arteriosclerosis	0	0	0	0
起立性低血圧 Orthostatic hypotension	0	0	0	0
表在性血栓性静脈炎 Thrombophlebitis superficial	0	0	0	0
静脈瘤 Varicose vein	0	0	0	0
大動脈硬化症 Aortic arteriosclerosis	0	0	0	0
出血 Haemorrhage	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
末梢動脈閉塞性疾患 Peripheral arterial occlusive disease	0	0	0	0
四肢静脈血栓症 Venous thrombosis limb	0	0	0	0
末梢動脈狭窄 Peripheral artery stenosis	0	0	0	0
末梢循環不良 Poor peripheral circulation	0	0	0	0
血栓症 Thrombosis	0	0	0	0
血管拡張 Vasodilatation	0	0	0	0
大動脈解離 Aortic dissection	0	0	0	0
大動脈血栓症 Aortic thrombosis	0	0	0	0
本態性高血圧症 Essential hypertension	0	0	0	0
末梢冷感 Peripheral coldness	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
静脈穿刺不良 Poor venous access	0	0	0	0
血栓性静脈炎 Thrombophlebitis	0	0	0	0
腎および尿路障害 Renal and urinary disorders	3 (50.0%)	1 (11.1%)	4 (26.7%)	4 (26.7%)
急性腎障害 Acute kidney injury	0	0	0	0
腎不全 Renal failure	0	0	0	0
腎機能障害 Renal impairment	2 (33.3%)	0	2 (13.3%)	2 (13.3%)
排尿困難 Dysuria	0	0	0	0
慢性腎臓病 Chronic kidney disease	0	0	0	0
血尿 Haematuria	0	0	0	1 (6.7%)
蛋白尿 Proteinuria	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
頻尿 Pollakiuria	0	0	0	0
夜間頻尿 Nocturia	0	0	0	0
腎仙痛 Renal colic	0	0	0	0
腎結石症 Nephrolithiasis	0	0	0	0
尿失禁 Urinary incontinence	0	0	0	0
膀胱痙縮 Bladder spasm	0	0	0	0
尿路結石 Calculus urinary	0	0	0	0
高血圧性腎症 Hypertensive nephropathy	0	0	0	0
緊張性膀胱 Hypertonic bladder	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
白血球尿 Leukocyturia	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
排尿異常 Micturition disorder	0	0	0	0
尿意切迫 Micturition urgency	0	0	0	0
腎症 Nephropathy	0	0	0	0
ネフローゼ症候群 Nephrotic syndrome	0	0	0	0
腎嚢胞 Renal cyst	0	0	0	0
腎障害 Renal disorder	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
腎尿細管壊死 Renal tubular necrosis	0	0	0	0
尿管結石症 Ureterolithiasis	0	0	0	0
尿道障害 Urethral disorder	0	0	0	0
着色尿 Chromaturia	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
多尿 Polyuria	0	0	0	0
膀胱ポリープ Urinary bladder polyp	0	0	0	0
尿閉 Urinary retention	0	0	0	0
尿路痛 Urinary tract pain	0	0	0	0
眼障害 Eye disorders	1 (16.7%)	2 (22.2%)	3 (20.0%)	4 (26.7%)
核性白内障 Cataract nuclear	0	0	0	0
皮質白内障 Cataract cortical	0	0	0	0
霧視 Vision blurred	0	0	0	0
視力障害 Visual impairment	0	0	0	0
ドライアイ Dry eye	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
結膜出血 Conjunctival haemorrhage	0	0	0	0
嚢下白内障 Cataract subcapsular	0	0	0	0
網膜出血 Retinal haemorrhage	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
糖尿病網膜症 Diabetic retinopathy	0	0	0	0
流涙増加 Lacrimation increased	0	0	0	0
眼痛 Eye pain	0	0	0	0
視力低下 Visual acuity reduced	0	0	0	0
複視 Diplopia	0	0	0	0
眼出血 Eye haemorrhage	0	0	0	0
緑内障 Glaucoma	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
眼充血 Ocular hyperaemia	0	0	0	0
白内障 Cataract	0	0	0	0
眼刺激 Eye irritation	0	0	0	0
眼瞼浮腫 Eyelid oedema	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
角膜炎 Keratitis	0	0	0	1 (6.7%)
黄斑変性 Macular degeneration	0	0	0	0
眼瞼腫脹 Swelling of eyelid	0	0	0	0
硝子体浮遊物 Vitreous floaters	0	0	0	0
眼瞼炎 Blepharitis	0	0	0	0
眼瞼紅斑 Erythema of eyelid	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
眼瞼下垂 Eyelid ptosis	0	0	0	0
睫毛の成長 Growth of eyelashes	0	0	0	0
マイボーム腺機能不全 Meibomian gland dysfunction	0	0	0	0
網膜剥離 Retinal detachment	0	0	0	0
網膜瘢痕 Retinal scar	0	0	0	0
閃輝暗点 Scintillating scotoma	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
硝子体変性 Vitreous degeneration	0	0	0	0
眼部腫脹 Eye swelling	0	0	0	0
星状硝子体症 Hyalosis asteroid	0	0	0	1 (6.7%)
眼窩浮腫 Orbital oedema	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
眼窩周囲浮腫 Periorbital oedema	0	0	0	0
光視症 Photopsia	0	0	0	0
傷害、中毒および処置合併症 Injury, poisoning and procedural complications	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
転倒 Fall	0	0	0	0
挫傷 Contusion	0	0	0	0
四肢損傷 Limb injury	0	0	0	0
処置による疼痛 Procedural pain	0	0	0	0
処置後出血 Post procedural haemorrhage	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
皮膚裂傷 Skin laceration	0	0	0	0
創傷 Wound	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
皮膚擦過傷 Skin abrasion	0	0	0	0
脊椎圧迫骨折 Spinal compression fracture	0	0	0	0
足骨折 Foot fracture	0	0	0	0
頭部損傷 Head injury	0	0	0	0
過量投与 Overdose	0	0	0	0
眼窩周囲血腫 Periorbital haematoma	0	0	0	0
膝蓋骨骨折 Patella fracture	0	0	0	0
創合併症 Wound complication	0	0	0	0
吻合部狭窄 Anastomotic stenosis	0	0	0	0
背部損傷 Back injury	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
第 1 度熱傷 Burns first degree	0	0	0	0
一酸化炭素中毒 Carbon monoxide poisoning	0	0	0	0
歯科修復不成功 Dental restoration failure	0	0	0	0
耳部損傷 Ear injury	0	0	0	0
顔面骨骨折 Facial bones fracture	0	0	0	0
発熱性非溶血性輸血反応 Febrile nonhaemolytic transfusion reaction	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
上腕骨骨折 Humerus fracture	0	0	0	0
筋損傷 Muscle injury	0	0	0	0
肉離れ Muscle strain	0	0	0	0
処置後炎症 Post procedural inflammation	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
処置による悪心 Procedural nausea	0	0	0	0
肋骨骨折 Rib fracture	0	0	0	0
交通事故 Road traffic accident	0	0	0	0
骨格損傷 Skeletal injury	0	0	0	0
皮膚損傷 Skin injury	0	0	0	0
脊椎骨折 Spinal fracture	0	0	0	0
脾破裂 Splenic rupture	0	0	0	0
皮下血腫 Subcutaneous haematoma	0	0	0	0
硬膜下血腫 Subdural haematoma	0	0	0	0
硬膜下出血 Subdural haemorrhage	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
腱断裂 Tendon rupture	0	0	0	0
外傷性血胸 Traumatic haemothorax	0	0	0	0
尺骨骨折 Ulna fracture	0	0	0	0
創部分泌 Wound secretion	0	0	0	0
節足動物咬傷 Arthropod bite	0	0	0	0
四肢圧挫損傷 Limb crushing injury	0	0	0	0
処置後合併症 Post procedural complication	0	0	0	0
処置後挫傷 Post procedural contusion	0	0	0	0
術後譫妄 Postoperative delirium	0	0	0	0
引っかき傷 Scratch	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
外傷性血腫 Traumatic haematoma	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） Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (16.7%)	2 (22.2%)	3 (20.0%)	4 (26.7%)
基底細胞癌 Basal cell carcinoma	0	0	0	0
皮膚有棘細胞癌 Squamous cell carcinoma of skin	0	0	0	0
急性骨髄性白血病 Acute myeloid leukaemia	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
骨髄線維症 Myelofibrosis	0	0	0	0
悪性黒色腫 Malignant melanoma	0	0	0	0
メラノサイト性母斑 Melanocytic naevus	0	0	0	0
ボーエン病 Bowen's disease	0	0	0	0
脂漏性角化症 Seborrhoeic keratosis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
子宮平滑筋腫 Uterine leiomyoma	0	0	0	0
子宮癌 Uterine cancer	0	0	0	0
良性腺腫 Adenoma benign	0	0	0	0
血管筋脂肪腫 Angiomyolipoma	0	0	0	0
再発膀胱移行上皮癌 Bladder transitional cell carcinoma recurrent	0	0	0	0
慢性リンパ性白血病 Chronic lymphocytic leukaemia	0	0	0	0
慢性骨髄性白血病 Chronic myeloid leukaemia	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
眼瞼腫瘍 Eyelid tumour	0	0	0	0
乳腺線維腺腫 Fibroadenoma of breast	0	0	0	0
骨血管腫 Haemangioma of bone	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
ランゲルハンス細胞肉腫 Langerhans cell sarcoma	0	0	0	0
白赤芽球症 Leukoerythroblastosis	0	0	0	0
表皮内悪性黒色腫 Malignant melanoma in situ	0	0	0	0
リンパ節転移 Metastases to lymph nodes	0	0	0	0
遠隔転移を伴う扁平上皮癌 Metastatic squamous cell carcinoma	0	0	0	0
新生物 Neoplasm	0	0	0	0
原発性骨髄線維症 Primary myelofibrosis	0	0	0	0
前立腺癌 Prostate cancer	0	0	0	0
直腸癌 Rectal cancer	0	0	0	0
セミノーマ Seminoma	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
鼻副鼻腔乳頭腫 Sinonasal papilloma	0	0	0	0
皮膚癌 Skin cancer	0	0	0	0
皮膚乳頭腫 Skin papilloma	0	0	0	0
舌扁平上皮癌 Squamous cell carcinoma of the tongue	0	0	0	0
急性骨髄性白血病への転化 Transformation to acute myeloid leukaemia	0	0	0	0
腫瘍熱 Tumour associated fever	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
膀胱移行上皮癌 Bladder transitional cell carcinoma	0	0	0	0
膵管内乳頭粘液性腫瘍 Intraductal papillary mucinous neoplasm	0	0	0	1 (6.7%)
食道扁平上皮癌 Oesophageal squamous cell carcinoma	0	0	0	0
卵巣明細胞癌 Ovarian clear cell carcinoma	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
脾臓辺縁帯リンパ腫 Splenic marginal zone lymphoma	0	0	0	0
心臓障害 Cardiac disorders	0	0	0	0
心房細動 Atrial fibrillation	0	0	0	0
心不全 Cardiac failure	0	0	0	0
心房粗動 Atrial flutter	0	0	0	0
動悸 Palpitations	0	0	0	0
急性心筋梗塞 Acute myocardial infarction	0	0	0	0
うっ血性心不全 Cardiac failure congestive	0	0	0	0
心停止 Cardiac arrest	0	0	0	0
狭心症 Angina pectoris	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
頻脈 Tachycardia	0	0	0	0
大動脈弁狭窄 Aortic valve stenosis	0	0	0	0
徐脈 Bradycardia	0	0	0	0
冠動脈疾患 Coronary artery disease	0	0	0	0
僧帽弁閉鎖不全症 Mitral valve incompetence	0	0	0	0
心筋梗塞 Myocardial infarction	0	0	0	0
不安定狭心症 Angina unstable	0	0	0	0
期外収縮 Extrasystoles	0	0	0	0
房室ブロック Atrioventricular block	0	0	0	0
第一度房室ブロック Atrioventricular block first degree	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
慢性心不全 Cardiac failure chronic	0	0	0	0
心臓弁膜疾患 Cardiac valve disease	0	0	0	0
心筋症 Cardiomyopathy	0	0	0	0
拡張機能障害 Diastolic dysfunction	0	0	0	0
左室機能不全 Left ventricular dysfunction	0	0	0	0
左室不全 Left ventricular failure	0	0	0	0
心筋虚血 Myocardial ischaemia	0	0	0	0
洞性徐脈 Sinus bradycardia	0	0	0	0
洞性頻脈 Sinus tachycardia	0	0	0	0
上室性期外収縮 Supraventricular extrasystoles	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
完全房室ブロック Atrioventricular block complete	0	0	0	0
心拡大 Cardiomegaly	0	0	0	0
心嚢液貯留 Pericardial effusion	0	0	0	0
上室性頻脈 Supraventricular tachycardia	0	0	0	0
三尖弁閉鎖不全症 Tricuspid valve incompetence	0	0	0	0
精神障害 Psychiatric disorders	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
不眠症 Insomnia	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
うつ病 Depression	0	0	0	0
不安 Anxiety	0	0	0	0
錯乱状態 Confusional state	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
リビドー減退 Libido decreased	0	0	0	0
失見当識 Disorientation	0	0	0	0
幻覚 Hallucination	0	0	0	0
精神状態変化 Mental status changes	0	0	0	0
神経過敏 Nervousness	0	0	0	0
感情障害 Affective disorder	0	0	0	0
譫妄 Delirium	0	0	0	0
妄想 Delusion	0	0	0	0
抑うつ気分 Depressed mood	0	0	0	0
睡眠障害 Sleep disorder	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
身体疾患による睡眠障害、不眠症型 Sleep disorder due to general medical condition, insomnia type	0	0	0	0
自殺念慮 Suicidal ideation	0	0	0	0
激越 Agitation	0	0	0	0
耳および迷路障害 Ear and labyrinth disorders	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
回転性めまい Vertigo	0	1 (11.1%)	1 (6.7%)	1 (6.7%)
耳鳴 Tinnitus	0	0	0	0
耳痛 Ear pain	0	0	0	0
聴力低下 Hypoacusis	0	0	0	0
難聴 Deafness	0	0	0	0
片耳難聴 Deafness unilateral	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
耳出血 Ear haemorrhage	0	0	0	0
乗物酔い Motion sickness	0	0	0	0
耳異常感覚 Paraesthesia ear	0	0	0	0
突発性難聴 Sudden hearing loss	0	0	0	0
鼓膜穿孔 Tympanic membrane perforation	0	0	0	0
耳不快感 Ear discomfort	0	0	0	0
肝胆道系障害 Hepatobiliary disorders	2 (33.3%)	1 (11.1%)	3 (20.0%)	4 (26.7%)
胆石症 Cholelithiasis	0	0	0	0
急性胆嚢炎 Cholecystitis acute	0	0	0	0
肝障害 Liver disorder	1 (16.7%)	1 (11.1%)	2 (13.3%)	2 (13.3%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
MedDRA Version 22.0/J Version 22.0
Population: Safety Analysis Set
GS_US_352_0101_vsall_table_ae_OL.sas 2.003.122.740

表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
黄疸眼 Ocular icterus	0	0	0	0
門脈圧亢進症 Portal hypertension	0	0	0	0
胆汁うっ滞 Cholestasis	0	0	0	0
肝硬変 Hepatic cirrhosis	0	0	0	0
肝不全 Hepatic failure	0	0	0	0
肝機能異常 Hepatic function abnormal	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
脂肪肝 Hepatic steatosis	0	0	0	0
肝腫大 Hepatomegaly	0	0	0	0
門脈血栓症 Portal vein thrombosis	0	0	0	0
過形成性胆嚢症 Hyperplastic cholecystopathy	0	0	0	1 (6.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
生殖系および乳房障害 Reproductive system and breast disorders	1 (16.7%)	0	1 (6.7%)	1 (6.7%)
良性前立腺肥大症 Benign prostatic hyperplasia	0	0	0	0
腟出血 Vaginal haemorrhage	0	0	0	0
乳房過形成 Breast hyperplasia	0	0	0	0
精巣上体嚢胞 Epididymal cyst	0	0	0	0
勃起不全 Erectile dysfunction	0	0	0	0
閉経後出血 Postmenopausal haemorrhage	0	0	0	0
精巣腫脹 Testicular swelling	0	0	0	0
子宮頚部びらん Uterine cervical erosion	0	0	0	0
子宮出血 Uterine haemorrhage	1 (16.7%)	0	1 (6.7%)	1 (6.7%)

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
腟分泌物 Vaginal discharge	0	0	0	0
腟脱 Vaginal prolapse	0	0	0	0
会陰痛 Perineal pain	0	0	0	0
外陰腟の炎症 Vulvovaginal inflammation	0	0	0	0
外陰腟痛 Vulvovaginal pain	0	0	0	0
内分泌障害 Endocrine disorders	0	0	0	0
甲状腺腫瘤 Thyroid mass	0	0	0	0
甲状腺機能低下症 Hypothyroidism	0	0	0	0
甲状腺腫 Goitre	0	0	0	0
甲状腺炎 Thyroiditis	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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表 SIMPLIFY-1-4 日本人及び全体集団における有害事象（SIMPLIFY-1試験：Open-Label Phase (Week 24 Onward) and Overall Exposed to MMB Period）

	有害事象（日本人）			
	OL Phase (Week 24 Onward)			Overall Exposed to MMB
System Organ Class Preferred Term	Continuing (MMB->MMB) (N=6)	Switch (RUX->MMB) (N=9)	Total (N=15)	Total (N=15)
低アルドステロン症 Hypoaldosteronism	0	0	0	0
免疫系障害 Immune system disorders	0	0	0	0
薬物過敏症 Drug hypersensitivity	0	0	0	0
過敏症 Hypersensitivity	0	0	0	0
季節性アレルギー Seasonal allergy	0	0	0	0
外科および内科処置 Surgical and medical procedures	0	0	0	0
抜歯 Tooth extraction	0	0	0	0
先天性、家族性および遺伝性障害 Congenital, familial and genetic disorders	0	0	0	0
陰嚢水瘤 Hydrocele	0	0	0	0

Data Source: GS-US-352-0101 CSR Table 15.11.2.2.1.2, 5.3.5.1 Japanese Table 1.3081
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