M16-852 試験［評価資料］

治験の標題： A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Upadacitinib in Subjects with Giant Cell Arteritis: SELECT-GCA	
施設数 / 実施国名： 100 施設（23 ヵ国：オーストリア，オーストラリア，ベルギー，カナダ，チェコ，デンマーク，フランス，ドイツ，ギリシャ，ハンガリー，イスラエル，イタリア，日本，オランダ，ニュージーランド，ノルウェー，ポルトガル，ロシア連邦，スペイン，スウェーデン，スイス，イギリス，米国）	
治験調整医師： Dr. Daniel Blockmans	
公表文献（参考資料）： なし	
治験期間： 最初の被験者の初回来院日：2019 年 2 月 6 日 最後の被験者の最終来院日（投与 52 週時）：2024 年 2 月 6 日（データカットオフ日）	開発のフェーズ： 第 III 相
治験の種類： 第 III 相，国際共同，多施設共同，ランダム化，二重盲検，プラセボ対照試験	
目的： <u>第 1 ピリオド</u> 巨細胞性動脈炎（以下「GCA」）を有する被験者を対象に，投与 52 週時に寛解維持を達成した被験者の割合を指標として，ウパダシチニブ 7.5 mg 1 日 1 回（以下「QD」）及び 15 mg QD と 26 週間の副腎皮質ステロイド（以下「CS」）漸減併用投与の有効性を，プラセボと 52 週間の CS 漸減併用投与と比較評価する。また，ウパダシチニブの安全性及び忍容性を評価する。 <u>第 2 ピリオド</u> 第 1 ピリオドで寛解維持を達成した被験者を対象に，寛解維持を指標として，ウパダシチニブの継続投与と投与中止の安全性及び有効性を評価する。	
被験者数（計画時と解析時）： 計画時：420 例，解析時（データカットオフ時点［2024 年 2 月 6 日］）：428 例	
診断と主要な組入れ基準： スクリーニング来院時に，下記の基準を満たす 50 歳以上の成人男女を本治験に組み入れた。 ● 下記の基準に従い，GCA と診断された患者： ・赤血球沈降速度（以下「ESR」）が 50 mm/hr 以上又は高感度 C 反応性たん白（以下「hsCRP」） / C-反応性たん白（以下「CRP」）が 1.0 mg/dL 以上の既往歴が確認されている。 ・以下のいずれかひとつ以上の条件を満たす。 – GCA の明確な頭蓋症状（新たに発症した限局性の頭痛，頭皮圧痛，側頭動脈の圧痛又は拍動低下，虚血性視力障害，他に説明のつかない咀嚼時の口や顎の痛み）， 又は – リウマチ性多発筋痛症（以下「PMR」）の明確な症状（肩甲帯及び / 又は腰帯部の朝のこわばり及び / 又は痛み） ・以下のいずれかひとつ以上の条件を満たす：側頭動脈生検により GCA の特徴的所見が認められる，又は血管造影若しくは断層撮影（核磁気共鳴画像法，コンピュータ断層撮影又は陽電子放出断層撮影な	

ど），若しくは側頭動脈の超音波検査により大型血管炎の所見が認められる（血管造影又は断層撮影は大型血管炎の評価経験を有する適格な放射線科医が評価を行う。超音波は大型血管炎の評価経験を有する適格な医師が評価を行う）。 ● ベースライン前 8 週間以内に活動性を示した新規発症又は再発性の GCA 患者。活動性とは，以下のいずれかひとつ以上に該当する場合とした：GCA の明確な頭蓋症状，PMR の明確な症状，又は治験責任医師により GCA 若しくは PMR の再燃に合致すると判断されるその他の特徴的所見のいずれかをひとつ以上を有し，かつ ESR が 30 mm/hr 以上又は hsCRP / CRP が 1 mg/dL 以上であること。 ● 被験者はベースライン前のいずれかの時点で 40 mg 以上の prednisone（又は同等の CS）による治療を受け，ベースライン時に prednisone（又はプレドニゾロン）20 mg QD 以上の投与を受けていること。 ● 臨床的に安定しており，治験実施計画書に規定された CS 漸減併用投与を安全に開始することができると治験責任医師により判断された GCA 患者。
治験方法： 本試験は，GCA を有する被験者を対象としてウパダシチニブの有効性及び安全性を評価する第 III 相，国際共同，多施設共同，ランダム化，二重盲検，プラセボ対照試験であり，現在実施中である。試験期間は，最大 35 日間のスクリーニング期，52 週間のランダム化，二重盲検，並行群投与期間（第 1 ピリオド），被験者が再ランダム化された又は当初割り付けられた治験薬の投与を継続する 52 週間の盲検継続投与期間（第 2 ピリオド），及び 30 日間の追跡期間で構成された。 第 1 ピリオド（52 週間）：適格基準に該当した被験者を以下の 3 つの投与群のいずれかひとつに 2：1：1 の割合でランダム化した。 ● ウパダシチニブ 15 mg QD + 26 週間 CS 漸減併用投与（以下「ウパダシチニブ 15 mg QD 群」） ● ウパダシチニブ 7.5 mg QD + 26 週間 CS 漸減併用投与（以下「ウパダシチニブ 7.5 mg QD 群」） ● プラセボ QD + 52 週間 CS 漸減併用投与（以下「プラセボ群」） すべての被験者はベースライン時に CS（prednisone 又はプレドニゾロン）20，30，40，50 又は 60 mg QD の投与を受けた。初回用量は，治験責任医師が疾患重症度や併存症に基づいて判断し，あらかじめ規定されたスケジュールに従ってウパダシチニブ群の被験者では 26 週間，プラセボ群の被験者では 52 週間かけて漸減した。prednisone 又はプレドニゾロンの投与は，用量が 20 mg/日に漸減されるまで非盲検下で行った。その後，プラセボ群の被験者では，投与 52 週時までの残りの期間で，prednisone 又はプレドニゾロンを盲検下で漸減投与した。ウパダシチニブ群の被験者では，投与 26 週時までの残りの期間で，prednisone 又はプレドニゾロンを盲検下で漸減投与し，その後，52 週時まで prednisone 又はプレドニゾロンのプラセボを盲検下で投与した。 第 2 ピリオド（52 週間）：第 1 ピリオドでウパダシチニブのいずれかの用量に割り付けられ，投与 52 週時の来院（第 1 ピリオド終了時）前に 24 週間以上の寛解維持を達成した被験者は，第 2 ピリオドでウパダシチニブの継続投与又はプラセボへの切替えに 2：1 の割合で再ランダム化された。第 1 ピリオドでプラセボに割り付けられ，投与 52 週時来院（第 1 ピリオド終了時）前に 24 週間以上の寛解維持を達成した被験者は，第 2 ピリオドで引き続きプラセボ投与を受けた。寛解は，GCA の徴候及び症状が認められず，かつ治験実施計画書に規定された CS 漸減投与を遵守している又は CS の併用を必要としない状態と定義した。投与 52 週時に GCA の徴候及び症状が認められず，かつ投与 52 週時に CS の併用を必要としない状態にあるが，投与 52 週時来院前に 24 週間以上の寛解基準を達成しなかった被験者は，当初ランダム化された治験薬の投与を第 2 ピリオドで継続することとした。それ以外のすべての被験者は，第 1 ピリオド終了時に治験薬の投与及び試験を中止した。 本中間報告では，ランダム化され，第 1 ピリオドで投与 52 週時の来院を完了又は投与 52 週時来院前に試験を中止した被験者を含む，治験薬を投与されたすべての被験者を対象にした有効性の結果，並びにデータカットオフ時点（2024 年 2 月 6 日）までの安全性の結果を示す。また，独立行政法人医薬品医療機器総合機構（以下「PMDA」）と合意した graphical multiple testing procedure を用いて得られた主要評価項目及び多重性を制御した副次評価項目の結果は，治験総括報告書の本文とは別に Appendix 16.1__9.4 に要約した（本結果は，「2.7.6 個々の試験のまとめ」には示さず，2.7.3 項に示す）。

治験薬，用量，投与方法及びバッチ番号：

治験薬	用量	投与方法	バルクロット番号
ウパダシチニブ	15 mg フィルムコート錠	経口	[redacted]
ウパダシチニブ	7.5 mg フィルムコート錠	経口	[redacted]
プレドニゾロン	1 mg カプセル	経口	[redacted]
プレドニゾロン	2 mg カプセル	経口	[redacted]
プレドニゾロン	5 mg カプセル	経口	[redacted]
プレドニゾロン	10 mg カプセル	経口	[redacted]
プレドニゾロン	1 mg 錠剤	経口	[redacted]
プレドニゾロン	5 mg 錠剤	経口	[redacted]
プレドニゾロン	10 mg 錠剤	経口	[redacted]
プレドニゾロン	20 mg 錠剤	経口	[redacted]
prednisone	1 mg 錠剤	経口	[redacted]
prednisone	5 mg 錠剤	経口	[redacted]
prednisone	10 mg 錠剤	経口	[redacted]
prednisone	20 mg 錠剤	経口	[redacted]
ウパダシチニブに対応するプラセボ	フィルムコート / 徐放性コート錠	経口	[redacted][1]
CS に対応するプラセボ	カプセル	経口	[redacted]

治療期間：52 週間の二重盲検プラセボ対照期間（第 1 ピリオド）及び 52 週間の盲検継続投与期間（第 2 ピリオド）

評価基準：

本中間報告では，ランダム化され，第 1 ピリオドで投与 52 週時の来院を完了又は投与 52 週時来院前に試験を中止した被験者を含む，治験薬を投与されたすべての被験者を対象にした有効性の結果，並びにデータカットオフ時点（2024 年 2 月 6 日）までの安全性の結果を示す。したがって，第 1 ピリオドに指定された評価項目を以下に示す。

有効性：

主要評価項目：
投与 52 週時に寛解維持を達成した被験者の割合
寛解維持は，下記の条件をいずれも満たしていることと定義した。

- 投与 12 週時から投与 52 週時までの期間に GCA の徴候及び症状が認められない
- 治験実施計画書に規定された CS 漸減投与を遵守している

多重性を制御した重要な副次評価項目（ウパダシチニブ対プラセボ）：

- 投与 12 週時から投与 52 週時までの期間に完全寛解維持を達成した被験者の割合
- 投与 52 週時までの CS の累積曝露量
- 投与 52 週時までの最初の再燃までの期間
- 投与 52 週時までの期間に 1 回以上の再燃をきたした被験者の割合
- 投与 52 週時に完全寛解を達成した被験者の割合
- 投与 24 週時に完全寛解を達成した被験者の割合
- 投与 52 週時の 36-item short-form health survey（以下「SF-36」）身体的側面のサマリースコア（以下「PCS」）のベースラインからの変化量
- グループとして扱う 4 つの評価項目：
  - 投与 52 週時までの被験者あたりの再燃回数
  - 投与 52 週時の functional assessment of chronic illness therapy - fatigue（以下「FACIT-Fatigue」）のベースラインからの変化量
  - 投与 52 週時の薬物治療の満足度に関する質問票（以下「TSQM」）の患者の全般的満足度下位尺度の評価
  - 投与 52 週時までの CS に関連した有害事象の発現率

第 1 ピリオドの追加評価項目：

- 投与 12 週時の完全寛解を達成した被験者の割合
- 各来院での SF-36 のベースラインからの変化量
- 各来院での FACIT-Fatigue のベースラインからの変化量
- 各来院での TSQM の患者の全般的満足度下位尺度の評価
- 各来院での European Quality of Life-5 Dimensions 5 Levels のベースラインからの変化量
- 各来院での Patient Global Impression of Change の評価
- 各来院での patient global assessment のベースラインからの変化量
- 各来院での GCA 関連の医療資源の利用状況が確認された被験者の割合
- 投与 52 週時までの各来院時に寛解を達成した被験者の割合

薬物動態：
第 1 ピリオド中，ウパダシチニブの血漿中薬物動態解析用の血液検体を治験実施スケジュールに示された来院時に採取した。

安全性：
安全性は，全試験期間中の有害事象のモニタリング，バイタルサイン，身体的所見，心電図及び臨床検査により評価した。

統計手法：
有効性：
第 1 ピリオドの最大の解析対象集団（以下「FAS1」）は，ランダム化された全被験者のうち，第 1 ピリオドで治験薬を 1 回以上投与した被験者とした。FAS1 を対象として，主要評価項目及び副次評価項目に関する主要な

有効性解析を実施した。なお，副次評価項目のうち，投与 52 週時までの CS に関連した有害事象の発現率は，第 1 ピリオドの安全性解析対象集団（以下「SS1」）を用いて解析した。選択された副次評価項目の感度分析は FAS1 を対象として実施した。第 1 ピリオドの追加評価項目の有効性解析は FAS1 を対象として実施した。
治験実施計画書に適合した解析対象集団（以下「PPS」）は，FAS1 の一部で本試験中に主要評価項目に影響を及ぼすと考えられる重大な治験実施計画書違反が認められなかった被験者を含めた。PPS は，主要評価項目の補足的な解析に用いた。

薬物動態：
個々の被験者のウパダシチニブ血漿中濃度を集計し，要約した。

安全性：
SS1 は，第 1 ピリオドで治験薬を 1 回以上投与した全被験者とした。長期安全性解析対象集団（以下「SS_LT」）は，第 1 ピリオドで治験薬を 1 回以上投与し，第 2 ピリオドでも同じ治験薬を 1 回以上投与した全被験者とした。特に指定しない限り，第 1 ピリオドの安全性データを SS1 で要約し，データカットオフ時点（2024 年 2 月 6 日）までの安全性データを第 1 ピリオド及び第 2 ピリオドを通して SS_LT で要約した。
安全性は，有害事象，身体的所見，臨床検査値及びバイタルサインの結果により評価した。投与群ごとの有害事象の発現被験者数及び発現割合は，ICH 国際医薬用語集の器官別大分類及び基本語別に集計した。100 人年あたりの曝露期間で調整した有害事象の発現件数（以下「EAER」）を SS1 及び SS_LT で集計した。また，治験責任医師の評価による重篤な有害事象及び有害事象を重症度別及び治験薬（又はプラセボ）若しくは prednisone / プレドニゾロン（又はプラセボ）との因果関係別に要約した。重篤な有害事象，投与中止に至った有害事象及び死亡に至った有害事象について一覧表を作成した。各来院時のバイタルサイン及び臨床検査値のベースラインからの変化量を要約した。ベースラインから規定された時点までの臨床検査値の変化のシフトテーブルを作成した。

有効性の結果

本第 III 相試験では，GCA を有する被験者に対し，ウパダシチニブ 15 mg QD + 26 週間 CS 漸減併用投与のレジメンが，プラセボ QD + 52 週間 CS 漸減併用投与のレジメンと比較して優れていることが示された。主要評価項目である投与 52 週時に寛解維持を達成した被験者の割合は，プラセボ群（29.0%）と比較してウパダシチニブ 15 mg QD 群（46.4%）の方が統計学的に有意に高かった（$P = 0.0019$）。

主要評価項目に関する部分集団解析の結果では，一連の人口統計学的特性及びベースラインの疾患特性（年齢，性別，人種，インターロイキン［以下「IL」］-6 阻害薬の前治療歴，ベースライン時の CS 用量，新規発症 / 再発性 GCA，過去の GCA の頭蓋症状を伴わない PMR の明確な症状，及び過去の PMR の明確な症状［追加解析］など）を通して，ウパダシチニブ 15 mg の有効性が一貫して認められ，プラセボ群との投与群間差よりウパダシチニブ 15 mg QD 群の有効性が良好であることが示された。

また，副次評価項目のうち，投与 12 週時から投与 52 週時までの期間に完全寛解維持を達成した被験者の割合，投与 52 週時までの CS の累積曝露量，投与 52 週時までの最初の再燃までの期間，投与 52 週時までの期間に 1 回以上の再燃をきたした被験者の割合，投与 52 週時に完全寛解を達成した被験者の割合，投与 24 週時に完全寛解を達成した被験者の割合，投与 52 週時の SF-36 PCS のベースラインからの変化量，投与 52 週時までの被験者あたりの再燃回数，及び

投与 52 週時の FACIT-Fatigue のベースラインからの変化量について，ウパダシチニブ 15 mg QD 群の治療効果はプラセボ群と比較して統計学的に有意に優れていることが示された。

なお，投与 52 週時の TSQM の患者の全般的満足度下位尺度の評価及び投与 52 週時までの CS に関連した有害事象の発現率（治験責任医師による判断）について，ウパダシチニブ 15 mg QD 群ではプラセボ群を上回る統計学的に有意な治療効果は示されなかった。

投与 52 週時までの CS に関連した有害事象の発現率（治験責任医師による判断）を除くすべての副次評価項目について，プラセボ群と比較してウパダシチニブ 7.5 mg QD 群で数値的に優れた有効性が認められたが，いずれも統計学的に有意ではなかった。

PMDA と合意した解析方法を用いた有効性の結果を 2.7.3.2.3 項に示す。

<u>薬物動態の結果</u>

ウパダシチニブ 7.5 mg QD を投与したときの投与後 24 時間までのウパダシチニブ血漿中濃度の平均値は，3.11–16.4 ng/mL の範囲であった。ウパダシチニブ 15 mg QD を投与したときの投与後 24 時間までのウパダシチニブ血漿中濃度の平均値は，5.66–41.4 ng/mL の範囲であった。本試験で得られたウパダシチニブ 7.5 mg QD 及び 15 mg QD 投与時の血漿中濃度は，以前に他の適応症（関節リウマチなど）で特徴づけられたウパダシチニブの薬物動態と一致していた。

<u>安全性の結果</u>

ウパダシチニブ 15 mg 及び 7.5 mg の QD 投与は，GCA を有する被験者でおおむね安全で，忍容性は良好であった。ウパダシチニブの既知の安全性プロファイルと比較して，新たな安全性リスクは特定されなかった。

投与 52 週時までの第 1 ピリオド（SS1）：

- 概して，有害事象の EAER は各投与群でおおむね同様であった。
- 重篤な有害事象及び治験薬の投与中止に至った有害事象の EAER は，プラセボ群と比較してウパダシチニブ 15 mg QD 群及びウパダシチニブ 7.5 mg QD 群の方が低かった。
- 有害事象共通用語規準（以下「CTCAE」）Grade 3 以上（高度）の有害事象の EAER は，プラセボ群とウパダシチニブ 15 mg QD 群で同様であり，ウパダシチニブ 7.5 mg QD 群の方が低かった。
- ウパダシチニブ（又はプラセボ）と関連ありの有害事象，prednisone / プレドニゾロン（又はプラセボ）と関連ありの有害事象，及び新型コロナウィルス感染症（以下「COVID-19」）に関連する有害事象は，ウパダシチニブ 7.5 mg QD 群及びプラセボ群と比較してウパダシチニブ 15 mg QD 群で多く発現した。
- 発現割合が高かった有害事象（いずれかの投与群で 10%以上）は，巨細胞性動脈炎，頭痛，高血圧，COVID-19，関節痛，尿路感染，背部痛，上咽頭炎及び下痢であった。なお，巨細胞性動脈炎の発現割合は，ウパダシチニブ 15 mg QD 群（23.0%）及び 7.5 mg QD 群（26.2%）と比較してプラセボ群（31.3%）の方が高かった。

- 報告された有害事象の大部分は重症度が軽度（Grade 1）又は中等度（Grade 2）であった。
- 4 例の死亡が報告され（ウパダシチニブ 15 mg QD 群 2 例，プラセボ群 2 例），ウパダシチニブ 15 mg QD 群の 2 例は，それぞれ COVID-19 に関連する死亡及び原因不明の死亡であった。加えて 1 例の治験薬の最終投与後 30 日より後に発現した死亡が認められた（ウパダシチニブ 15 mg QD 群）。
- 重篤な有害事象は，肺炎（プラセボ群 5 例，ウパダシチニブ 7.5 mg QD 群 3 例），肺塞栓症（ウパダシチニブ 15 mg QD 群 5 例），深部静脈血栓症（ウパダシチニブ 15 mg QD 群 3 例），及び巨細胞性動脈炎（ウパダシチニブ 15 mg QD 群 3 例）を除き，いずれの投与群も 2 例以下であった。
- 最も発現割合が高かった治験薬の投与中止に至った有害事象は，巨細胞性動脈炎（ウパダシチニブ 15 mg QD 群 2.4%，ウパダシチニブ 7.5 mg QD 群 5.6%，プラセボ群 6.3%）であった。
- 特に注目すべき有害事象のうち，活動性結核，リンパ腫及び消化管穿孔は，本試験のデータカットオフ日まで認められなかった。
- 重篤な感染症の EAER は，ウパダシチニブ 15 mg QD 群とウパダシチニブ 7.5 mg QD 群で同様（各 7.9 件/100 人年）であり，プラセボ群（12.7 件/100 人年）と比較して低かった。
- 日和見感染（結核及び帯状疱疹を除く）の EAER は，ウパダシチニブ 15 mg QD 群で 2.2 件/100 人年，プラセボ群で 1.1 件/100 人年であり，ウパダシチニブ 7.5 mg QD 群では日和見感染（結核及び帯状疱疹を除く）は認められなかった。
- 帯状疱疹の EAER は，ウパダシチニブ 7.5 mg QD 群（4.5 件/100 人年）及びプラセボ群（4.2 件/100 人年）と比較してウパダシチニブ 15 mg QD 群（7.3 件/100 人年）の方が高かった。ウパダシチニブ 15 mg QD 群で 2 件の眼帯状疱疹が報告され，いずれも重篤であり，重症度は高度であった。2 件中 1 件は治験薬の投与中止に至った。
- 非黒色腫皮膚癌（以下「NMSC」）の EAER は，ウパダシチニブ 15 mg QD 群（2.8 件/100 人年）とプラセボ群（2.1 件/100 人年）で同様であり，ウパダシチニブ 7.5 mg QD 群（1.1 件/100 人年）の方が低かった。NMSC を除く悪性腫瘍の EAER は，ウパダシチニブ 15 mg QD 群（2.2 件/100 人年）とプラセボ群（2.1 件/100 人年）で同様であり，ウパダシチニブ 7.5 mg QD 群では NMSC を除く悪性腫瘍は報告されなかった。
- 主要心血管事象（以下「MACE」）は，いずれのウパダシチニブ投与群でも認められず，プラセボ群で 2 例に 2 件認められた。2 件の MACE（2.1 件/100 人年）の内訳は，脳卒中及び心筋虚血であった。
- 静脈血栓塞栓症の有害事象の EAER は，ウパダシチニブ 7.5 mg QD 群（4.5 件/100 人年）及びプラセボ群（4.2 件/100 人年）と比較してウパダシチニブ 15 mg QD 群（5.6 件/100 人年）の方が高かった。
- CTCAE Grade 3 又は Grade 4 に該当する臨床検査値及び臨床的に重要と判断した臨床検査値 / バイタルサイン値は概してまれであった。

全体として，SS_LT を対象とした長期解析で観察された安全性の結果は，第 1 ピリオドでの安全性の結果とおおむね一致していた。

結論

本第 III 相試験では，GCA を有する被験者に対し，ウパダシチニブ 15 mg QD + 26 週間 CS 漸減併用投与のレジメンが，プラセボ QD + 52 週間 CS 漸減併用投与のレジメンと比較して優れていることが示された。主要評価項目である投与 52 週時に寛解維持を達成した被験者の割合は，プラセボ群（29.0%）と比較してウパダシチニブ 15 mg QD 群（46.4%）の方が統計学的に有意に高かった（$P = 0.0019$）。

主要評価項目に関する部分集団解析の結果では，一連の人口統計学的特性及びベースラインの疾患特性（年齢，性別，人種，IL-6 阻害薬の前治療歴，ベースライン時の CS 用量，新規発症 / 再発性 GCA，過去の GCA の頭蓋症状を伴わない PMR の明確な症状，及び過去の PMR の明確な症状［追加解析］など）を通して，ウパダシチニブ 15 mg の有効性が一貫して認められ，プラセボ群との投与群間差よりウパダシチニブ 15 mg QD 群の有効性が良好であることが示された。

総じて，副次評価項目のうち，投与 12 週時から投与 52 週時までの期間に完全寛解維持を達成した被験者の割合，投与 52 週時までの CS の累積曝露量，投与 52 週時までの最初の再燃までの期間，投与 52 週時までの期間に 1 回以上の再燃をきたした被験者の割合，投与 52 週時に完全寛解を達成した被験者の割合，投与 24 週時に完全寛解を達成した被験者の割合，投与 52 週時の SF-36 PCS のベースラインからの変化量，投与 52 週時までの被験者あたりの再燃回数，及び投与 52 週時の FACIT-Fatigue のベースラインからの変化量について，ウパダシチニブ 15 mg QD 群の治療効果はプラセボ群と比較して統計学的に有意に優れていることが示された。

投与 52 週時までの CS に関連した有害事象の発現率（治験責任医師による判断）を除くすべての副次評価項目について，プラセボ群と比較してウパダシチニブ 7.5 mg QD 群で数値的に優れた有効性が認められたが，いずれも統計学的に有意ではなかった。

安全性は，52 週間の第 1 ピリオドの安全性データ及びデータカットオフ日までの長期の追加安全性データに基づいて評価した。いずれのウパダシチニブ群でもおおむね安全で忍容性が良好であり，GCA 又はその他の適応症におけるウパダシチニブの全体的に良好なベネフィット・リスクの評価に影響を及ぼすような新たな重大な安全性上の懸念は認められなかった。

本試験で発現した有害事象を以下のとおり示す。

項目	全体集団	
	SS1（n%）	SS_LT（EAER）
すべての有害事象	表 1（Table 14.3__1.4.1.1）	表 2（Table 14.3__1.4.3.1）
ウパダシチニブ（又はプラセボ）との因果関係別の有害事象	表 3（Table 14.3__1.6.1）	表 4（Table 14.3__1.6.2）
重症度別の有害事象	表 5（Table 14.3__1.5.1）	表 6（Table 14.3__1.5.2）
死亡に至った有害事象	表 7（Table 14.3__2.3.1）	-
重篤な有害事象	表 8（Table 14.3__2.1.1）	表 9（Table 14.3__2.1.2）
中止に至った有害事象	表 10（Table 14.3__2.2.1）	表 11（Table 14.3__2.2.2）

項目	日本人部分集団	
	SS1（n%）	SS_LT（EAER）
すべての有害事象	表 1 (J)（Table 14.3__1.4.1.1_J）	表 2 (J)（Table 14.3__1.4.3.1_J）
重篤な有害事象	表 3 (J)（Table 14.3__2.1.1_J）	-
中止に至った有害事象	表 4 (J)（Table 14.3__2.2.1_J）	-

表1

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ABT-494 (GIANT CELL ARTERITIS)
STUDY M16-852 (CUTOFF 06FEB2024)
R&D/23/2455 - CLINICAL/STATISTICAL

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
Any adverse event	106 (94.6)	102 (95.3)	202 (96.7)	304 (96.2)
血液およびリンパ系障害	6 (5.4)	4 (3.7)	19 (9.1)	23 (7.3)
貧血	2 (1.8)	3 (2.8)	9 (4.3)	12 (3.8)
好酸球増加症	0	0	1 (0.5)	1 (0.3)
内出血発生の増加傾向	1 (0.9)	1 (0.9)	4 (1.9)	5 (1.6)
鉄欠乏性貧血	0	0	2 (1.0)	2 (0.6)
白血球増加症	0	0	1 (0.5)	1 (0.3)
白血球減少症	1 (0.9)	0	0	0
リンパ球増加症	0	0	1 (0.5)	1 (0.3)
リンパ球減少症	0	0	1 (0.5)	1 (0.3)
大赤血球症	1 (0.9)	0	1 (0.5)	1 (0.3)
好中球減少症	1 (0.9)	0	0	0
好中球増加症	0	0	1 (0.5)	1 (0.3)
血小板増加症	0	0	2 (1.0)	2 (0.6)
心臓障害	15 (13.4)	10 (9.3)	23 (11.0)	33 (10.4)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

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TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
心臓障害 (cont.)				
狭心症	1 (0.9)	0	0	0
大動脈弁石灰化	0	0	1 (0.5)	1 (0.3)
大動脈弁疾患	1 (0.9)	0	0	0
大動脈弁閉鎖不全症	1 (0.9)	0	0	0
大動脈弁狭窄	0	1 (0.9)	0	1 (0.3)
冠動脈硬化症	2 (1.8)	0	1 (0.5)	1 (0.3)
心房細動	2 (1.8)	0	4 (1.9)	4 (1.3)
心房頻脈	0	0	1 (0.5)	1 (0.3)
第一度房室ブロック	1 (0.9)	0	1 (0.5)	1 (0.3)
右脚ブロック	1 (0.9)	0	0	0
心不全	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
うっ血性心不全	0	1 (0.9)	2 (1.0)	3 (0.9)
心臓弁膜疾患	0	1 (0.9)	0	1 (0.3)
肺性心	0	0	1 (0.5)	1 (0.3)
冠動脈疾患	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

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TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
心臓障害 (cont.)				
冠動脈入口部狭窄	0	0	1 (0.5)	1 (0.3)
拡張機能障害	0	1 (0.9)	0	1 (0.3)
線維性心内膜炎	1 (0.9)	0	0	0
期外収縮	0	1 (0.9)	0	1 (0.3)
高血圧性心筋症	0	2 (1.9)	0	2 (0.6)
高血圧性心疾患	0	0	1 (0.5)	1 (0.3)
虚血性心筋症	0	0	1 (0.5)	1 (0.3)
左室肥大	0	0	1 (0.5)	1 (0.3)
僧帽弁閉鎖不全症	2 (1.8)	0	1 (0.5)	1 (0.3)
心筋虚血	1 (0.9)	0	0	0
動悸	2 (1.8)	2 (1.9)	4 (1.9)	6 (1.9)
右室不全	0	0	1 (0.5)	1 (0.3)
洞性不整脈	1 (0.9)	0	0	0
洞性徐脈	0	1 (0.9)	0	1 (0.3)
洞性頻脈	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

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TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
心臓障害 (cont.)				
頻脈	2 (1.8)	0	1 (0.5)	1 (0.3)
三尖弁閉鎖不全症	0	1 (0.9)	2 (1.0)	3 (0.9)
心室性期外収縮	1 (0.9)	0	0	0
先天性、家族性および遺伝性障害	2 (1.8)	1 (0.9)	0	1 (0.3)
心房中隔欠損症	1 (0.9)	0	0	0
播種状表在性光線性汗孔角化症	1 (0.9)	0	0	0
歯牙形成不全	0	1 (0.9)	0	1 (0.3)
耳および迷路障害	4 (3.6)	9 (8.4)	15 (7.2)	24 (7.6)
感音性難聴	0	1 (0.9)	0	1 (0.3)
耳不快感	0	0	1 (0.5)	1 (0.3)
耳痛	0	0	5 (2.4)	5 (1.6)
聴力低下	0	1 (0.9)	0	1 (0.3)
耳鳴	2 (1.8)	3 (2.8)	5 (2.4)	8 (2.5)
回転性めまい	2 (1.8)	4 (3.7)	7 (3.3)	11 (3.5)
内分泌障害	5 (4.5)	9 (8.4)	9 (4.3)	18 (5.7)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

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TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
内分泌障害 (cont.)				
副腎抑制	1 (0.9)	0	0	0
クッシング症候群	2 (1.8)	0	2 (1.0)	2 (0.6)
クッシング様症状	0	5 (4.7)	4 (1.9)	9 (2.8)
甲状腺腫	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
甲状腺機能亢進症	0	2 (1.9)	0	2 (0.6)
甲状腺腫瘤	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
眼障害	22 (19.6)	21 (19.6)	56 (26.8)	77 (24.4)
加齢黄斑変性	0	1 (0.9)	0	1 (0.3)
眼瞼炎	1 (0.9)	2 (1.9)	3 (1.4)	5 (1.6)
眼瞼痙攣	0	0	1 (0.5)	1 (0.3)
白内障	2 (1.8)	6 (5.6)	10 (4.8)	16 (5.1)
霰粒腫	0	0	2 (1.0)	2 (0.6)
結膜出血	1 (0.9)	1 (0.9)	5 (2.4)	6 (1.9)
アレルギー性結膜炎	1 (0.9)	0	0	0
角膜浮腫	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
眼障害 (cont.)				
複視	0	0	2 (1.0)	2 (0.6)
ドライアイ	3 (2.7)	2 (1.9)	8 (3.8)	10 (3.2)
眼出血	0	0	1 (0.5)	1 (0.3)
眼の炎症	0	0	2 (1.0)	2 (0.6)
眼刺激	1 (0.9)	0	1 (0.5)	1 (0.3)
眼痛	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
眼部腫脹	0	1 (0.9)	1 (0.5)	2 (0.6)
眼瞼下垂	0	0	1 (0.5)	1 (0.3)
眼の異物感	0	0	2 (1.0)	2 (0.6)
緑内障	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
遠視	0	0	1 (0.5)	1 (0.3)
流涙増加	2 (1.8)	0	0	0
黄斑変性	0	1 (0.9)	0	1 (0.3)
黄斑浮腫	0	0	1 (0.5)	1 (0.3)
散瞳	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
眼障害 (cont.)				
眼部不快感	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
眼充血	0	0	1 (0.5)	1 (0.3)
高眼圧症	0	1 (0.9)	2 (1.0)	3 (0.9)
開放隅角緑内障	0	1 (0.9)	0	1 (0.3)
視神経萎縮	0	0	1 (0.5)	1 (0.3)
視神経乳頭出血	0	0	1 (0.5)	1 (0.3)
眼窩浮腫	0	0	1 (0.5)	1 (0.3)
眼窩脂肪ヘルニア	1 (0.9)	0	0	0
眼窩周囲痛	0	0	1 (0.5)	1 (0.3)
羞明	0	0	1 (0.5)	1 (0.3)
光視症	0	0	2 (1.0)	2 (0.6)
後嚢部混濁	1 (0.9)	0	0	0
老視	0	0	1 (0.5)	1 (0.3)
網膜剥離	0	0	1 (0.5)	1 (0.3)
網膜出血	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
眼障害 (cont.)				
網膜裂孔	0	0	1 (0.5)	1 (0.3)
眼瞼腫脹	0	0	1 (0.5)	1 (0.3)
霧視	4 (3.6)	5 (4.7)	6 (2.9)	11 (3.5)
視力低下	1 (0.9)	0	1 (0.5)	1 (0.3)
視野欠損	0	0	2 (1.0)	2 (0.6)
視力障害	2 (1.8)	0	1 (0.5)	1 (0.3)
硝子体剥離	2 (1.8)	0	1 (0.5)	1 (0.3)
硝子体浮遊物	3 (2.7)	1 (0.9)	2 (1.0)	3 (0.9)
胃腸障害	37 (33.0)	31 (29.0)	93 (44.5)	124 (39.2)
腹部不快感	2 (1.8)	0	0	0
腹部膨満	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
腹痛	4 (3.6)	1 (0.9)	8 (3.8)	9 (2.8)
下腹部痛	2 (1.8)	2 (1.9)	3 (1.4)	5 (1.6)
上腹部痛	5 (4.5)	0	11 (5.3)	11 (3.5)
裂肛	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (cont.)				
アフタ性潰瘍	1 (0.9)	1 (0.9)	4 (1.9)	5 (1.6)
口唇炎	0	0	1 (0.5)	1 (0.3)
慢性胃炎	1 (0.9)	0	0	0
大腸炎	1 (0.9)	0	0	0
虚血性大腸炎	0	0	1 (0.5)	1 (0.3)
潰瘍性大腸炎	0	0	1 (0.5)	1 (0.3)
便秘	2 (1.8)	8 (7.5)	11 (5.3)	19 (6.0)
齲歯	1 (0.9)	1 (0.9)	0	1 (0.3)
下痢	12 (10.7)	5 (4.7)	18 (8.6)	23 (7.3)
腸憩室	0	1 (0.9)	1 (0.5)	2 (0.6)
口内乾燥	1 (0.9)	2 (1.9)	2 (1.0)	4 (1.3)
十二指腸炎	0	0	1 (0.5)	1 (0.3)
十二指腸胃逆流	0	0	1 (0.5)	1 (0.3)
消化不良	3 (2.7)	2 (1.9)	10 (4.8)	12 (3.8)
嚥下障害	0	2 (1.9)	1 (0.5)	3 (0.9)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (cont.)				
鼓腸	1 (0.9)	1 (0.9)	0	1 (0.3)
排便回数増加	1 (0.9)	1 (0.9)	0	1 (0.3)
胃炎	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
消化器痛	0	0	1 (0.5)	1 (0.3)
胃食道逆流性疾患	2 (1.8)	0	9 (4.3)	9 (2.8)
歯肉障害	0	1 (0.9)	0	1 (0.3)
歯肉痛	0	1 (0.9)	2 (1.0)	3 (0.9)
血便排泄	1 (0.9)	0	0	0
痔出血	0	0	1 (0.5)	1 (0.3)
痔核	0	0	3 (1.4)	3 (0.9)
歯の知覚過敏	0	0	1 (0.5)	1 (0.3)
単径ヘルニア	0	0	1 (0.5)	1 (0.3)
大腸ポリープ	3 (2.7)	0	2 (1.0)	2 (0.6)
口唇腫脹	0	1 (0.9)	0	1 (0.3)
腰ヘルニア	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (cont.)				
マロリー・ワイス症候群	0	1 (0.9)	0	1 (0.3)
口腔内潰瘍形成	0	0	3 (1.4)	3 (0.9)
悪心	4 (3.6)	6 (5.6)	11 (5.3)	17 (5.4)
非感染性歯肉炎	0	0	1 (0.5)	1 (0.3)
膵嚢胞	1 (0.9)	0	1 (0.5)	1 (0.3)
膵臓障害	0	0	1 (0.5)	1 (0.3)
膵炎	0	1 (0.9)	0	1 (0.3)
急性膵炎	2 (1.8)	0	0	0
慢性膵炎	0	0	1 (0.5)	1 (0.3)
歯状態不良	1 (0.9)	0	0	0
直腸出血	1 (0.9)	0	0	0
唾液腺痛	0	0	1 (0.5)	1 (0.3)
口内炎	0	1 (0.9)	0	1 (0.3)
舌不快感	0	0	1 (0.5)	1 (0.3)
舌潰瘍	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (cont.)				
歯の障害	0	0	1 (0.5)	1 (0.3)
歯痛	2 (1.8)	0	7 (3.3)	7 (2.2)
嘔吐	1 (0.9)	2 (1.9)	5 (2.4)	7 (2.2)
一般・全身障害および投与部位の状態	21 (18.8)	21 (19.6)	73 (34.9)	94 (29.7)
医薬品副作用	0	0	1 (0.5)	1 (0.3)
無力症	1 (0.9)	0	3 (1.4)	3 (0.9)
胸部不快感	0	0	2 (1.0)	2 (0.6)
胸痛	3 (2.7)	2 (1.9)	7 (3.3)	9 (2.8)
悪寒	0	1 (0.9)	1 (0.5)	2 (0.6)
死亡	0	0	1 (0.5)	1 (0.3)
不快感	0	1 (0.9)	0	1 (0.3)
疾患前駆期	1 (0.9)	0	0	0
顔面浮腫	0	0	1 (0.5)	1 (0.3)
脂肪組織増加	0	0	1 (0.5)	1 (0.3)
疲労	6 (5.4)	4 (3.7)	19 (9.1)	23 (7.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
一般・全身障害および投与部位の状態 (cont.)				
冷感	0	0	1 (0.5)	1 (0.3)
熱感	0	0	1 (0.5)	1 (0.3)
歩行障害	1 (0.9)	0	1 (0.5)	1 (0.3)
不明確な障害	1 (0.9)	0	1 (0.5)	1 (0.3)
インフルエンザ様疾患	2 (1.8)	0	2 (1.0)	2 (0.6)
注射部位疼痛	1 (0.9)	0	1 (0.5)	1 (0.3)
倦怠感	1 (0.9)	0	5 (2.4)	5 (1.6)
小結節	0	1 (0.9)	0	1 (0.3)
非心臓性胸痛	2 (1.8)	0	1 (0.5)	1 (0.3)
浮腫	0	0	2 (1.0)	2 (0.6)
末梢性浮腫	3 (2.7)	7 (6.5)	16 (7.7)	23 (7.3)
疼痛	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
末梢腫脹	3 (2.7)	0	5 (2.4)	5 (1.6)
体調不良	1 (0.9)	0	0	0
発熱	2 (1.8)	4 (3.7)	9 (4.3)	13 (4.1)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
一般・全身障害および投与部位の状態 (cont.)				
腫脹	1 (0.9)	0	0	0
顔面腫脹	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
治療非遵守	0	1 (0.9)	0	1 (0.3)
評価不能の事象	0	0	1 (0.5)	1 (0.3)
ワクチン接種部位疼痛	0	0	1 (0.5)	1 (0.3)
乾燥症	0	0	1 (0.5)	1 (0.3)
肝胆道系障害	6 (5.4)	1 (0.9)	6 (2.9)	7 (2.2)
胆管嚢胞	1 (0.9)	0	0	0
胆道ジスキネジア	0	0	1 (0.5)	1 (0.3)
硬化性胆管炎	1 (0.9)	0	0	0
慢性胆嚢炎	1 (0.9)	0	0	0
胆石症	1 (0.9)	0	0	0
薬物性肝障害	1 (0.9)	0	0	0
胆嚢ポリープ	1 (0.9)	0	0	0
肝嚢胞	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
肝胆道系障害 (cont.)				
肝細胞融解	1 (0.9)	0	1 (0.5)	1 (0.3)
肝機能異常	0	0	1 (0.5)	1 (0.3)
肝病変	1 (0.9)	0	1 (0.5)	1 (0.3)
脂肪肝	0	1 (0.9)	0	1 (0.3)
急性肝炎	1 (0.9)	0	0	0
肝腫大	0	0	1 (0.5)	1 (0.3)
免疫系障害	1 (0.9)	1 (0.9)	7 (3.3)	8 (2.5)
アナフィラキシー様反応	1 (0.9)	0	0	0
薬物過敏症	0	0	1 (0.5)	1 (0.3)
食物アレルギー	0	0	1 (0.5)	1 (0.3)
低γグロブリン血症	0	0	1 (0.5)	1 (0.3)
サルコイドーシス	0	0	1 (0.5)	1 (0.3)
季節性アレルギー	0	0	3 (1.4)	3 (0.9)
4型過敏症	0	1 (0.9)	0	1 (0.3)
感染症および寄生虫症	66 (58.9)	61 (57.0)	132 (63.2)	193 (61.1)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (cont.)				
急性副鼻腔炎	0	0	1 (0.5)	1 (0.3)
アデノウイルス結膜炎	0	0	1 (0.5)	1 (0.3)
無症候性細菌尿	0	0	1 (0.5)	1 (0.3)
気管支炎	1 (0.9)	0	8 (3.8)	8 (2.5)
感染性滑液包炎	0	1 (0.9)	1 (0.5)	2 (0.6)
COVID-19	12 (10.7)	12 (11.2)	28 (13.4)	40 (12.7)
COVID-19肺炎	0	0	2 (1.0)	2 (0.6)
カンジダ感染	1 (0.9)	1 (0.9)	0	1 (0.3)
蜂巣炎	0	0	1 (0.5)	1 (0.3)
結膜炎	4 (3.6)	1 (0.9)	4 (1.9)	5 (1.6)
膀胱炎	3 (2.7)	5 (4.7)	15 (7.2)	20 (6.3)
大腸菌性膀胱炎	0	0	1 (0.5)	1 (0.3)
皮膚糸状菌症	0	0	1 (0.5)	1 (0.3)
医療機器関連感染	0	0	1 (0.5)	1 (0.3)
憩室炎	0	0	1 (0.5)	1 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (cont.)				
耳感染	0	2 (1.9)	1 (0.5)	3 (0.9)
丹毒	0	1 (0.9)	1 (0.5)	2 (0.6)
遊走性紅斑	0	0	1 (0.5)	1 (0.3)
大腸菌性尿路感染	2 (1.8)	0	1 (0.5)	1 (0.3)
眼感染	0	0	1 (0.5)	1 (0.3)
熱性感染症	0	1 (0.9)	0	1 (0.3)
毛包炎	0	1 (0.9)	3 (1.4)	4 (1.3)
皮膚真菌感染	1 (0.9)	2 (1.9)	1 (0.5)	3 (0.9)
胃腸炎	4 (3.6)	2 (1.9)	3 (1.4)	5 (1.6)
クロストリジウム菌性胃腸炎	0	0	1 (0.5)	1 (0.3)
ウイルス性胃腸炎	0	0	1 (0.5)	1 (0.3)
消化管感染	0	1 (0.9)	1 (0.5)	2 (0.6)
陰部単純ヘルペス	0	0	1 (0.5)	1 (0.3)
泌尿生殖器感染	0	0	1 (0.5)	1 (0.3)
歯肉炎	0	1 (0.9)	2 (1.0)	3 (0.9)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (cont.)				
単純ヘルペス	2 (1.8)	0	1 (0.5)	1 (0.3)
帯状疱疹	3 (2.7)	3 (2.8)	8 (3.8)	11 (3.5)
耳帯状疱疹	0	0	1 (0.5)	1 (0.3)
麦粒腫	1 (0.9)	1 (0.9)	5 (2.4)	6 (1.9)
インフルエンザ	1 (0.9)	3 (2.8)	4 (1.9)	7 (2.2)
椎間板炎	0	0	1 (0.5)	1 (0.3)
潜伏結核	1 (0.9)	1 (0.9)	0	1 (0.3)
限局性感染	0	0	1 (0.5)	1 (0.3)
下気道感染	0	0	4 (1.9)	4 (1.3)
上咽頭炎	13 (11.6)	6 (5.6)	18 (8.6)	24 (7.6)
食道カンジダ症	1 (0.9)	0	1 (0.5)	1 (0.3)
爪真菌症	0	2 (1.9)	3 (1.4)	5 (1.6)
眼帯状疱疹	0	0	2 (1.0)	2 (0.6)
口腔カンジダ症	2 (1.8)	5 (4.7)	6 (2.9)	11 (3.5)
口腔真菌感染	0	0	2 (1.0)	2 (0.6)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (cont.)				
口腔ヘルペス	4 (3.6)	3 (2.8)	8 (3.8)	11 (3.5)
口腔感染	1 (0.9)	0	0	0
骨髄炎	1 (0.9)	0	0	0
外耳炎	1 (0.9)	0	0	0
中耳炎	0	1 (0.9)	0	1 (0.3)
慢性中耳炎	0	0	1 (0.5)	1 (0.3)
爪囲炎	2 (1.8)	1 (0.9)	2 (1.0)	3 (0.9)
咽頭炎	1 (0.9)	3 (2.8)	1 (0.5)	4 (1.3)
ニューモシスチス・イロベチイ肺炎	0	0	1 (0.5)	1 (0.3)
肺炎	5 (4.5)	5 (4.7)	1 (0.5)	6 (1.9)
細菌性肺炎	1 (0.9)	0	0	0
シュードモナス性肺炎	0	0	1 (0.5)	1 (0.3)
シュードモナス性菌血症	0	0	1 (0.5)	1 (0.3)
歯髄炎	0	0	1 (0.5)	1 (0.3)
RSウイルス感染	0	2 (1.9)	0	2 (0.6)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (cont.)				
気道感染	0	1 (0.9)	4 (1.9)	5 (1.6)
ウイルス性気道感染	0	0	1 (0.5)	1 (0.3)
鼻炎	1 (0.9)	1 (0.9)	5 (2.4)	6 (1.9)
サルモネラ症	0	0	1 (0.5)	1 (0.3)
敗血症	1 (0.9)	0	0	0
レンサ球菌性化膿性関節炎	0	1 (0.9)	0	1 (0.3)
唾液腺炎	0	0	1 (0.5)	1 (0.3)
副鼻腔炎	1 (0.9)	2 (1.9)	3 (1.4)	5 (1.6)
皮膚感染	0	0	1 (0.5)	1 (0.3)
軟部組織感染	0	1 (0.9)	0	1 (0.3)
ブドウ球菌性敗血症	1 (0.9)	0	0	0
重複感染	1 (0.9)	0	0	0
頭部白癬	0	1 (0.9)	0	1 (0.3)
足部白癬	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
真菌性舌感染	0	0	1 (0.5)	1 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (cont.)				
歯膿瘍	0	0	2 (1.0)	2 (0.6)
歯感染	3 (2.7)	3 (2.8)	1 (0.5)	4 (1.3)
気管気管支炎	0	0	1 (0.5)	1 (0.3)
上気道感染	8 (7.1)	8 (7.5)	11 (5.3)	19 (6.0)
尿路感染	18 (16.1)	15 (14.0)	21 (10.0)	36 (11.4)
細菌性尿路感染	1 (0.9)	0	0	0
尿路性敗血症	1 (0.9)	0	0	0
腟感染	0	0	1 (0.5)	1 (0.3)
ウイルス感染	0	1 (0.9)	1 (0.5)	2 (0.6)
ウイルス性咽頭炎	0	0	1 (0.5)	1 (0.3)
ウイルス性上気道感染	0	1 (0.9)	1 (0.5)	2 (0.6)
創傷感染	1 (0.9)	0	1 (0.5)	1 (0.3)
傷害、中毒および処置合併症	24 (21.4)	22 (20.6)	40 (19.1)	62 (19.6)
節足動物咬傷	3 (2.7)	0	0	0
節足動物刺傷	0	0	1 (0.5)	1 (0.3)

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PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (cont.)				
剥離骨折	0	0	1 (0.5)	1 (0.3)
骨挫傷	1 (0.9)	0	0	0
第1度熱傷	0	1 (0.9)	0	1 (0.3)
白内障手術合併症	0	1 (0.9)	0	1 (0.3)
脳振盪	1 (0.9)	0	0	0
挫傷	2 (1.8)	5 (4.7)	7 (3.3)	12 (3.8)
頭蓋顔面骨折	0	1 (0.9)	0	1 (0.3)
歯科修復不成功	1 (0.9)	0	0	0
上顎炎	0	0	1 (0.5)	1 (0.3)
顔面損傷	1 (0.9)	0	0	0
転倒	5 (4.5)	4 (3.7)	8 (3.8)	12 (3.8)
足骨折	1 (0.9)	0	1 (0.5)	1 (0.3)
頭部損傷	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
股関節部骨折	0	0	1 (0.5)	1 (0.3)
上腕骨骨折	0	1 (0.9)	0	1 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (cont.)				
腸脛靱帯症候群	0	1 (0.9)	0	1 (0.3)
免疫反応	0	0	1 (0.5)	1 (0.3)
注入に伴う反応	1 (0.9)	0	0	0
関節脱臼	0	0	2 (1.0)	2 (0.6)
靱帯捻挫	3 (2.7)	0	2 (1.0)	2 (0.6)
四肢損傷	1 (0.9)	1 (0.9)	0	1 (0.3)
下肢骨折	0	0	1 (0.5)	1 (0.3)
腰椎骨折	0	1 (0.9)	0	1 (0.3)
筋断裂	1 (0.9)	0	0	0
肉離れ	2 (1.8)	1 (0.9)	1 (0.5)	2 (0.6)
膝蓋骨骨折	0	1 (0.9)	1 (0.5)	2 (0.6)
処置後出血	0	0	1 (0.5)	1 (0.3)
術後創合併症	0	0	1 (0.5)	1 (0.3)
処置による疼痛	0	2 (1.9)	0	2 (0.6)
橈骨骨折	1 (0.9)	0	0	0

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Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (cont.)				
反応性胃障害	1 (0.9)	0	0	0
肋骨骨折	0	0	2 (1.0)	2 (0.6)
交通事故	0	1 (0.9)	0	1 (0.3)
肩甲骨骨折	1 (0.9)	0	0	0
皮膚擦過傷	0	3 (2.8)	1 (0.5)	4 (1.3)
皮膚裂傷	3 (2.7)	0	6 (2.9)	6 (1.9)
皮膚創傷	1 (0.9)	0	1 (0.5)	1 (0.3)
軟部組織損傷	0	0	1 (0.5)	1 (0.3)
脊椎圧迫骨折	2 (1.8)	1 (0.9)	5 (2.4)	6 (1.9)
脊椎骨折	0	1 (0.9)	1 (0.5)	2 (0.6)
ストレス骨折	1 (0.9)	1 (0.9)	0	1 (0.3)
腱損傷	0	0	2 (1.0)	2 (0.6)
腱断裂	0	3 (2.8)	1 (0.5)	4 (1.3)
熱傷	0	0	1 (0.5)	1 (0.3)
胸椎骨折	0	1 (0.9)	0	1 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (cont.)				
歯の完全脱臼	0	1 (0.9)	0	1 (0.3)
上肢骨折	0	1 (0.9)	0	1 (0.3)
創傷	1 (0.9)	0	0	0
手首関節骨折	0	0	1 (0.5)	1 (0.3)
臨床検査	19 (17.0)	13 (12.1)	35 (16.7)	48 (15.2)
アラニンアミノトランスフェラーゼ増加	0	0	3 (1.4)	3 (0.9)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	1 (0.5)	1 (0.3)
血中アルカリホスファターゼ増加	1 (0.9)	0	0	0
血中ビリルビン増加	0	0	1 (0.5)	1 (0.3)
血中コレステロール増加	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
血中クレアチンホスホキナーゼ増加	0	0	6 (2.9)	6 (1.9)
血中クレアチニン増加	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
血中ブドウ糖増加	0	1 (0.9)	0	1 (0.3)
血中鉄減少	0	0	1 (0.5)	1 (0.3)
血中カリウム減少	1 (0.9)	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
臨床検査 (cont.)				
血中ナトリウム減少	0	1 (0.9)	0	1 (0.3)
血中トリグリセリド増加	0	0	1 (0.5)	1 (0.3)
骨密度異常	1 (0.9)	0	0	0
C-反応性蛋白増加	0	0	1 (0.5)	1 (0.3)
心雑音	0	0	1 (0.5)	1 (0.3)
心電図QT延長	1 (0.9)	0	0	0
エプスタイン・バーウイルス抗体陽性	1 (0.9)	0	0	0
Γ-グルタミルトランスフェラーゼ増加	1 (0.9)	0	0	0
ヘモグロビン減少	1 (0.9)	0	3 (1.4)	3 (0.9)
B型肝炎ウイルス検査陽性	0	0	1 (0.5)	1 (0.3)
眼圧上昇	1 (0.9)	0	1 (0.5)	1 (0.3)
肝機能検査異常	0	0	2 (1.0)	2 (0.6)
肝機能検査値上昇	1 (0.9)	0	0	0
リンパ球数減少	0	1 (0.9)	2 (1.0)	3 (0.9)
平均赤血球容積増加	0	0	1 (0.5)	1 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
臨床検査 (cont.)				
モノクローナル免疫グロブリン増加	0	1 (0.9)	0	1 (0.3)
尿中亜硝酸塩陽性	0	0	1 (0.5)	1 (0.3)
壁細胞抗体陽性	0	1 (0.9)	0	1 (0.3)
前立腺特異性抗原増加	1 (0.9)	0	0	0
血沈亢進	2 (1.8)	1 (0.9)	1 (0.5)	2 (0.6)
尿中赤血球陽性	0	0	1 (0.5)	1 (0.3)
腎機能検査異常	1 (0.9)	0	0	0
トランスアミナーゼ上昇	0	1 (0.9)	1 (0.5)	2 (0.6)
トロポニンT増加	0	0	1 (0.5)	1 (0.3)
体重減少	2 (1.8)	0	1 (0.5)	1 (0.3)
体重増加	4 (3.6)	6 (5.6)	6 (2.9)	12 (3.8)
尿中白血球陽性	1 (0.9)	0	0	0
代謝および栄養障害	16 (14.3)	11 (10.3)	28 (13.4)	39 (12.3)
高クロール血性アシドーシス	0	0	1 (0.5)	1 (0.3)
中心性肥満	1 (0.9)	0	0	0

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Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
代謝および栄養障害 (cont.)				
食欲減退	2 (1.8)	1 (0.9)	0	1 (0.3)
脱水	0	1 (0.9)	0	1 (0.3)
糖尿病	4 (3.6)	1 (0.9)	4 (1.9)	5 (1.6)
脂質異常症	1 (0.9)	2 (1.9)	3 (1.4)	5 (1.6)
体液貯留	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
葉酸欠乏	1 (0.9)	0	0	0
食物不耐性	0	0	1 (0.5)	1 (0.3)
痛風	0	0	1 (0.5)	1 (0.3)
高コレステロール血症	0	1 (0.9)	2 (1.0)	3 (0.9)
高血糖	1 (0.9)	0	1 (0.5)	1 (0.3)
高脂血症	0	1 (0.9)	2 (1.0)	3 (0.9)
高尿酸血症	1 (0.9)	1 (0.9)	0	1 (0.3)
低カルシウム血症	0	0	1 (0.5)	1 (0.3)
低クロール血症	0	0	1 (0.5)	1 (0.3)
低血糖	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
代謝および栄養障害 (cont.)				
低カリウム血症	1 (0.9)	2 (1.9)	5 (2.4)	7 (2.2)
低マグネシウム血症	1 (0.9)	0	0	0
低ナトリウム血症	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
低蛋白血症	0	0	1 (0.5)	1 (0.3)
食欲亢進	0	0	1 (0.5)	1 (0.3)
鉄欠乏	3 (2.7)	0	0	0
脂肪腫症	1 (0.9)	0	1 (0.5)	1 (0.3)
ステロイド糖尿病	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
2型糖尿病	0	1 (0.9)	1 (0.5)	2 (0.6)
ビタミンD欠乏	1 (0.9)	0	0	0
筋骨格系および結合組織障害	56 (50.0)	45 (42.1)	108 (51.7)	153 (48.4)
関節痛	15 (13.4)	7 (6.5)	29 (13.9)	36 (11.4)
関節炎	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
関節障害	1 (0.9)	0	0	0
背部痛	15 (13.4)	6 (5.6)	25 (12.0)	31 (9.8)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (cont.)				
滑液包炎	2 (1.8)	1 (0.9)	3 (1.4)	4 (1.3)
頚部脊柱管狭窄症	0	0	1 (0.5)	1 (0.3)
椎間関節症候群	0	0	1 (0.5)	1 (0.3)
線維筋痛	0	1 (0.9)	2 (1.0)	3 (0.9)
指変形	0	0	1 (0.5)	1 (0.3)
側腹部痛	0	1 (0.9)	1 (0.5)	2 (0.6)
大転子疼痛症候群	3 (2.7)	2 (1.9)	2 (1.0)	4 (1.3)
単径部痛	0	1 (0.9)	0	1 (0.3)
椎間板障害	1 (0.9)	0	0	0
椎間板突出	4 (3.6)	2 (1.9)	2 (1.0)	4 (1.3)
顎関節クリッキング	0	0	1 (0.5)	1 (0.3)
顎障害	0	0	1 (0.5)	1 (0.3)
関節滲出液	0	0	1 (0.5)	1 (0.3)
関節雑音	0	0	1 (0.5)	1 (0.3)
関節可動域低下	1 (0.9)	0	1 (0.5)	1 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (cont.)				
関節硬直	1 (0.9)	0	0	0
関節腫脹	1 (0.9)	0	4 (1.9)	4 (1.3)
腰部脊柱管狭窄症	0	1 (0.9)	2 (1.0)	3 (0.9)
半月板変性	0	0	1 (0.5)	1 (0.3)
筋不快感	0	0	1 (0.5)	1 (0.3)
筋肉疲労	1 (0.9)	0	0	0
筋痙縮	8 (7.1)	6 (5.6)	13 (6.2)	19 (6.0)
筋力低下	1 (0.9)	3 (2.8)	2 (1.0)	5 (1.6)
筋骨格系胸痛	1 (0.9)	1 (0.9)	5 (2.4)	6 (1.9)
筋骨格不快感	0	1 (0.9)	0	1 (0.3)
筋骨格障害	0	0	1 (0.5)	1 (0.3)
筋骨格痛	1 (0.9)	0	0	0
筋骨格硬直	0	0	4 (1.9)	4 (1.3)
筋肉痛	5 (4.5)	7 (6.5)	9 (4.3)	16 (5.1)
ミオパチー	2 (1.8)	1 (0.9)	4 (1.9)	5 (1.6)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (cont.)				
頚部痛	6 (5.4)	1 (0.9)	3 (1.4)	4 (1.3)
変形性関節症	5 (4.5)	3 (2.8)	13 (6.2)	16 (5.1)
骨端症	0	1 (0.9)	1 (0.5)	2 (0.6)
骨減少症	2 (1.8)	0	3 (1.4)	3 (0.9)
骨粗鬆症	3 (2.7)	3 (2.8)	7 (3.3)	10 (3.2)
四肢痛	6 (5.4)	4 (3.7)	15 (7.2)	19 (6.0)
顎痛	1 (0.9)	2 (1.9)	2 (1.0)	4 (1.3)
膝蓋大腿関節痛症候群	0	0	1 (0.5)	1 (0.3)
関節周囲炎	0	0	1 (0.5)	1 (0.3)
足底筋膜炎	0	1 (0.9)	0	1 (0.3)
リウマチ性多発筋痛	5 (4.5)	1 (0.9)	2 (1.0)	3 (0.9)
乾癬性関節症	0	0	1 (0.5)	1 (0.3)
関節リウマチ	1 (0.9)	0	0	0
肩回旋筋腱板症候群	3 (2.7)	1 (0.9)	1 (0.5)	2 (0.6)
肩甲帯痛	0	1 (0.9)	0	1 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (cont.)				
シェーグレン症候群	1 (0.9)	0	2 (1.0)	2 (0.6)
軟部組織腫瘤	0	0	1 (0.5)	1 (0.3)
変形性脊椎症	0	2 (1.9)	0	2 (0.6)
脊椎痛	1 (0.9)	0	2 (1.0)	2 (0.6)
脊柱管狭窄症	0	0	1 (0.5)	1 (0.3)
脊椎滑液嚢腫	0	0	1 (0.5)	1 (0.3)
滑液嚢腫	2 (1.8)	1 (0.9)	0	1 (0.3)
顎関節症候群	0	2 (1.9)	2 (1.0)	4 (1.3)
腱障害	2 (1.8)	4 (3.7)	1 (0.5)	5 (1.6)
腱痛	1 (0.9)	1 (0.9)	0	1 (0.3)
腱炎	0	1 (0.9)	3 (1.4)	4 (1.3)
腱鞘炎	0	0	1 (0.5)	1 (0.3)
弾発指	0	1 (0.9)	0	1 (0.3)
椎間孔狭窄	0	0	2 (1.0)	2 (0.6)
手関節変形	1 (0.9)	0	0	0

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	7 (6.3)	6 (5.6)	16 (7.7)	22 (7.0)
副腎腺腫	0	1 (0.9)	0	1 (0.3)
血管筋脂肪腫	1 (0.9)	0	0	0
基底細胞癌	2 (1.8)	0	2 (1.0)	2 (0.6)
結腸直腸腺腫	0	2 (1.9)	0	2 (0.6)
線維腫	0	0	1 (0.5)	1 (0.3)
血管腫	1 (0.9)	0	0	0
良性毛包腫瘍	0	0	1 (0.5)	1 (0.3)
膵管内乳頭粘液性腫瘍	1 (0.9)	0	0	0
悪性黒子	0	0	1 (0.5)	1 (0.3)
脂肪腫	0	0	1 (0.5)	1 (0.3)
ファーター膨大部の悪性新生物	0	0	1 (0.5)	1 (0.3)
メラノサイト性母斑	0	0	2 (1.0)	2 (0.6)
皮膚の新生物	0	0	1 (0.5)	1 (0.3)
神経線維腫	1 (0.9)	0	0	0

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (cont.)				
前立腺癌	1 (0.9)	0	0	0
脂漏性角化症	0	0	2 (1.0)	2 (0.6)
皮膚乳頭腫	0	2 (1.9)	0	2 (0.6)
肺扁平上皮癌	0	0	1 (0.5)	1 (0.3)
皮膚有棘細胞癌	0	1 (0.9)	3 (1.4)	4 (1.3)
舌の悪性新生物、病期不明	0	0	1 (0.5)	1 (0.3)
遠隔転移を伴う扁桃癌	1 (0.9)	0	0	0
神経系障害	32 (28.6)	39 (36.4)	81 (38.8)	120 (38.0)
健忘	0	0	2 (1.0)	2 (0.6)
無嗅覚	0	0	1 (0.5)	1 (0.3)
反射消失	0	1 (0.9)	0	1 (0.3)
平衡障害	1 (0.9)	0	1 (0.5)	1 (0.3)
ブレインフォグ	1 (0.9)	0	1 (0.5)	1 (0.3)
灼熱感	0	1 (0.9)	1 (0.5)	2 (0.6)
頚動脈狭窄	0	0	1 (0.5)	1 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (cont.)				
手根管症候群	0	0	4 (1.9)	4 (1.3)
小脳性運動失調	0	0	1 (0.5)	1 (0.3)
脳アミロイド血管障害	1 (0.9)	0	0	0
脳梗塞	1 (0.9)	0	0	0
脳脊髄癆	1 (0.9)	0	0	0
脳卒中	1 (0.9)	0	0	0
頚腕症候群	0	0	1 (0.5)	1 (0.3)
認知障害	1 (0.9)	0	0	0
脱髄	1 (0.9)	0	0	0
注意力障害	0	1 (0.9)	0	1 (0.3)
浮動性めまい	6 (5.4)	6 (5.6)	10 (4.8)	16 (5.1)
労作性めまい	0	0	1 (0.5)	1 (0.3)
体位性めまい	0	0	2 (1.0)	2 (0.6)
異常感覚	1 (0.9)	0	0	0
味覚不全	1 (0.9)	3 (2.8)	3 (1.4)	6 (1.9)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (cont.)				
ジストニア	0	0	1 (0.5)	1 (0.3)
電気ショック様感覚	0	1 (0.9)	0	1 (0.3)
頭部不快感	0	1 (0.9)	1 (0.5)	2 (0.6)
頭痛	13 (11.6)	16 (15.0)	34 (16.3)	50 (15.8)
感覚鈍麻	1 (0.9)	0	2 (1.0)	2 (0.6)
味覚減退	0	1 (0.9)	0	1 (0.3)
肋間神経痛	0	0	1 (0.5)	1 (0.3)
脳圧低下	0	1 (0.9)	0	1 (0.3)
腰髄神経根障害	1 (0.9)	0	1 (0.5)	1 (0.3)
記憶障害	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
片頭痛	2 (1.8)	2 (1.9)	1 (0.5)	3 (0.9)
単神経炎	0	0	1 (0.5)	1 (0.3)
不随意性筋収縮	0	0	1 (0.5)	1 (0.3)
神経圧迫	0	0	1 (0.5)	1 (0.3)
神経痛	2 (1.8)	0	0	0

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Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (cont.)				
末梢性ニューロパチー	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
後頭神経痛	0	1 (0.9)	2 (1.0)	3 (0.9)
錯感覚	1 (0.9)	2 (1.9)	4 (1.9)	6 (1.9)
嗅覚錯誤	0	0	1 (0.5)	1 (0.3)
梨状筋症候群	0	1 (0.9)	0	1 (0.3)
多発ニューロパチー	1 (0.9)	0	0	0
ヘルペス後神経痛	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
失神寸前の状態	0	0	1 (0.5)	1 (0.3)
偽性根症候群	0	1 (0.9)	2 (1.0)	3 (0.9)
精神運動亢進	0	0	1 (0.5)	1 (0.3)
4分の1盲	0	0	1 (0.5)	1 (0.3)
神経根障害	0	0	2 (1.0)	2 (0.6)
下肢静止不能症候群	0	0	3 (1.4)	3 (0.9)
坐骨神経痛	0	3 (2.8)	6 (2.9)	9 (2.8)
副鼻腔炎に伴う頭痛	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (cont.)				
傾眠	0	2 (1.9)	2 (1.0)	4 (1.3)
失神	4 (3.6)	1 (0.9)	4 (1.9)	5 (1.6)
味覚障害	0	0	2 (1.0)	2 (0.6)
緊張性頭痛	0	1 (0.9)	4 (1.9)	5 (1.6)
一過性失語症	0	1 (0.9)	0	1 (0.3)
一過性脳虚血発作	0	2 (1.9)	0	2 (0.6)
振戦	5 (4.5)	2 (1.9)	1 (0.5)	3 (0.9)
トンネル状視野	0	0	1 (0.5)	1 (0.3)
椎骨動脈狭窄	0	0	1 (0.5)	1 (0.3)
精神障害	13 (11.6)	8 (7.5)	20 (9.6)	28 (8.9)
不安	1 (0.9)	0	3 (1.4)	3 (0.9)
歯ぎしり	0	0	1 (0.5)	1 (0.3)
燃え尽き症候群	0	0	1 (0.5)	1 (0.3)
錯乱状態	0	0	2 (1.0)	2 (0.6)
譫妄	1 (0.9)	0	0	0

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Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
精神障害 (cont.)				
抑うつ気分	0	1 (0.9)	1 (0.5)	2 (0.6)
うつ病	1 (0.9)	2 (1.9)	3 (1.4)	5 (1.6)
初期不眠症	1 (0.9)	0	0	0
不眠症	5 (4.5)	3 (2.8)	4 (1.9)	7 (2.2)
リビドー減退	0	1 (0.9)	0	1 (0.3)
躁病	1 (0.9)	0	0	0
混合性不安抑うつ障害	1 (0.9)	0	0	0
気分動揺	1 (0.9)	0	0	0
神経過敏	1 (0.9)	0	1 (0.5)	1 (0.3)
人格変化	0	0	1 (0.5)	1 (0.3)
睡眠の質低下	1 (0.9)	0	0	0
落ち着きのなさ	0	1 (0.9)	1 (0.5)	2 (0.6)
睡眠障害	0	1 (0.9)	1 (0.5)	2 (0.6)
物質誘発性精神病性障害	0	0	2 (1.0)	2 (0.6)
腎および尿路障害	13 (11.6)	5 (4.7)	19 (9.1)	24 (7.6)

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Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
腎および尿路障害 (cont.)				
急性腎障害	3 (2.7)	0	2 (1.0)	2 (0.6)
慢性腎臓病	0	1 (0.9)	0	1 (0.3)
排尿困難	1 (0.9)	0	3 (1.4)	3 (0.9)
血尿	4 (3.6)	0	4 (1.9)	4 (1.3)
緊張性膀胱	1 (0.9)	0	1 (0.5)	1 (0.3)
尿意切迫	1 (0.9)	0	1 (0.5)	1 (0.3)
腎炎	0	0	1 (0.5)	1 (0.3)
腎結石症	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
夜間頻尿	0	0	1 (0.5)	1 (0.3)
頻尿	1 (0.9)	2 (1.9)	2 (1.0)	4 (1.3)
蛋白尿	1 (0.9)	0	0	0
腎仙痛	1 (0.9)	0	0	0
腎嚢胞	1 (0.9)	0	1 (0.5)	1 (0.3)
腎不全	0	0	1 (0.5)	1 (0.3)
腎機能障害	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
腎および尿路障害 (cont.)				
腎損傷	0	0	1 (0.5)	1 (0.3)
尿失禁	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
生殖系および乳房障害	4 (3.6)	1 (0.9)	8 (3.8)	9 (2.8)
良性前立腺肥大症	0	1 (0.9)	1 (0.5)	2 (0.6)
乳房腫瘤	0	0	1 (0.5)	1 (0.3)
乳房痛	1 (0.9)	0	1 (0.5)	1 (0.3)
子宮頚部上皮異形成	0	0	1 (0.5)	1 (0.3)
膀胱瘤	0	0	1 (0.5)	1 (0.3)
乳頭痛	0	0	1 (0.5)	1 (0.3)
骨盤痛	1 (0.9)	0	0	0
前立腺障害	0	0	1 (0.5)	1 (0.3)
前立腺腫大	1 (0.9)	0	0	0
外陰腟乾燥	0	0	1 (0.5)	1 (0.3)
外陰腟そう痒症	1 (0.9)	0	0	0
呼吸器、胸郭および縦隔障害	14 (12.5)	20 (18.7)	49 (23.4)	69 (21.8)

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Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
呼吸器、胸郭および縦隔障害 (cont.)				
急性呼吸不全	0	1 (0.9)	0	1 (0.3)
喘息	0	1 (0.9)	4 (1.9)	5 (1.6)
無気肺	0	0	1 (0.5)	1 (0.3)
気管支拡張症	0	0	1 (0.5)	1 (0.3)
慢性気管支炎	0	0	1 (0.5)	1 (0.3)
気管支痙攣	0	0	1 (0.5)	1 (0.3)
慢性閉塞性肺疾患	0	0	3 (1.4)	3 (0.9)
咳嗽	4 (3.6)	5 (4.7)	14 (6.7)	19 (6.0)
発声障害	0	2 (1.9)	0	2 (0.6)
呼吸困難	5 (4.5)	1 (0.9)	7 (3.3)	8 (2.5)
労作性呼吸困難	2 (1.8)	2 (1.9)	2 (1.0)	4 (1.3)
鼻出血	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
血胸	0	1 (0.9)	0	1 (0.3)
下咽頭癒着	0	0	1 (0.5)	1 (0.3)
上気道分泌増加	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
呼吸器、胸郭および縦隔障害 (cont.)				
肺障害	0	0	1 (0.5)	1 (0.3)
口腔咽頭痛	1 (0.9)	4 (3.7)	6 (2.9)	10 (3.2)
起坐呼吸	0	1 (0.9)	0	1 (0.3)
湿性咳嗽	0	0	2 (1.0)	2 (0.6)
肺塞栓症	2 (1.8)	2 (1.9)	6 (2.9)	8 (2.5)
肺腫瘤	0	0	2 (1.0)	2 (0.6)
ラ音	0	1 (0.9)	0	1 (0.3)
アレルギー性鼻炎	0	0	1 (0.5)	1 (0.3)
鼻漏	1 (0.9)	0	2 (1.0)	2 (0.6)
咳払い	1 (0.9)	0	0	0
咽喉刺激感	0	0	1 (0.5)	1 (0.3)
皮膚および皮下組織障害	26 (23.2)	20 (18.7)	57 (27.3)	77 (24.4)
ざ瘡	1 (0.9)	0	7 (3.3)	7 (2.2)
光線角化症	0	0	1 (0.5)	1 (0.3)
脱毛症	3 (2.7)	0	5 (2.4)	5 (1.6)

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Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (cont.)				
円形脱毛症	0	0	1 (0.5)	1 (0.3)
汎発性脱毛症	0	0	1 (0.5)	1 (0.3)
アンドロゲン性脱毛症	0	1 (0.9)	0	1 (0.3)
血管浮腫	0	1 (0.9)	0	1 (0.3)
水疱	2 (1.8)	0	0	0
腕橈骨筋そう痒症	0	0	1 (0.5)	1 (0.3)
冷汗	1 (0.9)	0	0	0
皮膚炎	1 (0.9)	0	2 (1.0)	2 (0.6)
ざ瘡様皮膚炎	0	0	1 (0.5)	1 (0.3)
アレルギー性皮膚炎	1 (0.9)	0	0	0
接触皮膚炎	1 (0.9)	0	2 (1.0)	2 (0.6)
皮膚症	0	0	1 (0.5)	1 (0.3)
びまん性脱毛症	0	2 (1.9)	0	2 (0.6)
皮膚乾燥	0	0	6 (2.9)	6 (1.9)
斑状出血	1 (0.9)	0	0	0

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Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (cont.)				
湿疹	0	1 (0.9)	1 (0.5)	2 (0.6)
紅斑	1 (0.9)	0	4 (1.9)	4 (1.3)
毛髪成長異常	0	1 (0.9)	0	1 (0.3)
男性型多毛症	0	0	2 (1.0)	2 (0.6)
多汗症	3 (2.7)	3 (2.8)	5 (2.4)	8 (2.5)
過角化	1 (0.9)	0	0	0
硬化性苔癬	1 (0.9)	0	0	0
後天性リポジストロフィー	1 (0.9)	0	0	0
脂肪肥大症	1 (0.9)	0	1 (0.5)	1 (0.3)
網状皮斑	1 (0.9)	0	0	0
爪変色	0	0	1 (0.5)	1 (0.3)
神経皮膚炎	1 (0.9)	0	0	0
寝汗	1 (0.9)	2 (1.9)	1 (0.5)	3 (0.9)
爪破損	0	0	1 (0.5)	1 (0.3)
皮膚疼痛	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (cont.)				
丘疹	1 (0.9)	0	0	0
類天疱瘡	1 (0.9)	0	0	0
陰茎潰瘍形成	0	0	1 (0.5)	1 (0.3)
口囲皮膚炎	1 (0.9)	0	3 (1.4)	3 (0.9)
光線性皮膚症	0	0	1 (0.5)	1 (0.3)
そう痒症	2 (1.8)	0	2 (1.0)	2 (0.6)
乾癬	1 (0.9)	0	0	0
発疹	3 (2.7)	3 (2.8)	11 (5.3)	14 (4.4)
紅斑性皮疹	0	1 (0.9)	0	1 (0.3)
斑状皮疹	1 (0.9)	1 (0.9)	0	1 (0.3)
斑状丘疹状皮疹	0	1 (0.9)	1 (0.5)	2 (0.6)
小水疱性皮疹	1 (0.9)	0	0	0
酒さ	1 (0.9)	0	3 (1.4)	3 (0.9)
痂皮	0	0	1 (0.5)	1 (0.3)
脂漏性皮膚炎	3 (2.7)	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (cont.)				
皮膚変色	1 (0.9)	0	0	0
皮膚亀裂	0	0	1 (0.5)	1 (0.3)
皮膚色素過剰	0	1 (0.9)	0	1 (0.3)
皮膚硬結	0	0	1 (0.5)	1 (0.3)
皮膚刺激	0	1 (0.9)	0	1 (0.3)
皮膚病変	0	1 (0.9)	2 (1.0)	3 (0.9)
皮膚軟化	0	1 (0.9)	0	1 (0.3)
皮膚腫瘤	0	0	1 (0.5)	1 (0.3)
皮膚潰瘍	1 (0.9)	0	2 (1.0)	2 (0.6)
うっ滞性皮膚炎	0	0	1 (0.5)	1 (0.3)
乾皮症	1 (0.9)	0	0	0
黄色皮膚	0	0	1 (0.5)	1 (0.3)
血管障害	47 (42.0)	48 (44.9)	83 (39.7)	131 (41.5)
大動脈解離	0	0	1 (0.5)	1 (0.3)
大動脈狭窄	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
血管障害 (cont.)				
大動脈血栓症	0	0	1 (0.5)	1 (0.3)
動脈出血	0	1 (0.9)	0	1 (0.3)
動脈硬化症	1 (0.9)	1 (0.9)	0	1 (0.3)
深部静脈血栓症	2 (1.8)	1 (0.9)	4 (1.9)	5 (1.6)
本態性高血圧症	0	1 (0.9)	0	1 (0.3)
巨細胞性動脈炎	35 (31.3)	28 (26.2)	48 (23.0)	76 (24.1)
血腫	5 (4.5)	2 (1.9)	4 (1.9)	6 (1.9)
ほてり	0	0	1 (0.5)	1 (0.3)
高血圧	13 (11.6)	16 (15.0)	28 (13.4)	44 (13.9)
高血圧クリーゼ	0	0	1 (0.5)	1 (0.3)
低血圧	0	0	1 (0.5)	1 (0.3)
間欠性跛行	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
リンパ浮腫	0	1 (0.9)	0	1 (0.3)
リンパうっ滞	0	0	2 (1.0)	2 (0.6)
大血管障害	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
血管障害 (cont.)				
起立性低血圧	2 (1.8)	1 (0.9)	1 (0.5)	2 (0.6)
末梢動脈閉塞性疾患	0	0	1 (0.5)	1 (0.3)
末梢動脈狭窄	1 (0.9)	0	0	0
末梢冷感	1 (0.9)	0	2 (1.0)	2 (0.6)
末梢血管塞栓症	0	0	1 (0.5)	1 (0.3)
末梢静脈疾患	1 (0.9)	0	0	0
レイノー現象	0	1 (0.9)	0	1 (0.3)
表在性静脈血栓症	0	2 (1.9)	0	2 (0.6)
血栓性静脈炎	0	1 (0.9)	0	1 (0.3)
静脈瘤性静脈炎	0	0	1 (0.5)	1 (0.3)
静脈瘤	0	0	3 (1.4)	3 (0.9)
白衣性高血圧	0	0	2 (1.0)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

表2

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ABT-494 (GIANT CELL ARTERITIS)
STUDY M16-852 (CUTOFF 06FEB2024)
R&D/23/2455 - CLINICAL/STATISTICAL

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
Any adverse event	396 (548.0)	264 (363.6)	874 (509.9)	1138 (466.4)
血液およびリンパ系障害	2 (2.8)	5 (6.9)	17 (9.9)	22 (9.0)
貧血	1 (1.4)	3 (4.1)	8 (4.7)	11 (4.5)
骨髄浮腫	0	1 (1.4)	0	1 (0.4)
好酸球増加症	0	0	1 (0.6)	1 (0.4)
内出血発生の増加傾向	1 (1.4)	0	1 (0.6)	1 (0.4)
鉄欠乏性貧血	0	1 (1.4)	1 (0.6)	2 (0.8)
白血球増加症	0	0	1 (0.6)	1 (0.4)
リンパ球減少症	0	0	1 (0.6)	1 (0.4)
好中球増加症	0	0	1 (0.6)	1 (0.4)
正色素性正球性貧血	0	0	2 (1.2)	2 (0.8)
血小板増加症	0	0	1 (0.6)	1 (0.4)
心臓障害	8 (11.1)	3 (4.1)	20 (11.7)	23 (9.4)
狭心症	0	0	1 (0.6)	1 (0.4)
大動脈弁疾患	1 (1.4)	0	0	0
冠動脈硬化症	0	0	2 (1.2)	2 (0.8)
心房細動	2 (2.8)	0	2 (1.2)	2 (0.8)
心房頻脈	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
心臓障害 (cont.)				
右脚ブロック	1 (1.4)	0	0	0
心不全	1 (1.4)	0	4 (2.3)	4 (1.6)
冠動脈疾患	0	1 (1.4)	0	1 (0.4)
冠動脈入口部狭窄	0	0	1 (0.6)	1 (0.4)
僧帽弁石灰化	0	0	1 (0.6)	1 (0.4)
僧帽弁閉鎖不全症	0	0	1 (0.6)	1 (0.4)
心筋虚血	0	0	1 (0.6)	1 (0.4)
動悸	2 (2.8)	1 (1.4)	3 (1.8)	4 (1.6)
心嚢液貯留	0	0	1 (0.6)	1 (0.4)
洞性徐脈	0	1 (1.4)	0	1 (0.4)
洞性頻脈	1 (1.4)	0	0	0
頻脈	0	0	1 (0.6)	1 (0.4)
三尖弁閉鎖不全症	0	0	1 (0.6)	1 (0.4)
先天性、家族性および遺伝性障害	0	1 (1.4)	0	1 (0.4)
歯牙形成不全	0	1 (1.4)	0	1 (0.4)
耳および迷路障害	3 (4.2)	5 (6.9)	15 (8.8)	20 (8.2)
耳不快感	0	0	1 (0.6)	1 (0.4)
耳痛	0	0	4 (2.3)	4 (1.6)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
耳および迷路障害 (cont.)				
聴力低下	0	1 (1.4)	0	1 (0.4)
耳鳴	2 (2.8)	2 (2.8)	2 (1.2)	4 (1.6)
回転性めまい	1 (1.4)	2 (2.8)	7 (4.1)	9 (3.7)
頭位性回転性めまい	0	0	1 (0.6)	1 (0.4)
内分泌障害	3 (4.2)	2 (2.8)	3 (1.8)	5 (2.0)
クッシング症候群	1 (1.4)	0	1 (0.6)	1 (0.4)
クッシング様症状	0	1 (1.4)	2 (1.2)	3 (1.2)
甲状腺腫	1 (1.4)	0	0	0
甲状腺腫瘤	0	1 (1.4)	0	1 (0.4)
中毒性結節性甲状腺腫	1 (1.4)	0	0	0
眼障害	24 (33.2)	11 (15.2)	45 (26.3)	56 (23.0)
加齢黄斑変性	0	2 (2.8)	1 (0.6)	3 (1.2)
眼瞼炎	0	0	5 (2.9)	5 (2.0)
白内障	4 (5.5)	2 (2.8)	8 (4.7)	10 (4.1)
霰粒腫	0	0	2 (1.2)	2 (0.8)
結膜出血	0	1 (1.4)	3 (1.8)	4 (1.6)
アレルギー性結膜炎	1 (1.4)	0	0	0
角膜浮腫	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
眼障害 (cont.)				
複視	0	0	1 (0.6)	1 (0.4)
ドライアイ	2 (2.8)	1 (1.4)	2 (1.2)	3 (1.2)
眼出血	0	0	1 (0.6)	1 (0.4)
眼の炎症	0	0	1 (0.6)	1 (0.4)
眼刺激	0	0	1 (0.6)	1 (0.4)
眼痛	1 (1.4)	0	2 (1.2)	2 (0.8)
眼部腫脹	0	1 (1.4)	1 (0.6)	2 (0.8)
眼の異物感	1 (1.4)	0	1 (0.6)	1 (0.4)
緑内障	1 (1.4)	0	1 (0.6)	1 (0.4)
遠視	0	0	1 (0.6)	1 (0.4)
黄斑変性	1 (1.4)	1 (1.4)	0	1 (0.4)
眼部不快感	1 (1.4)	0	0	0
眼充血	0	0	1 (0.6)	1 (0.4)
高眼圧症	0	0	1 (0.6)	1 (0.4)
開放隅角緑内障	1 (1.4)	0	1 (0.6)	1 (0.4)
視神経乳頭出血	0	0	1 (0.6)	1 (0.4)
虚血性視神経症	1 (1.4)	0	0	0
眼窩浮腫	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
眼障害 (cont.)				
眼窩周囲痛	0	1 (1.4)	0	1 (0.4)
羞明	0	0	1 (0.6)	1 (0.4)
光視症	0	0	1 (0.6)	1 (0.4)
老視	0	0	1 (0.6)	1 (0.4)
網膜裂孔	1 (1.4)	0	0	0
眼瞼腫脹	0	0	1 (0.6)	1 (0.4)
霧視	2 (2.8)	0	1 (0.6)	1 (0.4)
視力低下	1 (1.4)	0	0	0
視野欠損	0	0	1 (0.6)	1 (0.4)
視力障害	1 (1.4)	1 (1.4)	0	1 (0.4)
硝子体剥離	3 (4.2)	0	1 (0.6)	1 (0.4)
硝子体浮遊物	2 (2.8)	1 (1.4)	1 (0.6)	2 (0.8)
胃腸障害	32 (44.3)	32 (44.1)	70 (40.8)	102 (41.8)
腹部膨満	1 (1.4)	0	2 (1.2)	2 (0.8)
腹痛	3 (4.2)	1 (1.4)	2 (1.2)	3 (1.2)
下腹部痛	1 (1.4)	2 (2.8)	0	2 (0.8)
上腹部痛	3 (4.2)	0	9 (5.3)	9 (3.7)
裂肛	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (cont.)				
アフタ性潰瘍	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
慢性胃炎	2 (2.8)	0	0	0
虚血性大腸炎	0	0	1 (0.6)	1 (0.4)
便秘	3 (4.2)	4 (5.5)	5 (2.9)	9 (3.7)
齲歯	1 (1.4)	0	1 (0.6)	1 (0.4)
下痢	0	4 (5.5)	9 (5.3)	13 (5.3)
憩室	0	1 (1.4)	0	1 (0.4)
腸憩室	1 (1.4)	0	1 (0.6)	1 (0.4)
口内乾燥	1 (1.4)	0	1 (0.6)	1 (0.4)
消化不良	1 (1.4)	0	6 (3.5)	6 (2.5)
嚥下障害	0	0	1 (0.6)	1 (0.4)
鼓腸	0	1 (1.4)	0	1 (0.4)
食中毒	0	0	1 (0.6)	1 (0.4)
排便回数増加	1 (1.4)	1 (1.4)	0	1 (0.4)
胃炎	3 (4.2)	1 (1.4)	1 (0.6)	2 (0.8)
胃食道逆流性疾患	1 (1.4)	0	5 (2.9)	5 (2.0)
歯肉障害	0	1 (1.4)	0	1 (0.4)
歯肉痛	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (cont.)				
裂孔ヘルニア	1 (1.4)	0	1 (0.6)	1 (0.4)
単径ヘルニア	0	1 (1.4)	1 (0.6)	2 (0.8)
過敏性腸症候群	0	0	1 (0.6)	1 (0.4)
大腸ポリープ	2 (2.8)	0	1 (0.6)	1 (0.4)
口唇腫脹	0	1 (1.4)	0	1 (0.4)
口腔内潰瘍形成	0	0	4 (2.3)	4 (1.6)
悪心	2 (2.8)	6 (8.3)	7 (4.1)	13 (5.3)
嚥下痛	0	0	1 (0.6)	1 (0.4)
食道炎	0	0	1 (0.6)	1 (0.4)
膵嚢胞	1 (1.4)	0	0	0
膵炎	0	1 (1.4)	0	1 (0.4)
直腸出血	1 (1.4)	0	0	0
口内炎	1 (1.4)	0	1 (0.6)	1 (0.4)
歯痛	1 (1.4)	0	1 (0.6)	1 (0.4)
臍ヘルニア	0	1 (1.4)	0	1 (0.4)
嘔吐	0	5 (6.9)	3 (1.8)	8 (3.3)
一般・全身障害および投与部位の状態	20 (27.7)	14 (19.3)	48 (28.0)	62 (25.4)
医薬品副作用	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
一般・全身障害および投与部位の状態 (cont.)				
無力症	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
胸部不快感	0	0	1 (0.6)	1 (0.4)
胸痛	0	2 (2.8)	6 (3.5)	8 (3.3)
疾患前駆期	1 (1.4)	0	0	0
顔面浮腫	0	0	1 (0.6)	1 (0.4)
疲労	4 (5.5)	3 (4.1)	10 (5.8)	13 (5.3)
冷感	0	0	1 (0.6)	1 (0.4)
歩行障害	1 (1.4)	0	2 (1.2)	2 (0.8)
不明確な障害	1 (1.4)	0	0	0
インフルエンザ様疾患	1 (1.4)	0	3 (1.8)	3 (1.2)
注射部位疼痛	0	0	1 (0.6)	1 (0.4)
倦怠感	1 (1.4)	0	1 (0.6)	1 (0.4)
小結節	0	1 (1.4)	0	1 (0.4)
非心臓性胸痛	0	1 (1.4)	0	1 (0.4)
浮腫	0	0	2 (1.2)	2 (0.8)
末梢性浮腫	3 (4.2)	2 (2.8)	7 (4.1)	9 (3.7)
疼痛	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
末梢腫脹	1 (1.4)	0	3 (1.8)	3 (1.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
一般・全身障害および投与部位の状態 (cont.)				
発熱	3 (4.2)	1 (1.4)	3 (1.8)	4 (1.6)
腫脹	1 (1.4)	0	0	0
顔面腫脹	1 (1.4)	2 (2.8)	1 (0.6)	3 (1.2)
評価不能の事象	0	0	1 (0.6)	1 (0.4)
乾燥症	0	0	1 (0.6)	1 (0.4)
肝胆道系障害	2 (2.8)	2 (2.8)	1 (0.6)	3 (1.2)
胆石症	0	1 (1.4)	0	1 (0.4)
肝病変	1 (1.4)	0	0	0
脂肪肝	1 (1.4)	1 (1.4)	0	1 (0.4)
肝腫大	0	0	1 (0.6)	1 (0.4)
免疫系障害	0	2 (2.8)	4 (2.3)	6 (2.5)
薬物過敏症	0	1 (1.4)	0	1 (0.4)
過敏症	0	0	1 (0.6)	1 (0.4)
低γグロブリン血症	0	0	1 (0.6)	1 (0.4)
季節性アレルギー	0	0	2 (1.2)	2 (0.8)
4型過敏症	0	1 (1.4)	0	1 (0.4)
感染症および寄生虫症	75 (103.8)	55 (75.8)	164 (95.7)	219 (89.8)
急性副鼻腔炎	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (cont.)				
アデノウイルス結膜炎	0	0	1 (0.6)	1 (0.4)
アスペルギルス感染	1 (1.4)	0	0	0
気管支炎	0	0	3 (1.8)	3 (1.2)
COVID-19	12 (16.6)	9 (12.4)	29 (16.9)	38 (15.6)
蜂巣炎	1 (1.4)	0	1 (0.6)	1 (0.4)
結膜炎	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
膀胱炎	2 (2.8)	1 (1.4)	10 (5.8)	11 (4.5)
憩室炎	0	1 (1.4)	0	1 (0.4)
耳感染	0	1 (1.4)	1 (0.6)	2 (0.8)
大腸菌性尿路感染	1 (1.4)	0	0	0
眼感染	0	0	1 (0.6)	1 (0.4)
毛包炎	0	0	2 (1.2)	2 (0.8)
真菌性足感染	0	0	1 (0.6)	1 (0.4)
皮膚真菌感染	1 (1.4)	0	2 (1.2)	2 (0.8)
胃腸炎	3 (4.2)	1 (1.4)	0	1 (0.4)
歯肉炎	0	1 (1.4)	3 (1.8)	4 (1.6)
単純ヘルペス	3 (4.2)	0	1 (0.6)	1 (0.4)
帯状疱疹	2 (2.8)	3 (4.1)	5 (2.9)	8 (3.3)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (cont.)				
麦粒腫	0	0	1 (0.6)	1 (0.4)
インフルエンザ	1 (1.4)	0	3 (1.8)	3 (1.2)
潜伏結核	1 (1.4)	2 (2.8)	2 (1.2)	4 (1.6)
下気道感染	0	1 (1.4)	1 (0.6)	2 (0.8)
上咽頭炎	7 (9.7)	8 (11.0)	14 (8.2)	22 (9.0)
食道カンジダ症	0	0	1 (0.6)	1 (0.4)
爪真菌症	0	0	1 (0.6)	1 (0.4)
眼帯状疱疹	0	0	1 (0.6)	1 (0.4)
口腔カンジダ症	0	1 (1.4)	4 (2.3)	5 (2.0)
口腔ヘルペス	1 (1.4)	0	11 (6.4)	11 (4.5)
口腔感染	1 (1.4)	0	0	0
慢性中耳炎	0	0	1 (0.6)	1 (0.4)
爪囲炎	2 (2.8)	0	3 (1.8)	3 (1.2)
咽頭炎	1 (1.4)	2 (2.8)	2 (1.2)	4 (1.6)
肺炎	2 (2.8)	3 (4.1)	4 (2.3)	7 (2.9)
術後創感染	0	0	1 (0.6)	1 (0.4)
RSウイルス感染	0	2 (2.8)	0	2 (0.8)
気道感染	1 (1.4)	2 (2.8)	4 (2.3)	6 (2.5)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (cont.)				
ウイルス性気道感染	0	0	1 (0.6)	1 (0.4)
鼻炎	0	1 (1.4)	3 (1.8)	4 (1.6)
サルモネラ症	0	0	1 (0.6)	1 (0.4)
唾液腺炎	0	0	1 (0.6)	1 (0.4)
副鼻腔炎	2 (2.8)	2 (2.8)	5 (2.9)	7 (2.9)
皮膚感染	0	0	2 (1.2)	2 (0.8)
足部白癬	1 (1.4)	0	1 (0.6)	1 (0.4)
歯膿瘍	1 (1.4)	0	1 (0.6)	1 (0.4)
歯感染	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
気管気管支炎	0	0	2 (1.2)	2 (0.8)
上気道感染	7 (9.7)	1 (1.4)	10 (5.8)	11 (4.5)
尿路感染	16 (22.1)	9 (12.4)	13 (7.6)	22 (9.0)
細菌性尿路感染	1 (1.4)	0	0	0
尿路性敗血症	1 (1.4)	0	0	0
ウイルス感染	0	1 (1.4)	2 (1.2)	3 (1.2)
ウイルス性上気道感染	0	1 (1.4)	0	1 (0.4)
創傷感染	1 (1.4)	0	2 (1.2)	2 (0.8)
ブドウ球菌性創感染	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
傷害、中毒および処置合併症	15 (20.8)	11 (15.2)	44 (25.7)	55 (22.5)
術後貧血	0	0	1 (0.6)	1 (0.4)
足関節部骨折	0	1 (1.4)	0	1 (0.4)
節足動物咬傷	1 (1.4)	0	1 (0.6)	1 (0.4)
剥離骨折	0	0	1 (0.6)	1 (0.4)
骨挫傷	1 (1.4)	0	3 (1.8)	3 (1.2)
低温による損傷	1 (1.4)	0	0	0
挫傷	1 (1.4)	3 (4.1)	6 (3.5)	9 (3.7)
歯科修復不成功	1 (1.4)	0	0	0
上顎炎	0	0	1 (0.6)	1 (0.4)
転倒	3 (4.2)	1 (1.4)	8 (4.7)	9 (3.7)
足骨折	1 (1.4)	0	1 (0.6)	1 (0.4)
免疫反応	0	0	1 (0.6)	1 (0.4)
関節脱臼	0	0	2 (1.2)	2 (0.8)
靭帯捻挫	0	0	3 (1.8)	3 (1.2)
下肢骨折	0	0	1 (0.6)	1 (0.4)
肉離れ	1 (1.4)	0	1 (0.6)	1 (0.4)
術後創合併症	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
傷害、中毒および処置合併症 (cont.)				
処置による悪心	0	0	1 (0.6)	1 (0.4)
処置による疼痛	0	2 (2.8)	0	2 (0.8)
処置による気胸	0	0	1 (0.6)	1 (0.4)
肋骨骨折	0	0	2 (1.2)	2 (0.8)
肩甲骨骨折	1 (1.4)	0	0	0
植皮生着不全	0	0	1 (0.6)	1 (0.4)
皮膚裂傷	1 (1.4)	0	1 (0.6)	1 (0.4)
軟部組織損傷	1 (1.4)	0	1 (0.6)	1 (0.4)
脊椎圧迫骨折	1 (1.4)	0	1 (0.6)	1 (0.4)
ストレス骨折	1 (1.4)	1 (1.4)	0	1 (0.4)
縫合関連合併症	0	1 (1.4)	0	1 (0.4)
腱断裂	0	0	1 (0.6)	1 (0.4)
熱傷	0	0	1 (0.6)	1 (0.4)
胸椎骨折	0	1 (1.4)	0	1 (0.4)
歯牙破折	0	0	1 (0.6)	1 (0.4)
創傷	0	1 (1.4)	1 (0.6)	2 (0.8)
手首関節骨折	0	0	1 (0.6)	1 (0.4)
臨床検査	23 (31.8)	1 (1.4)	34 (19.8)	35 (14.3)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
臨床検査 (cont.)				
アラニンアミノトランスフェラーゼ増加	0	0	3 (1.8)	3 (1.2)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	2 (1.2)	2 (0.8)
血中アルカリホスファターゼ増加	1 (1.4)	0	0	0
血中コレステロール増加	1 (1.4)	0	0	0
血中クレアチンホスホキナーゼ増加	0	0	8 (4.7)	8 (3.3)
血中クレアチニン増加	4 (5.5)	0	1 (0.6)	1 (0.4)
血中ブドウ糖増加	1 (1.4)	0	0	0
血中トリグリセリド増加	0	0	1 (0.6)	1 (0.4)
血中尿素増加	1 (1.4)	0	0	0
血中尿酸増加	1 (1.4)	0	0	0
体温上昇	0	0	1 (0.6)	1 (0.4)
心雑音	0	0	1 (0.6)	1 (0.4)
Γ-グルタミルトランスフェラーゼ増加	1 (1.4)	0	0	0
ヘマトクリット減少	1 (1.4)	0	0	0
ヘモグロビン減少	2 (2.8)	0	0	0
B型肝炎ウイルス検査陽性	0	0	1 (0.6)	1 (0.4)
高比重リポ蛋白増加	0	0	1 (0.6)	1 (0.4)
眼圧上昇	1 (1.4)	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
臨床検査 (cont.)				
脂質増加	0	0	1 (0.6)	1 (0.4)
肝機能検査異常	0	0	1 (0.6)	1 (0.4)
尿中亜硝酸塩陽性	0	0	1 (0.6)	1 (0.4)
便潜血陽性	0	0	1 (0.6)	1 (0.4)
血小板数増加	0	0	1 (0.6)	1 (0.4)
前立腺特異性抗原増加	1 (1.4)	0	0	0
赤血球数減少	1 (1.4)	0	0	0
血沈亢進	2 (2.8)	0	2 (1.2)	2 (0.8)
尿中赤血球陽性	0	0	1 (0.6)	1 (0.4)
腎機能検査異常	1 (1.4)	0	0	0
トロポニンT増加	0	0	1 (0.6)	1 (0.4)
ビタミンB12減少	0	0	1 (0.6)	1 (0.4)
体重減少	2 (2.8)	0	0	0
体重増加	2 (2.8)	1 (1.4)	3 (1.8)	4 (1.6)
白血球数減少	0	0	1 (0.6)	1 (0.4)
代謝および栄養障害	9 (12.5)	7 (9.6)	25 (14.6)	32 (13.1)
食欲減退	1 (1.4)	1 (1.4)	0	1 (0.4)
糖尿病	1 (1.4)	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
代謝および栄養障害 (cont.)				
脂質異常症	0	1 (1.4)	2 (1.2)	3 (1.2)
体液貯留	0	0	1 (0.6)	1 (0.4)
葉酸欠乏	1 (1.4)	0	0	0
高コレステロール血症	0	2 (2.8)	5 (2.9)	7 (2.9)
高血糖	0	0	1 (0.6)	1 (0.4)
高脂血症	0	0	1 (0.6)	1 (0.4)
高尿酸血症	0	1 (1.4)	0	1 (0.4)
低カルシウム血症	0	0	1 (0.6)	1 (0.4)
低クロール血症	0	0	1 (0.6)	1 (0.4)
低血糖	0	0	1 (0.6)	1 (0.4)
低カリウム血症	3 (4.2)	1 (1.4)	4 (2.3)	5 (2.0)
低ナトリウム血症	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
低蛋白血症	0	0	1 (0.6)	1 (0.4)
鉄欠乏	1 (1.4)	0	0	0
脂肪腫症	0	0	1 (0.6)	1 (0.4)
ステロイド糖尿病	1 (1.4)	0	2 (1.2)	2 (0.8)
ビタミンD欠乏	0	0	1 (0.6)	1 (0.4)
筋骨格系および結合組織障害	67 (92.7)	34 (46.8)	141 (82.3)	175 (71.7)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (cont.)				
関節痛	15 (20.8)	3 (4.1)	24 (14.0)	27 (11.1)
関節炎	0	0	1 (0.6)	1 (0.4)
関節障害	1 (1.4)	0	0	0
背部痛	9 (12.5)	3 (4.1)	21 (12.3)	24 (9.8)
滑液包炎	0	0	3 (1.8)	3 (1.2)
頚部脊柱管狭窄症	0	0	1 (0.6)	1 (0.4)
線維筋痛	0	2 (2.8)	2 (1.2)	4 (1.6)
側腹部痛	0	0	1 (0.6)	1 (0.4)
大転子疼痛症候群	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
単径部痛	0	0	1 (0.6)	1 (0.4)
椎間板障害	1 (1.4)	0	0	0
椎間板突出	3 (4.2)	1 (1.4)	2 (1.2)	3 (1.2)
関節滲出液	0	0	1 (0.6)	1 (0.4)
関節可動域低下	1 (1.4)	0	1 (0.6)	1 (0.4)
関節腫脹	0	0	1 (0.6)	1 (0.4)
腰部脊柱管狭窄症	1 (1.4)	1 (1.4)	0	1 (0.4)
半月板変性	0	0	1 (0.6)	1 (0.4)
筋痙縮	4 (5.5)	1 (1.4)	7 (4.1)	8 (3.3)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (cont.)				
筋力低下	2 (2.8)	1 (1.4)	2 (1.2)	3 (1.2)
筋骨格系胸痛	2 (2.8)	1 (1.4)	2 (1.2)	3 (1.2)
筋骨格障害	0	0	1 (0.6)	1 (0.4)
筋骨格痛	0	0	2 (1.2)	2 (0.8)
筋骨格硬直	3 (4.2)	0	1 (0.6)	1 (0.4)
筋肉痛	2 (2.8)	3 (4.1)	6 (3.5)	9 (3.7)
ミオパチー	0	1 (1.4)	1 (0.6)	2 (0.8)
頚部痛	4 (5.5)	0	5 (2.9)	5 (2.0)
変形性関節症	4 (5.5)	1 (1.4)	12 (7.0)	13 (5.3)
骨端症	0	0	1 (0.6)	1 (0.4)
骨減少症	0	0	3 (1.8)	3 (1.2)
骨粗鬆症	3 (4.2)	1 (1.4)	5 (2.9)	6 (2.5)
四肢痛	4 (5.5)	1 (1.4)	16 (9.3)	17 (7.0)
顎痛	0	3 (4.1)	2 (1.2)	5 (2.0)
関節周囲炎	0	0	1 (0.6)	1 (0.4)
足底筋膜炎	0	0	1 (0.6)	1 (0.4)
リウマチ性多発筋痛	1 (1.4)	1 (1.4)	0	1 (0.4)
肩回旋筋腱板症候群	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (cont.)				
肩甲帯痛	0	1 (1.4)	0	1 (0.4)
シェーグレン症候群	1 (1.4)	0	1 (0.6)	1 (0.4)
脊椎痛	1 (1.4)	0	2 (1.2)	2 (0.8)
脊柱管狭窄症	0	0	1 (0.6)	1 (0.4)
脊椎滑液嚢腫	0	0	1 (0.6)	1 (0.4)
滑液嚢腫	1 (1.4)	0	1 (0.6)	1 (0.4)
顎関節症候群	0	1 (1.4)	0	1 (0.4)
腱障害	1 (1.4)	2 (2.8)	1 (0.6)	3 (1.2)
腱痛	0	1 (1.4)	0	1 (0.4)
腱炎	0	0	2 (1.2)	2 (0.8)
腱鞘炎	0	0	1 (0.6)	1 (0.4)
狭窄性腱鞘炎	1 (1.4)	0	1 (0.6)	1 (0.4)
弾発指	0	2 (2.8)	0	2 (0.8)
椎間孔狭窄	0	1 (1.4)	0	1 (0.4)
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)	4 (5.5)	4 (5.5)	17 (9.9)	21 (8.6)
副腎腺腫	0	1 (1.4)	0	1 (0.4)
血管筋脂肪腫	1 (1.4)	0	0	0
基底細胞癌	2 (2.8)	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (cont.)				
良性毛包腫瘍	0	0	1 (0.6)	1 (0.4)
悪性黒子	0	0	1 (0.6)	1 (0.4)
脂肪腫	0	0	1 (0.6)	1 (0.4)
肺腺癌	0	1 (1.4)	0	1 (0.4)
メラノサイト性母斑	0	0	1 (0.6)	1 (0.4)
骨髄異形成症候群	0	0	1 (0.6)	1 (0.4)
粘液腫	0	0	1 (0.6)	1 (0.4)
皮膚の新生物	0	0	1 (0.6)	1 (0.4)
神経線維腫	1 (1.4)	0	0	0
甲状腺乳頭癌	0	1 (1.4)	0	1 (0.4)
前立腺癌	0	0	1 (0.6)	1 (0.4)
前立腺腺腫	0	0	1 (0.6)	1 (0.4)
脂漏性角化症	0	0	2 (1.2)	2 (0.8)
皮膚乳頭腫	0	1 (1.4)	0	1 (0.4)
皮膚有棘細胞癌	0	0	5 (2.9)	5 (2.0)
神経系障害	30 (41.5)	32 (44.1)	76 (44.3)	108 (44.3)
健忘	0	0	1 (0.6)	1 (0.4)
無嗅覚	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (cont.)				
平衡障害	1 (1.4)	0	0	0
ブレインフォグ	1 (1.4)	0	0	0
灼熱感	0	1 (1.4)	2 (1.2)	3 (1.2)
頚動脈狭窄	0	0	2 (1.2)	2 (0.8)
手根管症候群	0	0	3 (1.8)	3 (1.2)
脳アミロイド血管障害	1 (1.4)	0	0	0
脳脊髄瘻	1 (1.4)	0	0	0
頚腕症候群	0	0	1 (0.6)	1 (0.4)
注意力障害	0	1 (1.4)	0	1 (0.4)
浮動性めまい	6 (8.3)	2 (2.8)	4 (2.3)	6 (2.5)
労作性めまい	0	0	1 (0.6)	1 (0.4)
異常感覚	1 (1.4)	0	0	0
ジストニア	0	0	1 (0.6)	1 (0.4)
電気ショック様感覚	0	1 (1.4)	0	1 (0.4)
頭痛	7 (9.7)	11 (15.2)	26 (15.2)	37 (15.2)
感覚鈍麻	0	0	4 (2.3)	4 (1.6)
味覚減退	0	1 (1.4)	0	1 (0.4)
脳圧低下	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (cont.)				
腰髄神経根障害	1 (1.4)	0	1 (0.6)	1 (0.4)
記憶障害	0	1 (1.4)	1 (0.6)	2 (0.8)
片頭痛	1 (1.4)	0	0	0
不随意性筋収縮	0	0	1 (0.6)	1 (0.4)
神経痛	1 (1.4)	0	0	0
神経痛性筋萎縮症	0	1 (1.4)	0	1 (0.4)
末梢性ニューロパチー	1 (1.4)	0	0	0
後頭神経痛	0	0	4 (2.3)	4 (1.6)
視神経炎	1 (1.4)	0	0	0
錯感覚	1 (1.4)	2 (2.8)	2 (1.2)	4 (1.6)
多発ニューロパチー	1 (1.4)	0	0	0
ヘルペス後神経痛	0	1 (1.4)	1 (0.6)	2 (0.8)
失神寸前の状態	0	0	3 (1.8)	3 (1.2)
偽性根症候群	0	1 (1.4)	1 (0.6)	2 (0.8)
精神運動亢進	0	0	1 (0.6)	1 (0.4)
4分の1盲	0	0	1 (0.6)	1 (0.4)
神経根障害	0	0	3 (1.8)	3 (1.2)
下肢静止不能症候群	0	0	2 (1.2)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (cont.)				
坐骨神経痛	1 (1.4)	3 (4.1)	4 (2.3)	7 (2.9)
失神	2 (2.8)	0	1 (0.6)	1 (0.4)
緊張性頭痛	0	2 (2.8)	2 (1.2)	4 (1.6)
一過性失語症	0	1 (1.4)	0	1 (0.4)
一過性脳虚血発作	0	1 (1.4)	0	1 (0.4)
振戦	2 (2.8)	1 (1.4)	0	1 (0.4)
トンネル状視野	0	0	1 (0.6)	1 (0.4)
椎骨動脈狭窄	0	0	1 (0.6)	1 (0.4)
精神障害	7 (9.7)	4 (5.5)	9 (5.3)	13 (5.3)
不安	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
歯ぎしり	0	0	1 (0.6)	1 (0.4)
錯乱状態	0	0	1 (0.6)	1 (0.4)
譫妄	1 (1.4)	0	0	0
抑うつ気分	0	1 (1.4)	1 (0.6)	2 (0.8)
不眠症	2 (2.8)	0	3 (1.8)	3 (1.2)
リビドー減退	0	1 (1.4)	0	1 (0.4)
躁病	1 (1.4)	0	0	0
混合性不安抑うつ障害	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
精神障害 (cont.)				
神経過敏	1 (1.4)	0	1 (0.6)	1 (0.4)
落ち着きのなさ	0	1 (1.4)	0	1 (0.4)
腎および尿路障害	11 (15.2)	2 (2.8)	7 (4.1)	9 (3.7)
急性腎障害	1 (1.4)	0	0	0
血尿	3 (4.2)	0	1 (0.6)	1 (0.4)
緊張性膀胱	1 (1.4)	0	0	0
腎結石症	1 (1.4)	1 (1.4)	0	1 (0.4)
夜間頻尿	0	0	1 (0.6)	1 (0.4)
頻尿	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
蛋白尿	1 (1.4)	0	0	0
腎仙痛	1 (1.4)	0	0	0
腎嚢胞	1 (1.4)	0	0	0
腎損傷	0	0	2 (1.2)	2 (0.8)
尿道狭窄	0	0	1 (0.6)	1 (0.4)
尿失禁	1 (1.4)	0	0	0
生殖系および乳房障害	2 (2.8)	3 (4.1)	7 (4.1)	10 (4.1)
亀頭包皮炎	1 (1.4)	0	0	0
乳房腫瘤	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
生殖系および乳房障害 (cont.)				
乳房痛	0	0	1 (0.6)	1 (0.4)
膀胱瘤	0	0	1 (0.6)	1 (0.4)
勃起不全	0	1 (1.4)	1 (0.6)	2 (0.8)
乳頭痛	0	0	1 (0.6)	1 (0.4)
骨盤痛	0	0	1 (0.6)	1 (0.4)
前立腺腫大	0	0	1 (0.6)	1 (0.4)
外陰腟灼熱感	0	1 (1.4)	0	1 (0.4)
外陰腟乾燥	0	1 (1.4)	0	1 (0.4)
外陰腟そう痒症	1 (1.4)	0	0	0
呼吸器、胸郭および縦隔障害	11 (15.2)	9 (12.4)	32 (18.7)	41 (16.8)
喘息	0	0	4 (2.3)	4 (1.6)
慢性気管支炎	0	0	1 (0.6)	1 (0.4)
気管支痙攣	0	0	1 (0.6)	1 (0.4)
咳嗽	5 (6.9)	3 (4.1)	10 (5.8)	13 (5.3)
呼吸困難	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
労作性呼吸困難	1 (1.4)	0	0	0
鼻出血	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
下咽頭癒着	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
呼吸器、胸郭および縦隔障害 (cont.)				
鼻閉	0	0	1 (0.6)	1 (0.4)
口腔咽頭痛	1 (1.4)	1 (1.4)	3 (1.8)	4 (1.6)
起坐呼吸	0	1 (1.4)	0	1 (0.4)
胸水	0	0	1 (0.6)	1 (0.4)
湿性咳嗽	0	0	1 (0.6)	1 (0.4)
肺塞栓症	0	0	1 (0.6)	1 (0.4)
肺腫瘤	0	2 (2.8)	0	2 (0.8)
呼吸障害	0	0	1 (0.6)	1 (0.4)
アレルギー性鼻炎	0	0	1 (0.6)	1 (0.4)
鼻漏	1 (1.4)	0	2 (1.2)	2 (0.8)
咳払い	1 (1.4)	0	0	0
咽喉刺激感	0	0	1 (0.6)	1 (0.4)
皮膚および皮下組織障害	19 (26.3)	9 (12.4)	48 (28.0)	57 (23.4)
ざ瘡	0	0	6 (3.5)	6 (2.5)
光線角化症	0	1 (1.4)	1 (0.6)	2 (0.8)
脱毛症	0	0	3 (1.8)	3 (1.2)
円形脱毛症	0	0	1 (0.6)	1 (0.4)
水疱	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (cont.)				
冷汗	1 (1.4)	0	0	0
皮膚嚢腫	0	0	1 (0.6)	1 (0.4)
皮膚炎	0	0	1 (0.6)	1 (0.4)
アレルギー性皮膚炎	1 (1.4)	0	0	0
接触皮膚炎	0	0	2 (1.2)	2 (0.8)
びまん性脱毛症	0	0	1 (0.6)	1 (0.4)
皮膚乾燥	1 (1.4)	0	2 (1.2)	2 (0.8)
斑状出血	1 (1.4)	0	0	0
湿疹	0	0	1 (0.6)	1 (0.4)
紅斑	1 (1.4)	0	2 (1.2)	2 (0.8)
毛髪成長異常	0	1 (1.4)	0	1 (0.4)
男性型多毛症	0	0	1 (0.6)	1 (0.4)
多汗症	0	1 (1.4)	2 (1.2)	3 (1.2)
過角化	1 (1.4)	1 (1.4)	0	1 (0.4)
汗疹	0	0	1 (0.6)	1 (0.4)
爪変色	0	0	1 (0.6)	1 (0.4)
寝汗	1 (1.4)	2 (2.8)	1 (0.6)	3 (1.2)
爪破損	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (cont.)				
皮膚疼痛	0	0	1 (0.6)	1 (0.4)
丘疹	1 (1.4)	0	0	0
類天疱瘡	1 (1.4)	0	0	0
口囲皮膚炎	0	0	1 (0.6)	1 (0.4)
痒疹	1 (1.4)	0	0	0
そう痒症	1 (1.4)	0	0	0
乾癬	1 (1.4)	0	0	0
発疹	2 (2.8)	2 (2.8)	8 (4.7)	10 (4.1)
斑状皮疹	1 (1.4)	0	0	0
斑状丘疹状皮疹	0	1 (1.4)	1 (0.6)	2 (0.8)
酒さ	0	0	2 (1.2)	2 (0.8)
痂皮	0	0	1 (0.6)	1 (0.4)
脂漏性皮膚炎	1 (1.4)	0	0	0
皮膚硬結	0	0	1 (0.6)	1 (0.4)
皮膚病変	0	0	1 (0.6)	1 (0.4)
皮膚潰瘍	2 (2.8)	0	2 (1.2)	2 (0.8)
うっ滞性皮膚炎	0	0	1 (0.6)	1 (0.4)
黄色皮膚	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
血管障害	29 (40.1)	16 (22.0)	47 (27.4)	63 (25.8)
大動脈瘤	1 (1.4)	0	0	0
大動脈炎	1 (1.4)	0	0	0
動脈出血	0	1 (1.4)	0	1 (0.4)
動脈硬化症	1 (1.4)	0	0	0
巨細胞性動脈炎	13 (18.0)	6 (8.3)	20 (11.7)	26 (10.7)
血腫	3 (4.2)	0	1 (0.6)	1 (0.4)
高血圧	5 (6.9)	7 (9.6)	20 (11.7)	27 (11.1)
間欠性跛行	1 (1.4)	0	1 (0.6)	1 (0.4)
リンパ浮腫	0	0	1 (0.6)	1 (0.4)
リンパうっ滞	0	0	1 (0.6)	1 (0.4)
起立性低血圧	0	0	1 (0.6)	1 (0.4)
末梢冷感	1 (1.4)	0	0	0
末梢静脈疾患	1 (1.4)	0	0	0
レイノー現象	1 (1.4)	1 (1.4)	0	1 (0.4)
血栓性静脈炎	0	1 (1.4)	0	1 (0.4)
静脈瘤	1 (1.4)	0	1 (0.6)	1 (0.4)
白衣性高血圧	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

表3

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ABT-494 (GIANT CELL ARTERITIS)
STUDY M16-852 (CUTOFF 06FEB2024)
R&D/23/2455 - CLINICAL/STATISTICAL

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
Any adverse event	106 (94.6)	102 (95.3)	202 (96.7)	304 (96.2)
No reasonable possibility	57 (50.9)	60 (56.1)	92 (44.0)	152 (48.1)
Reasonable possibility	49 (43.8)	42 (39.3)	110 (52.6)	152 (48.1)
血液およびリンパ系障害	6 (5.4)	4 (3.7)	19 (9.1)	23 (7.3)
No reasonable possibility	5 (4.5)	3 (2.8)	13 (6.2)	16 (5.1)
Reasonable possibility	1 (0.9)	1 (0.9)	6 (2.9)	7 (2.2)
貧血	2 (1.8)	3 (2.8)	9 (4.3)	12 (3.8)
No reasonable possibility	2 (1.8)	2 (1.9)	5 (2.4)	7 (2.2)
Reasonable possibility	0	1 (0.9)	4 (1.9)	5 (1.6)
内出血発生の増加傾向	1 (0.9)	1 (0.9)	4 (1.9)	5 (1.6)
No reasonable possibility	1 (0.9)	1 (0.9)	4 (1.9)	5 (1.6)
鉄欠乏性貧血	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
血液およびリンパ系障害 (Cont.)				
血小板増加症	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
大赤血球症	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	0	0
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
好酸球増加症	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
白血球増加症	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
リンパ球増加症	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
血液およびリンパ系障害 (Cont.)				
リンパ球減少症	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
好中球増加症	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
白血球減少症	1 (0.9)	0	0	0
Reasonable possibility	1 (0.9)	0	0	0
好中球減少症	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
心臓障害	15 (13.4)	10 (9.3)	23 (11.0)	33 (10.4)
No reasonable possibility	14 (12.5)	10 (9.3)	19 (9.1)	29 (9.2)
Reasonable possibility	1 (0.9)	0	4 (1.9)	4 (1.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
心臓障害 (Cont.)				
動悸	2 (1.8)	2 (1.9)	4 (1.9)	6 (1.9)
No reasonable possibility	2 (1.8)	2 (1.9)	3 (1.4)	5 (1.6)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
心房細動	2 (1.8)	0	4 (1.9)	4 (1.3)
No reasonable possibility	2 (1.8)	0	3 (1.4)	3 (0.9)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
心不全	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
うっ血性心不全	0	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	0	1 (0.9)	2 (1.0)	3 (0.9)
三尖弁閉鎖不全症	0	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	0	1 (0.9)	2 (1.0)	3 (0.9)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
心臓障害 (Cont.)				
高血圧性心筋症	0	2 (1.9)	0	2 (0.6)
No reasonable possibility	0	2 (1.9)	0	2 (0.6)
冠動脈硬化症	2 (1.8)	0	1 (0.5)	1 (0.3)
No reasonable possibility	2 (1.8)	0	1 (0.5)	1 (0.3)
僧帽弁閉鎖不全症	2 (1.8)	0	1 (0.5)	1 (0.3)
No reasonable possibility	2 (1.8)	0	1 (0.5)	1 (0.3)
頻脈	2 (1.8)	0	1 (0.5)	1 (0.3)
No reasonable possibility	2 (1.8)	0	0	0
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
第一度房室ブロック	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
心臓障害 (Cont.)				
大動脈弁石灰化	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
大動脈弁狭窄	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
心房頻脈	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
心臓弁膜疾患	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
肺性心	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
心臓障害 (Cont.)				
冠動脈疾患	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
冠動脈入口部狭窄	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
拡張機能障害	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
期外収縮	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
高血圧性心疾患	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
心臓障害 (Cont.)				
虚血性心筋症	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
左室肥大	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
右室不全	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
洞性徐脈	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
洞性頻脈	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
心臓障害 (Cont.)				
狭心症	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
大動脈弁疾患	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
大動脈弁閉鎖不全症	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
右脚ブロック	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
線維性心内膜炎	1 (0.9)	0	0	0
Reasonable possibility	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
心臓障害 (Cont.)				
心筋虚血	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
洞性不整脈	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
心室性期外収縮	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
先天性、家族性および遺伝性障害	2 (1.8)	1 (0.9)	0	1 (0.3)
No reasonable possibility	2 (1.8)	1 (0.9)	0	1 (0.3)
歯牙形成不全	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
先天性、家族性および遺伝性障害 (Cont.)				
心房中隔欠損症	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
播種状表在性光線性汗孔角化症	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
耳および迷路障害	4 (3.6)	9 (8.4)	15 (7.2)	24 (7.6)
No reasonable possibility	4 (3.6)	9 (8.4)	14 (6.7)	23 (7.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
回転性めまい	2 (1.8)	4 (3.7)	7 (3.3)	11 (3.5)
No reasonable possibility	2 (1.8)	4 (3.7)	6 (2.9)	10 (3.2)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
耳鳴	2 (1.8)	3 (2.8)	5 (2.4)	8 (2.5)
No reasonable possibility	2 (1.8)	3 (2.8)	5 (2.4)	8 (2.5)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
耳および迷路障害 (Cont.)				
耳痛	0	0	5 (2.4)	5 (1.6)
No reasonable possibility	0	0	5 (2.4)	5 (1.6)
感音性難聴	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
耳不快感	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
聴力低下	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
内分泌障害	5 (4.5)	9 (8.4)	9 (4.3)	18 (5.7)
No reasonable possibility	5 (4.5)	9 (8.4)	9 (4.3)	18 (5.7)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
内分泌障害 (Cont.)				
クッシング様症状	0	5 (4.7)	4 (1.9)	9 (2.8)
No reasonable possibility	0	5 (4.7)	4 (1.9)	9 (2.8)
甲状腺腫瘤	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
クッシング症候群	2 (1.8)	0	2 (1.0)	2 (0.6)
No reasonable possibility	2 (1.8)	0	2 (1.0)	2 (0.6)
甲状腺腫	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
甲状腺機能亢進症	0	2 (1.9)	0	2 (0.6)
No reasonable possibility	0	2 (1.9)	0	2 (0.6)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
内分泌障害 (Cont.)				
副腎抑制	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
眼障害	22 (19.6)	21 (19.6)	56 (26.8)	77 (24.4)
No reasonable possibility	20 (17.9)	18 (16.8)	52 (24.9)	70 (22.2)
Reasonable possibility	2 (1.8)	3 (2.8)	4 (1.9)	7 (2.2)
白内障	2 (1.8)	6 (5.6)	10 (4.8)	16 (5.1)
No reasonable possibility	2 (1.8)	4 (3.7)	10 (4.8)	14 (4.4)
Reasonable possibility	0	2 (1.9)	0	2 (0.6)
霧視	4 (3.6)	5 (4.7)	6 (2.9)	11 (3.5)
No reasonable possibility	4 (3.6)	4 (3.7)	6 (2.9)	10 (3.2)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
ドライアイ	3 (2.7)	2 (1.9)	8 (3.8)	10 (3.2)
No reasonable possibility	3 (2.7)	2 (1.9)	8 (3.8)	10 (3.2)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
眼障害 (Cont.)				
結膜出血	1 (0.9)	1 (0.9)	5 (2.4)	6 (1.9)
No reasonable possibility	1 (0.9)	1 (0.9)	5 (2.4)	6 (1.9)
眼瞼炎	1 (0.9)	2 (1.9)	3 (1.4)	5 (1.6)
No reasonable possibility	1 (0.9)	2 (1.9)	2 (1.0)	4 (1.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
眼痛	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
No reasonable possibility	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
緑内障	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
No reasonable possibility	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
硝子体浮遊物	3 (2.7)	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	3 (2.7)	1 (0.9)	2 (1.0)	3 (0.9)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
眼障害 (Cont.)				
高眼圧症	0	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	0	1 (0.9)	2 (1.0)	3 (0.9)
眼部不快感	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
霰粒腫	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
複視	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
眼の炎症	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
眼障害 (Cont.)				
眼部腫脹	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
眼の異物感	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
光視症	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
視野欠損	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
視力障害	2 (1.8)	0	1 (0.5)	1 (0.3)
No reasonable possibility	2 (1.8)	0	0	0
Reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
眼障害 (Cont.)				
硝子体剥離	2 (1.8)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
Reasonable possibility	1 (0.9)	0	0	0
眼刺激	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
視力低下	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
加齢黄斑変性	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
眼瞼痙攣	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
眼障害 (Cont.)				
角膜浮腫	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
眼出血	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
眼瞼下垂	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
遠視	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
黄斑変性	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
眼障害 (Cont.)				
黄斑浮腫	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
眼充血	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
開放隅角緑内障	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
視神経萎縮	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
視神経乳頭出血	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
眼障害 (Cont.)				
眼窩浮腫	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
眼窩周囲痛	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
羞明	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
老視	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
網膜剥離	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
眼障害 (Cont.)				
網膜出血	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
網膜裂孔	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
眼瞼腫脹	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
流涙増加	2 (1.8)	0	0	0
No reasonable possibility	2 (1.8)	0	0	0
アレルギー性結膜炎	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
眼障害 (Cont.)				
散瞳	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
眼窩脂肪ヘルニア	1 (0.9)	0	0	0
Reasonable possibility	1 (0.9)	0	0	0
後嚢部混濁	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
胃腸障害	37 (33.0)	31 (29.0)	93 (44.5)	124 (39.2)
No reasonable possibility	29 (25.9)	25 (23.4)	75 (35.9)	100 (31.6)
Reasonable possibility	8 (7.1)	6 (5.6)	18 (8.6)	24 (7.6)
下痢	12 (10.7)	5 (4.7)	18 (8.6)	23 (7.3)
No reasonable possibility	10 (8.9)	4 (3.7)	12 (5.7)	16 (5.1)
Reasonable possibility	2 (1.8)	1 (0.9)	6 (2.9)	7 (2.2)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
胃腸障害 (Cont.)				
便秘	2 (1.8)	8 (7.5)	11 (5.3)	19 (6.0)
No reasonable possibility	2 (1.8)	8 (7.5)	9 (4.3)	17 (5.4)
Reasonable possibility	0	0	2 (1.0)	2 (0.6)
悪心	4 (3.6)	6 (5.6)	11 (5.3)	17 (5.4)
No reasonable possibility	3 (2.7)	5 (4.7)	7 (3.3)	12 (3.8)
Reasonable possibility	1 (0.9)	1 (0.9)	4 (1.9)	5 (1.6)
消化不良	3 (2.7)	2 (1.9)	10 (4.8)	12 (3.8)
No reasonable possibility	2 (1.8)	2 (1.9)	8 (3.8)	10 (3.2)
Reasonable possibility	1 (0.9)	0	2 (1.0)	2 (0.6)
上腹部痛	5 (4.5)	0	11 (5.3)	11 (3.5)
No reasonable possibility	2 (1.8)	0	8 (3.8)	8 (2.5)
Reasonable possibility	3 (2.7)	0	3 (1.4)	3 (0.9)
腹痛	4 (3.6)	1 (0.9)	8 (3.8)	9 (2.8)
No reasonable possibility	4 (3.6)	1 (0.9)	7 (3.3)	8 (2.5)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
胃食道逆流性疾患	2 (1.8)	0	9 (4.3)	9 (2.8)
No reasonable possibility	2 (1.8)	0	8 (3.8)	8 (2.5)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
歯痛	2 (1.8)	0	7 (3.3)	7 (2.2)
No reasonable possibility	2 (1.8)	0	7 (3.3)	7 (2.2)
嘔吐	1 (0.9)	2 (1.9)	5 (2.4)	7 (2.2)
No reasonable possibility	1 (0.9)	2 (1.9)	4 (1.9)	6 (1.9)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
下腹部痛	2 (1.8)	2 (1.9)	3 (1.4)	5 (1.6)
No reasonable possibility	1 (0.9)	2 (1.9)	2 (1.0)	4 (1.3)
Reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
アフタ性潰瘍	1 (0.9)	1 (0.9)	4 (1.9)	5 (1.6)
No reasonable possibility	1 (0.9)	0	3 (1.4)	3 (0.9)
Reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
腹部膨満	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
No reasonable possibility	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
口内乾燥	1 (0.9)	2 (1.9)	2 (1.0)	4 (1.3)
No reasonable possibility	1 (0.9)	2 (1.9)	2 (1.0)	4 (1.3)
嚥下障害	0	2 (1.9)	1 (0.5)	3 (0.9)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
歯肉痛	0	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	0	1 (0.9)	2 (1.0)	3 (0.9)
痔核	0	0	3 (1.4)	3 (0.9)
No reasonable possibility	0	0	3 (1.4)	3 (0.9)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
口腔内潰瘍形成	0	0	3 (1.4)	3 (0.9)
No reasonable possibility	0	0	3 (1.4)	3 (0.9)
大腸ポリープ	3 (2.7)	0	2 (1.0)	2 (0.6)
No reasonable possibility	3 (2.7)	0	2 (1.0)	2 (0.6)
胃炎	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
腸憩室	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
齲歯	1 (0.9)	1 (0.9)	0	1 (0.3)
No reasonable possibility	1 (0.9)	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
鼓腸	1 (0.9)	1 (0.9)	0	1 (0.3)
No reasonable possibility	1 (0.9)	0	0	0
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
排便回数増加	1 (0.9)	1 (0.9)	0	1 (0.3)
No reasonable possibility	1 (0.9)	0	0	0
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
膵嚢胞	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
裂肛	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
口唇炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
虚血性大腸炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
潰瘍性大腸炎	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
十二指腸炎	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
十二指腸胃逆流	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
消化器痛	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
歯肉障害	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
痔出血	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
歯の知覚過敏	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
鼠径ヘルニア	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
口唇腫脹	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
腰ヘルニア	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
マロリー・ワイス症候群	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
非感染性歯肉炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
膵臓障害	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
膵炎	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
慢性膵炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
唾液腺痛	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
口内炎	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
舌不快感	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
舌潰瘍	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
胃腸障害 (Cont.)				
歯の障害	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
腹部不快感	2 (1.8)	0	0	0
No reasonable possibility	2 (1.8)	0	0	0
急性膵炎	2 (1.8)	0	0	0
No reasonable possibility	2 (1.8)	0	0	0
慢性胃炎	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
大腸炎	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
胃腸障害 (Cont.)				
血便排泄	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
歯状態不良	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
直腸出血	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
一般・全身障害および投与部位の状態	21 (18.8)	21 (19.6)	73 (34.9)	94 (29.7)
No reasonable possibility	19 (17.0)	20 (18.7)	60 (28.7)	80 (25.3)
Reasonable possibility	2 (1.8)	1 (0.9)	13 (6.2)	14 (4.4)
疲労	6 (5.4)	4 (3.7)	19 (9.1)	23 (7.3)
No reasonable possibility	5 (4.5)	4 (3.7)	17 (8.1)	21 (6.6)
Reasonable possibility	1 (0.9)	0	2 (1.0)	2 (0.6)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
末梢性浮腫	3 (2.7)	7 (6.5)	16 (7.7)	23 (7.3)
No reasonable possibility	3 (2.7)	7 (6.5)	12 (5.7)	19 (6.0)
Reasonable possibility	0	0	4 (1.9)	4 (1.3)
発熱	2 (1.8)	4 (3.7)	9 (4.3)	13 (4.1)
No reasonable possibility	2 (1.8)	3 (2.8)	7 (3.3)	10 (3.2)
Reasonable possibility	0	1 (0.9)	2 (1.0)	3 (0.9)
胸痛	3 (2.7)	2 (1.9)	7 (3.3)	9 (2.8)
No reasonable possibility	3 (2.7)	2 (1.9)	4 (1.9)	6 (1.9)
Reasonable possibility	0	0	3 (1.4)	3 (0.9)
末梢腫脹	3 (2.7)	0	5 (2.4)	5 (1.6)
No reasonable possibility	3 (2.7)	0	5 (2.4)	5 (1.6)
倦怠感	1 (0.9)	0	5 (2.4)	5 (1.6)
No reasonable possibility	1 (0.9)	0	5 (2.4)	5 (1.6)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
無力症	1 (0.9)	0	3 (1.4)	3 (0.9)
No reasonable possibility	1 (0.9)	0	3 (1.4)	3 (0.9)
顔面腫脹	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	0	1 (0.9)	2 (1.0)	3 (0.9)
Reasonable possibility	1 (0.9)	0	0	0
インフルエンザ様疾患	2 (1.8)	0	2 (1.0)	2 (0.6)
No reasonable possibility	2 (1.8)	0	2 (1.0)	2 (0.6)
疼痛	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
胸部不快感	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
悪寒	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
浮腫	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
非心臓性胸痛	2 (1.8)	0	1 (0.5)	1 (0.3)
No reasonable possibility	2 (1.8)	0	1 (0.5)	1 (0.3)
歩行障害	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
不明確な障害	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
注射部位疼痛	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
医薬品副作用	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
死亡	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
不快感	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
顔面浮腫	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
脂肪組織増加	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
冷感	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
熱感	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
小結節	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
治療非遵守	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
評価不能の事象	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
ワクチン接種部位疼痛	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
乾燥症	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
疾患前駆期	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
体調不良	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

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Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
腫脹	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
肝胆道系障害	6 (5.4)	1 (0.9)	6 (2.9)	7 (2.2)
No reasonable possibility	4 (3.6)	1 (0.9)	6 (2.9)	7 (2.2)
Reasonable possibility	2 (1.8)	0	0	0
肝細胞融解	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	1 (0.9)	0	0	0
肝病変	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
胆道ジスキネジア	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

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Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
肝胆道系障害 (Cont.)				
肝嚢胞	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
肝機能異常	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
脂肪肝	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
肝腫大	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
胆管嚢胞	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
肝胆道系障害 (Cont.)				
硬化性胆管炎	1 (0.9)	0	0	0
Reasonable possibility	1 (0.9)	0	0	0
慢性胆嚢炎	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
胆石症	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
薬物性肝障害	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
胆嚢ポリープ	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
肝胆道系障害 (Cont.)				
急性肝炎	1 (0.9)	0	0	0
Reasonable possibility	1 (0.9)	0	0	0
免疫系障害	1 (0.9)	1 (0.9)	7 (3.3)	8 (2.5)
No reasonable possibility	1 (0.9)	1 (0.9)	5 (2.4)	6 (1.9)
Reasonable possibility	0	0	2 (1.0)	2 (0.6)
季節性アレルギー	0	0	3 (1.4)	3 (0.9)
No reasonable possibility	0	0	3 (1.4)	3 (0.9)
薬物過敏症	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
食物アレルギー	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
免疫系障害 (Cont.)				
低γグロブリン血症	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
サルコイドーシス	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
4型過敏症	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
アナフィラキシー様反応	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
感染症および寄生虫症	66 (58.9)	61 (57.0)	132 (63.2)	193 (61.1)
No reasonable possibility	36 (32.1)	33 (30.8)	75 (35.9)	108 (34.2)
Reasonable possibility	30 (26.8)	28 (26.2)	57 (27.3)	85 (26.9)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
COVID-19	12 (10.7)	12 (11.2)	28 (13.4)	40 (12.7)
No reasonable possibility	10 (8.9)	11 (10.3)	26 (12.4)	37 (11.7)
Reasonable possibility	2 (1.8)	1 (0.9)	2 (1.0)	3 (0.9)
尿路感染	18 (16.1)	15 (14.0)	21 (10.0)	36 (11.4)
No reasonable possibility	13 (11.6)	7 (6.5)	12 (5.7)	19 (6.0)
Reasonable possibility	5 (4.5)	8 (7.5)	9 (4.3)	17 (5.4)
上咽頭炎	13 (11.6)	6 (5.6)	18 (8.6)	24 (7.6)
No reasonable possibility	11 (9.8)	5 (4.7)	14 (6.7)	19 (6.0)
Reasonable possibility	2 (1.8)	1 (0.9)	4 (1.9)	5 (1.6)
膀胱炎	3 (2.7)	5 (4.7)	15 (7.2)	20 (6.3)
No reasonable possibility	2 (1.8)	3 (2.8)	9 (4.3)	12 (3.8)
Reasonable possibility	1 (0.9)	2 (1.9)	6 (2.9)	8 (2.5)
上気道感染	8 (7.1)	8 (7.5)	11 (5.3)	19 (6.0)
No reasonable possibility	5 (4.5)	8 (7.5)	4 (1.9)	12 (3.8)
Reasonable possibility	3 (2.7)	0	7 (3.3)	7 (2.2)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
口腔ヘルペス	4 (3.6)	3 (2.8)	8 (3.8)	11 (3.5)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Reasonable possibility	3 (2.7)	2 (1.9)	7 (3.3)	9 (2.8)
帯状疱疹	3 (2.7)	3 (2.8)	8 (3.8)	11 (3.5)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
Reasonable possibility	3 (2.7)	3 (2.8)	6 (2.9)	9 (2.8)
口腔カンジダ症	2 (1.8)	5 (4.7)	6 (2.9)	11 (3.5)
No reasonable possibility	1 (0.9)	4 (3.7)	3 (1.4)	7 (2.2)
Reasonable possibility	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
気管支炎	1 (0.9)	0	8 (3.8)	8 (2.5)
No reasonable possibility	1 (0.9)	0	6 (2.9)	6 (1.9)
Reasonable possibility	0	0	2 (1.0)	2 (0.6)
インフルエンザ	1 (0.9)	3 (2.8)	4 (1.9)	7 (2.2)
No reasonable possibility	0	3 (2.8)	2 (1.0)	5 (1.6)
Reasonable possibility	1 (0.9)	0	2 (1.0)	2 (0.6)

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PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
肺炎	5 (4.5)	5 (4.7)	1 (0.5)	6 (1.9)
No reasonable possibility	2 (1.8)	3 (2.8)	0	3 (0.9)
Reasonable possibility	3 (2.7)	2 (1.9)	1 (0.5)	3 (0.9)
麦粒腫	1 (0.9)	1 (0.9)	5 (2.4)	6 (1.9)
No reasonable possibility	1 (0.9)	1 (0.9)	4 (1.9)	5 (1.6)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
鼻炎	1 (0.9)	1 (0.9)	5 (2.4)	6 (1.9)
No reasonable possibility	0	0	3 (1.4)	3 (0.9)
Reasonable possibility	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
結膜炎	4 (3.6)	1 (0.9)	4 (1.9)	5 (1.6)
No reasonable possibility	3 (2.7)	1 (0.9)	3 (1.4)	4 (1.3)
Reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
胃腸炎	4 (3.6)	2 (1.9)	3 (1.4)	5 (1.6)
No reasonable possibility	3 (2.7)	2 (1.9)	3 (1.4)	5 (1.6)
Reasonable possibility	1 (0.9)	0	0	0

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
副鼻腔炎	1 (0.9)	2 (1.9)	3 (1.4)	5 (1.6)
No reasonable possibility	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
Reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
爪真菌症	0	2 (1.9)	3 (1.4)	5 (1.6)
No reasonable possibility	0	2 (1.9)	3 (1.4)	5 (1.6)
気道感染	0	1 (0.9)	4 (1.9)	5 (1.6)
No reasonable possibility	0	0	4 (1.9)	4 (1.3)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
歯感染	3 (2.7)	3 (2.8)	1 (0.5)	4 (1.3)
No reasonable possibility	1 (0.9)	2 (1.9)	1 (0.5)	3 (0.9)
Reasonable possibility	2 (1.8)	1 (0.9)	0	1 (0.3)
咽頭炎	1 (0.9)	3 (2.8)	1 (0.5)	4 (1.3)
No reasonable possibility	1 (0.9)	2 (1.9)	1 (0.5)	3 (0.9)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
毛包炎	0	1 (0.9)	3 (1.4)	4 (1.3)
No reasonable possibility	0	0	3 (1.4)	3 (0.9)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
下気道感染	0	0	4 (1.9)	4 (1.3)
No reasonable possibility	0	0	3 (1.4)	3 (0.9)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
爪囲炎	2 (1.8)	1 (0.9)	2 (1.0)	3 (0.9)
Reasonable possibility	2 (1.8)	1 (0.9)	2 (1.0)	3 (0.9)
皮膚真菌感染	1 (0.9)	2 (1.9)	1 (0.5)	3 (0.9)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
耳感染	0	2 (1.9)	1 (0.5)	3 (0.9)
No reasonable possibility	0	2 (1.9)	1 (0.5)	3 (0.9)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
歯肉炎	0	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
足部白癬	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
感染性滑液包炎	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
COVID-19肺炎	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
丹毒	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
消化管感染	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
眼帯状疱疹	0	0	2 (1.0)	2 (0.6)
Reasonable possibility	0	0	2 (1.0)	2 (0.6)
口腔真菌感染	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
RSウイルス感染	0	2 (1.9)	0	2 (0.6)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
歯膿瘍	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
ウイルス感染	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
ウイルス性上気道感染	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
大腸菌性尿路感染	2 (1.8)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
Reasonable possibility	1 (0.9)	0	0	0
単純ヘルペス	2 (1.8)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	0	0
Reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
カンジダ感染	1 (0.9)	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
Reasonable possibility	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
潜伏結核	1 (0.9)	1 (0.9)	0	1 (0.3)
No reasonable possibility	1 (0.9)	0	0	0
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
食道カンジダ症	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
創傷感染	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	0	0
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
急性副鼻腔炎	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
アデノウイルス結膜炎	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
無症候性細菌尿	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
蜂巣炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
大腸菌性膀胱炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
皮膚糸状菌症	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
医療機器関連感染	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
憩室炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
遊走性紅斑	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
眼感染	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
熱性感染症	0	1 (0.9)	0	1 (0.3)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
クロストリジウム菌性胃腸炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
ウイルス性胃腸炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
陰部単純ヘルペス	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
泌尿生殖器感染	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
耳帯状疱疹	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
椎間板炎	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
限局性感染	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
中耳炎	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
慢性中耳炎	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
ニューモシスチス・イロベチイ肺炎	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
シュードモナス性肺炎	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
シュードモナス性菌血症	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
歯髄炎	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
ウイルス性気道感染	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
サルモネラ症	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
レンサ球菌性化膿性関節炎	0	1 (0.9)	0	1 (0.3)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
唾液腺炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
皮膚感染	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
軟部組織感染	0	1 (0.9)	0	1 (0.3)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
頭部白癬	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
真菌性舌感染	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
気管気管支炎	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
膣感染	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
ウイルス性咽頭炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
口腔感染	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
骨髄炎	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
外耳炎	1 (0.9)	0	0	0
Reasonable possibility	1 (0.9)	0	0	0
細菌性肺炎	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
敗血症	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
ブドウ球菌性敗血症	1 (0.9)	0	0	0
Reasonable possibility	1 (0.9)	0	0	0
重複感染	1 (0.9)	0	0	0
Reasonable possibility	1 (0.9)	0	0	0

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Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
細菌性尿路感染	1 (0.9)	0	0	0
Reasonable possibility	1 (0.9)	0	0	0
尿路性敗血症	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
傷害、中毒および処置合併症	24 (21.4)	22 (20.6)	40 (19.1)	62 (19.6)
No reasonable possibility	23 (20.5)	21 (19.6)	39 (18.7)	60 (19.0)
Reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
転倒	5 (4.5)	4 (3.7)	8 (3.8)	12 (3.8)
No reasonable possibility	5 (4.5)	4 (3.7)	8 (3.8)	12 (3.8)
挫傷	2 (1.8)	5 (4.7)	7 (3.3)	12 (3.8)
No reasonable possibility	2 (1.8)	5 (4.7)	6 (2.9)	11 (3.5)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
皮膚裂傷	3 (2.7)	0	6 (2.9)	6 (1.9)
No reasonable possibility	3 (2.7)	0	5 (2.4)	5 (1.6)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
脊椎圧迫骨折	2 (1.8)	1 (0.9)	5 (2.4)	6 (1.9)
No reasonable possibility	1 (0.9)	0	5 (2.4)	5 (1.6)
Reasonable possibility	1 (0.9)	1 (0.9)	0	1 (0.3)
皮膚擦過傷	0	3 (2.8)	1 (0.5)	4 (1.3)
No reasonable possibility	0	3 (2.8)	1 (0.5)	4 (1.3)
腱断裂	0	3 (2.8)	1 (0.5)	4 (1.3)
No reasonable possibility	0	3 (2.8)	1 (0.5)	4 (1.3)
靭帯捻挫	3 (2.7)	0	2 (1.0)	2 (0.6)
No reasonable possibility	3 (2.7)	0	2 (1.0)	2 (0.6)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
肉離れ	2 (1.8)	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	2 (1.8)	1 (0.9)	1 (0.5)	2 (0.6)
頭部損傷	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
関節脱臼	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
膝蓋骨骨折	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
処置による疼痛	0	2 (1.9)	0	2 (0.6)
No reasonable possibility	0	2 (1.9)	0	2 (0.6)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
肋骨骨折	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
脊椎骨折	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
腱損傷	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
足骨折	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
四肢損傷	1 (0.9)	1 (0.9)	0	1 (0.3)
No reasonable possibility	1 (0.9)	1 (0.9)	0	1 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
皮膚創傷	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
ストレス骨折	1 (0.9)	1 (0.9)	0	1 (0.3)
No reasonable possibility	1 (0.9)	1 (0.9)	0	1 (0.3)
節足動物刺傷	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
剥離骨折	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
第1度熱傷	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)

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PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
白内障手術合併症	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
頭蓋顔面骨折	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
上顎炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
股関節部骨折	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
上腕骨骨折	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
腸脛靱帯症候群	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
免疫反応	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
下肢骨折	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
腰椎骨折	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
処置後出血	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
術後創合併症	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
交通事故	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
軟部組織損傷	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
熱傷	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
胸椎骨折	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
歯の完全脱臼	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
上肢骨折	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
手首関節骨折	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
節足動物咬傷	3 (2.7)	0	0	0
No reasonable possibility	3 (2.7)	0	0	0
骨挫傷	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
脳振盪	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
歯科修復不成功	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
顔面損傷	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
注入に伴う反応	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
筋断裂	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
橈骨骨折	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
反応性胃障害	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
肩甲骨骨折	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
創傷	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
臨床検査	19 (17.0)	13 (12.1)	35 (16.7)	48 (15.2)
No reasonable possibility	15 (13.4)	13 (12.1)	23 (11.0)	36 (11.4)
Reasonable possibility	4 (3.6)	0	12 (5.7)	12 (3.8)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
臨床検査 (Cont.)				
体重増加	4 (3.6)	6 (5.6)	6 (2.9)	12 (3.8)
No reasonable possibility	4 (3.6)	6 (5.6)	6 (2.9)	12 (3.8)
血中クレアチンホスホキナーゼ増加	0	0	6 (2.9)	6 (1.9)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	5 (2.4)	5 (1.6)
血中コレステロール増加	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Reasonable possibility	0	0	2 (1.0)	2 (0.6)
ヘモグロビン減少	1 (0.9)	0	3 (1.4)	3 (0.9)
No reasonable possibility	1 (0.9)	0	3 (1.4)	3 (0.9)
アラニンアミノトランスフェラーゼ増加	0	0	3 (1.4)	3 (0.9)
Reasonable possibility	0	0	3 (1.4)	3 (0.9)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
臨床検査 (Cont.)				
リンパ球数減少	0	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
血沈亢進	2 (1.8)	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	2 (1.8)	1 (0.9)	1 (0.5)	2 (0.6)
血中クレアチニン増加	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
肝機能検査異常	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
トランスアミナーゼ上昇	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
臨床検査 (Cont.)				
体重減少	2 (1.8)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
Reasonable possibility	1 (0.9)	0	0	0
血中カリウム減少	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
眼圧上昇	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
血中ビリルビン増加	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
臨床検査 (Cont.)				
血中ブドウ糖増加	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
血中鉄減少	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
血中ナトリウム減少	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
血中トリグリセリド増加	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
C-反応性蛋白増加	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
臨床検査 (Cont.)				
心雑音	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
B型肝炎ウイルス検査陽性	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
平均赤血球容積増加	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
モノクローナル免疫グロブリン増加	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
尿中亜硝酸塩陽性	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

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PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
臨床検査 (Cont.)				
壁細胞抗体陽性	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
尿中赤血球陽性	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
トロポニンT増加	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
血中アルカリホスファターゼ増加	1 (0.9)	0	0	0
Reasonable possibility	1 (0.9)	0	0	0
骨密度異常	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
臨床検査 (Cont.)				
心電図QT延長	1 (0.9)	0	0	0
Reasonable possibility	1 (0.9)	0	0	0
エプスタイン・バーウイルス抗体陽性	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
Γ-グルタミルトランスフェラーゼ増加	1 (0.9)	0	0	0
Reasonable possibility	1 (0.9)	0	0	0
肝機能検査値上昇	1 (0.9)	0	0	0
Reasonable possibility	1 (0.9)	0	0	0
前立腺特異性抗原増加	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
臨床検査 (Cont.)				
腎機能検査異常	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
尿中白血球陽性	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
代謝および栄養障害	16 (14.3)	11 (10.3)	28 (13.4)	39 (12.3)
No reasonable possibility	14 (12.5)	11 (10.3)	20 (9.6)	31 (9.8)
Reasonable possibility	2 (1.8)	0	8 (3.8)	8 (2.5)
低カリウム血症	1 (0.9)	2 (1.9)	5 (2.4)	7 (2.2)
No reasonable possibility	1 (0.9)	2 (1.9)	5 (2.4)	7 (2.2)
糖尿病	4 (3.6)	1 (0.9)	4 (1.9)	5 (1.6)
No reasonable possibility	4 (3.6)	1 (0.9)	2 (1.0)	3 (0.9)
Reasonable possibility	0	0	2 (1.0)	2 (0.6)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
代謝および栄養障害 (Cont.)				
脂質異常症	1 (0.9)	2 (1.9)	3 (1.4)	5 (1.6)
No reasonable possibility	0	2 (1.9)	1 (0.5)	3 (0.9)
Reasonable possibility	1 (0.9)	0	2 (1.0)	2 (0.6)
ステロイド糖尿病	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
No reasonable possibility	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
低ナトリウム血症	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
高コレステロール血症	0	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
高脂血症	0	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
代謝および栄養障害 (Cont.)				
体液貯留	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
2型糖尿病	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
食欲減退	2 (1.8)	1 (0.9)	0	1 (0.3)
No reasonable possibility	1 (0.9)	1 (0.9)	0	1 (0.3)
Reasonable possibility	1 (0.9)	0	0	0
高血糖	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
高尿酸血症	1 (0.9)	1 (0.9)	0	1 (0.3)
No reasonable possibility	1 (0.9)	1 (0.9)	0	1 (0.3)

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PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
代謝および栄養障害 (Cont.)				
脂肪腫症	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
高クロール血性アシドーシス	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
脱水	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
食物不耐性	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
痛風	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
代謝および栄養障害 (Cont.)				
低カルシウム血症	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
低クロール血症	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
低血糖	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
低蛋白血症	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
食欲亢進	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
代謝および栄養障害 (Cont.)				
鉄欠乏	3 (2.7)	0	0	0
No reasonable possibility	3 (2.7)	0	0	0
中心性肥満	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
葉酸欠乏	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
低マグネシウム血症	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
ビタミンD欠乏	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害	56 (50.0)	45 (42.1)	108 (51.7)	153 (48.4)
No reasonable possibility	53 (47.3)	45 (42.1)	103 (49.3)	148 (46.8)
Reasonable possibility	3 (2.7)	0	5 (2.4)	5 (1.6)
関節痛	15 (13.4)	7 (6.5)	29 (13.9)	36 (11.4)
No reasonable possibility	15 (13.4)	7 (6.5)	28 (13.4)	35 (11.1)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
背部痛	15 (13.4)	6 (5.6)	25 (12.0)	31 (9.8)
No reasonable possibility	13 (11.6)	6 (5.6)	25 (12.0)	31 (9.8)
Reasonable possibility	2 (1.8)	0	0	0
筋痙縮	8 (7.1)	6 (5.6)	13 (6.2)	19 (6.0)
No reasonable possibility	7 (6.3)	6 (5.6)	13 (6.2)	19 (6.0)
Reasonable possibility	1 (0.9)	0	0	0
四肢痛	6 (5.4)	4 (3.7)	15 (7.2)	19 (6.0)
No reasonable possibility	6 (5.4)	4 (3.7)	15 (7.2)	19 (6.0)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
筋肉痛	5 (4.5)	7 (6.5)	9 (4.3)	16 (5.1)
No reasonable possibility	5 (4.5)	7 (6.5)	8 (3.8)	15 (4.7)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
変形性関節症	5 (4.5)	3 (2.8)	13 (6.2)	16 (5.1)
No reasonable possibility	5 (4.5)	3 (2.8)	13 (6.2)	16 (5.1)
骨粗鬆症	3 (2.7)	3 (2.8)	7 (3.3)	10 (3.2)
No reasonable possibility	3 (2.7)	3 (2.8)	7 (3.3)	10 (3.2)
筋骨格系胸痛	1 (0.9)	1 (0.9)	5 (2.4)	6 (1.9)
No reasonable possibility	1 (0.9)	1 (0.9)	5 (2.4)	6 (1.9)
ミオパチー	2 (1.8)	1 (0.9)	4 (1.9)	5 (1.6)
No reasonable possibility	2 (1.8)	1 (0.9)	4 (1.9)	5 (1.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
腱障害	2 (1.8)	4 (3.7)	1 (0.5)	5 (1.6)
No reasonable possibility	2 (1.8)	4 (3.7)	1 (0.5)	5 (1.6)
筋力低下	1 (0.9)	3 (2.8)	2 (1.0)	5 (1.6)
No reasonable possibility	1 (0.9)	3 (2.8)	2 (1.0)	5 (1.6)
頚部痛	6 (5.4)	1 (0.9)	3 (1.4)	4 (1.3)
No reasonable possibility	6 (5.4)	1 (0.9)	3 (1.4)	4 (1.3)
椎間板突出	4 (3.6)	2 (1.9)	2 (1.0)	4 (1.3)
No reasonable possibility	4 (3.6)	2 (1.9)	2 (1.0)	4 (1.3)
大転子疼痛症候群	3 (2.7)	2 (1.9)	2 (1.0)	4 (1.3)
No reasonable possibility	3 (2.7)	2 (1.9)	2 (1.0)	4 (1.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
滑液包炎	2 (1.8)	1 (0.9)	3 (1.4)	4 (1.3)
No reasonable possibility	2 (1.8)	1 (0.9)	3 (1.4)	4 (1.3)
関節腫脹	1 (0.9)	0	4 (1.9)	4 (1.3)
No reasonable possibility	1 (0.9)	0	3 (1.4)	3 (0.9)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
顎痛	1 (0.9)	2 (1.9)	2 (1.0)	4 (1.3)
No reasonable possibility	1 (0.9)	2 (1.9)	2 (1.0)	4 (1.3)
筋骨格硬直	0	0	4 (1.9)	4 (1.3)
No reasonable possibility	0	0	4 (1.9)	4 (1.3)
顎関節症候群	0	2 (1.9)	2 (1.0)	4 (1.3)
No reasonable possibility	0	2 (1.9)	2 (1.0)	4 (1.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
腱炎	0	1 (0.9)	3 (1.4)	4 (1.3)
No reasonable possibility	0	1 (0.9)	3 (1.4)	4 (1.3)
リウマチ性多発筋痛	5 (4.5)	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	5 (4.5)	1 (0.9)	2 (1.0)	3 (0.9)
骨減少症	2 (1.8)	0	3 (1.4)	3 (0.9)
No reasonable possibility	2 (1.8)	0	3 (1.4)	3 (0.9)
線維筋痛	0	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
腰部脊柱管狭窄症	0	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	0	1 (0.9)	2 (1.0)	3 (0.9)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
肩回旋筋腱板症候群	3 (2.7)	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	3 (2.7)	1 (0.9)	1 (0.5)	2 (0.6)
関節炎	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
シェーグレン症候群	1 (0.9)	0	2 (1.0)	2 (0.6)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
脊椎痛	1 (0.9)	0	2 (1.0)	2 (0.6)
No reasonable possibility	1 (0.9)	0	2 (1.0)	2 (0.6)
側腹部痛	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
骨端症	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
変形性脊椎症	0	2 (1.9)	0	2 (0.6)
No reasonable possibility	0	2 (1.9)	0	2 (0.6)
椎間孔狭窄	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
滑液嚢腫	2 (1.8)	1 (0.9)	0	1 (0.3)
No reasonable possibility	2 (1.8)	1 (0.9)	0	1 (0.3)
関節可動域低下	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
腱痛	1 (0.9)	1 (0.9)	0	1 (0.3)
No reasonable possibility	1 (0.9)	1 (0.9)	0	1 (0.3)
頚部脊柱管狭窄症	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
椎間関節症候群	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
指変形	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
単径部痛	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
顎関節クリッキング	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
顎障害	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
関節滲出液	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
関節雑音	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
半月板変性	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
筋不快感	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
筋骨格不快感	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
筋骨格障害	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
膝蓋大腿関節痛症候群	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
関節周囲炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
足底筋膜炎	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
乾癬性関節症	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
肩甲帯痛	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
軟部組織腫瘤	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
脊柱管狭窄症	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
脊椎滑液嚢腫	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
腱鞘炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
弾発指	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
関節障害	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
椎間板障害	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
関節硬直	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
筋肉疲労	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
筋骨格痛	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
関節リウマチ	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
手関節変形	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	7 (6.3)	6 (5.6)	16 (7.7)	22 (7.0)
No reasonable possibility	6 (5.4)	5 (4.7)	15 (7.2)	20 (6.3)
Reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
皮膚有棘細胞癌	0	1 (0.9)	3 (1.4)	4 (1.3)
No reasonable possibility	0	1 (0.9)	2 (1.0)	3 (0.9)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
基底細胞癌	2 (1.8)	0	2 (1.0)	2 (0.6)
No reasonable possibility	1 (0.9)	0	2 (1.0)	2 (0.6)
Reasonable possibility	1 (0.9)	0	0	0
結腸直腸腺腫	0	2 (1.9)	0	2 (0.6)
No reasonable possibility	0	2 (1.9)	0	2 (0.6)
メラノサイト性母斑	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
脂漏性角化症	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
皮膚乳頭腫	0	2 (1.9)	0	2 (0.6)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
副腎腺腫	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
線維腫	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
良性毛包腫瘍	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
悪性黒子	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
脂肪腫	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
ファーター膨大部の悪性新生物	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
皮膚の新生物	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
肺扁平上皮癌	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
舌の悪性新生物、病期不明	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
血管筋脂肪腫	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
血管腫	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
膵管内乳頭粘液性腫瘍	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
神経線維腫	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
前立腺癌	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
遠隔転移を伴う扁桃癌	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
神経系障害	32 (28.6)	39 (36.4)	81 (38.8)	120 (38.0)
No reasonable possibility	29 (25.9)	35 (32.7)	69 (33.0)	104 (32.9)
Reasonable possibility	3 (2.7)	4 (3.7)	12 (5.7)	16 (5.1)
頭痛	13 (11.6)	16 (15.0)	34 (16.3)	50 (15.8)
No reasonable possibility	13 (11.6)	16 (15.0)	28 (13.4)	44 (13.9)
Reasonable possibility	0	0	6 (2.9)	6 (1.9)
浮動性めまい	6 (5.4)	6 (5.6)	10 (4.8)	16 (5.1)
No reasonable possibility	5 (4.5)	6 (5.6)	9 (4.3)	15 (4.7)
Reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
神経系障害 (Cont.)				
坐骨神経痛	0	3 (2.8)	6 (2.9)	9 (2.8)
No reasonable possibility	0	3 (2.8)	6 (2.9)	9 (2.8)
味覚不全	1 (0.9)	3 (2.8)	3 (1.4)	6 (1.9)
No reasonable possibility	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
Reasonable possibility	0	2 (1.9)	0	2 (0.6)
錯感覚	1 (0.9)	2 (1.9)	4 (1.9)	6 (1.9)
No reasonable possibility	1 (0.9)	2 (1.9)	4 (1.9)	6 (1.9)
失神	4 (3.6)	1 (0.9)	4 (1.9)	5 (1.6)
No reasonable possibility	4 (3.6)	1 (0.9)	4 (1.9)	5 (1.6)
緊張性頭痛	0	1 (0.9)	4 (1.9)	5 (1.6)
No reasonable possibility	0	1 (0.9)	4 (1.9)	5 (1.6)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
手根管症候群	0	0	4 (1.9)	4 (1.3)
No reasonable possibility	0	0	4 (1.9)	4 (1.3)
傾眠	0	2 (1.9)	2 (1.0)	4 (1.3)
No reasonable possibility	0	1 (0.9)	2 (1.0)	3 (0.9)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
振戦	5 (4.5)	2 (1.9)	1 (0.5)	3 (0.9)
No reasonable possibility	4 (3.6)	2 (1.9)	1 (0.5)	3 (0.9)
Reasonable possibility	1 (0.9)	0	0	0
片頭痛	2 (1.8)	2 (1.9)	1 (0.5)	3 (0.9)
No reasonable possibility	2 (1.8)	2 (1.9)	1 (0.5)	3 (0.9)
記憶障害	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
ヘルペス後神経痛	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
Reasonable possibility	1 (0.9)	0	2 (1.0)	2 (0.6)
後頭神経痛	0	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	0	1 (0.9)	2 (1.0)	3 (0.9)
偽性根症候群	0	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	0	1 (0.9)	2 (1.0)	3 (0.9)
下肢静止不能症候群	0	0	3 (1.4)	3 (0.9)
No reasonable possibility	0	0	3 (1.4)	3 (0.9)
感覚鈍麻	1 (0.9)	0	2 (1.0)	2 (0.6)
No reasonable possibility	1 (0.9)	0	2 (1.0)	2 (0.6)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
末梢性ニューロパチー	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
健忘	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
灼熱感	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
体位性めまい	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
頭部不快感	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
神経根障害	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
味覚障害	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
一過性脳虚血発作	0	2 (1.9)	0	2 (0.6)
No reasonable possibility	0	2 (1.9)	0	2 (0.6)
平衡障害	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
ブレインフォグ	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
腰髄神経根障害	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
無嗅覚	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
反射消失	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
頚動脈狭窄	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
小脳性運動失調	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
頚腕症候群	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
注意力障害	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
労作性めまい	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
ジストニア	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
電気ショック様感覚	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
味覚減退	0	1 (0.9)	0	1 (0.3)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
肋間神経痛	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
脳圧低下	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
単神経炎	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
不随意性筋収縮	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
神経圧迫	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
嗅覚錯誤	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
梨状筋症候群	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
失神寸前の状態	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
精神運動亢進	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
4分の1盲	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
副鼻腔炎に伴う頭痛	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
一過性失語症	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
トンネル状視野	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
椎骨動脈狭窄	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
神経系障害 (Cont.)				
神経痛	2 (1.8)	0	0	0
No reasonable possibility	2 (1.8)	0	0	0
脳アミロイド血管障害	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
脳梗塞	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
脳脊髄瘻	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
脳卒中	1 (0.9)	0	0	0
Reasonable possibility	1 (0.9)	0	0	0

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
神経系障害 (Cont.)				
認知障害	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
脱髄	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
異常感覚	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
多発ニューロパチー	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
精神障害	13 (11.6)	8 (7.5)	20 (9.6)	28 (8.9)
No reasonable possibility	13 (11.6)	7 (6.5)	18 (8.6)	25 (7.9)
Reasonable possibility	0	1 (0.9)	2 (1.0)	3 (0.9)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
精神障害 (Cont.)				
不眠症	5 (4.5)	3 (2.8)	4 (1.9)	7 (2.2)
No reasonable possibility	5 (4.5)	3 (2.8)	4 (1.9)	7 (2.2)
うつ病	1 (0.9)	2 (1.9)	3 (1.4)	5 (1.6)
No reasonable possibility	1 (0.9)	2 (1.9)	2 (1.0)	4 (1.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
不安	1 (0.9)	0	3 (1.4)	3 (0.9)
No reasonable possibility	1 (0.9)	0	3 (1.4)	3 (0.9)
錯乱状態	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
抑うつ気分	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
精神障害 (Cont.)				
落ち着きのなさ	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
睡眠障害	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
物質誘発性精神病性障害	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
神経過敏	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
歯ぎしり	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
精神障害 (Cont.)				
燃え尽き症候群	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
リビドー減退	0	1 (0.9)	0	1 (0.3)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
人格変化	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
譫妄	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
初期不眠症	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
精神障害 (Cont.)				
躁病	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
混合性不安抑うつ障害	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
気分動揺	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
睡眠の質低下	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
腎および尿路障害	13 (11.6)	5 (4.7)	19 (9.1)	24 (7.6)
No reasonable possibility	12 (10.7)	4 (3.7)	19 (9.1)	23 (7.3)
Reasonable possibility	1 (0.9)	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
腎および尿路障害 (Cont.)				
血尿	4 (3.6)	0	4 (1.9)	4 (1.3)
No reasonable possibility	4 (3.6)	0	4 (1.9)	4 (1.3)
頻尿	1 (0.9)	2 (1.9)	2 (1.0)	4 (1.3)
No reasonable possibility	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
排尿困難	1 (0.9)	0	3 (1.4)	3 (0.9)
No reasonable possibility	1 (0.9)	0	3 (1.4)	3 (0.9)
急性腎障害	3 (2.7)	0	2 (1.0)	2 (0.6)
No reasonable possibility	2 (1.8)	0	2 (1.0)	2 (0.6)
Reasonable possibility	1 (0.9)	0	0	0
腎結石症	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
腎および尿路障害 (Cont.)				
尿失禁	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
緊張性膀胱	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
尿意切迫	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
腎嚢胞	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
慢性腎臓病	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
腎および尿路障害 (Cont.)				
腎炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
夜間頻尿	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
腎不全	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
腎機能障害	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
腎損傷	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
腎および尿路障害 (Cont.)				
蛋白尿	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
腎仙痛	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
生殖系および乳房障害	4 (3.6)	1 (0.9)	8 (3.8)	9 (2.8)
No reasonable possibility	4 (3.6)	1 (0.9)	7 (3.3)	8 (2.5)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
良性前立腺肥大症	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
乳房痛	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
生殖系および乳房障害 (Cont.)				
乳房腫瘤	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
子宮頚部上皮異形成	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
膀胱瘤	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
乳頭痛	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
前立腺障害	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
生殖系および乳房障害 (Cont.)				
外陰膣乾燥	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
骨盤痛	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
前立腺腫大	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
外陰膣そう痒症	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
呼吸器、胸郭および縦隔障害	14 (12.5)	20 (18.7)	49 (23.4)	69 (21.8)
No reasonable possibility	11 (9.8)	16 (15.0)	38 (18.2)	54 (17.1)
Reasonable possibility	3 (2.7)	4 (3.7)	11 (5.3)	15 (4.7)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)				
咳嗽	4 (3.6)	5 (4.7)	14 (6.7)	19 (6.0)
No reasonable possibility	4 (3.6)	5 (4.7)	11 (5.3)	16 (5.1)
Reasonable possibility	0	0	3 (1.4)	3 (0.9)
口腔咽頭痛	1 (0.9)	4 (3.7)	6 (2.9)	10 (3.2)
No reasonable possibility	1 (0.9)	1 (0.9)	5 (2.4)	6 (1.9)
Reasonable possibility	0	3 (2.8)	1 (0.5)	4 (1.3)
呼吸困難	5 (4.5)	1 (0.9)	7 (3.3)	8 (2.5)
No reasonable possibility	4 (3.6)	1 (0.9)	4 (1.9)	5 (1.6)
Reasonable possibility	1 (0.9)	0	3 (1.4)	3 (0.9)
肺塞栓症	2 (1.8)	2 (1.9)	6 (2.9)	8 (2.5)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
Reasonable possibility	2 (1.8)	1 (0.9)	5 (2.4)	6 (1.9)
喘息	0	1 (0.9)	4 (1.9)	5 (1.6)
No reasonable possibility	0	1 (0.9)	3 (1.4)	4 (1.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)				
労作性呼吸困難	2 (1.8)	2 (1.9)	2 (1.0)	4 (1.3)
No reasonable possibility	2 (1.8)	2 (1.9)	2 (1.0)	4 (1.3)
鼻出血	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
No reasonable possibility	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
慢性閉塞性肺疾患	0	0	3 (1.4)	3 (0.9)
No reasonable possibility	0	0	3 (1.4)	3 (0.9)
鼻漏	1 (0.9)	0	2 (1.0)	2 (0.6)
No reasonable possibility	1 (0.9)	0	2 (1.0)	2 (0.6)
発声障害	0	2 (1.9)	0	2 (0.6)
No reasonable possibility	0	2 (1.9)	0	2 (0.6)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)				
湿性咳嗽	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
肺腫瘤	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
急性呼吸不全	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
無気肺	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
気管支拡張症	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

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PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)				
慢性気管支炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
気管支痙攣	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
血胸	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
下咽頭癒着	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
上気道分泌増加	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)				
肺障害	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
起坐呼吸	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
ラ音	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
アレルギー性鼻炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
咽喉刺激感	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)				
咳払い	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
皮膚および皮下組織障害	26 (23.2)	20 (18.7)	57 (27.3)	77 (24.4)
No reasonable possibility	20 (17.9)	16 (15.0)	45 (21.5)	61 (19.3)
Reasonable possibility	6 (5.4)	4 (3.7)	12 (5.7)	16 (5.1)
発疹	3 (2.7)	3 (2.8)	11 (5.3)	14 (4.4)
No reasonable possibility	3 (2.7)	3 (2.8)	10 (4.8)	13 (4.1)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
多汗症	3 (2.7)	3 (2.8)	5 (2.4)	8 (2.5)
No reasonable possibility	3 (2.7)	3 (2.8)	4 (1.9)	7 (2.2)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
ざ瘡	1 (0.9)	0	7 (3.3)	7 (2.2)
No reasonable possibility	1 (0.9)	0	6 (2.9)	6 (1.9)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
皮膚乾燥	0	0	6 (2.9)	6 (1.9)
No reasonable possibility	0	0	5 (2.4)	5 (1.6)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
脱毛症	3 (2.7)	0	5 (2.4)	5 (1.6)
No reasonable possibility	2 (1.8)	0	4 (1.9)	4 (1.3)
Reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
紅斑	1 (0.9)	0	4 (1.9)	4 (1.3)
No reasonable possibility	0	0	3 (1.4)	3 (0.9)
Reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
寝汗	1 (0.9)	2 (1.9)	1 (0.5)	3 (0.9)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
口囲皮膚炎	1 (0.9)	0	3 (1.4)	3 (0.9)
No reasonable possibility	1 (0.9)	0	2 (1.0)	2 (0.6)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
酒さ	1 (0.9)	0	3 (1.4)	3 (0.9)
No reasonable possibility	1 (0.9)	0	3 (1.4)	3 (0.9)
皮膚病変	0	1 (0.9)	2 (1.0)	3 (0.9)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
そう痒症	2 (1.8)	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
Reasonable possibility	2 (1.8)	0	0	0
皮膚炎	1 (0.9)	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
Reasonable possibility	1 (0.9)	0	0	0
接触皮膚炎	1 (0.9)	0	2 (1.0)	2 (0.6)
No reasonable possibility	1 (0.9)	0	2 (1.0)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
皮膚疼痛	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
皮膚潰瘍	1 (0.9)	0	2 (1.0)	2 (0.6)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
びまん性脱毛症	0	2 (1.9)	0	2 (0.6)
Reasonable possibility	0	2 (1.9)	0	2 (0.6)
湿疹	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
男性型多毛症	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
斑状丘疹状皮疹	0	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	0	1 (0.9)	1 (0.5)	2 (0.6)
脂漏性皮膚炎	3 (2.7)	0	1 (0.5)	1 (0.3)
No reasonable possibility	3 (2.7)	0	1 (0.5)	1 (0.3)
脂肪肥大症	1 (0.9)	0	1 (0.5)	1 (0.3)
No reasonable possibility	1 (0.9)	0	1 (0.5)	1 (0.3)
斑状皮疹	1 (0.9)	1 (0.9)	0	1 (0.3)
No reasonable possibility	1 (0.9)	1 (0.9)	0	1 (0.3)
光線角化症	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
円形脱毛症	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
汎発性脱毛症	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
アンドロゲン性脱毛症	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
血管浮腫	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
腕橈骨筋そう痒症	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
ざ瘡様皮膚炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
皮膚症	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
毛髪成長異常	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
爪変色	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
爪破損	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
陰茎潰瘍形成	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
光線性皮膚症	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
紅斑性皮疹	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
痂皮	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
皮膚亀裂	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
皮膚色素過剰	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
皮膚硬結	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
皮膚刺激	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
皮膚軟化	0	1 (0.9)	0	1 (0.3)
Reasonable possibility	0	1 (0.9)	0	1 (0.3)
皮膚腫瘤	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
うっ滞性皮膚炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
黄色皮膚	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
水疱	2 (1.8)	0	0	0
No reasonable possibility	2 (1.8)	0	0	0
冷汗	1 (0.9)	0	0	0
Reasonable possibility	1 (0.9)	0	0	0
アレルギー性皮膚炎	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
斑状出血	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
過角化	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
硬化性苔癬	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
後天性リポジストロフィー	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
網状皮斑	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
神経皮膚炎	1 (0.9)	0	0	0
Reasonable possibility	1 (0.9)	0	0	0
丘疹	1 (0.9)	0	0	0
Reasonable possibility	1 (0.9)	0	0	0
類天疱瘡	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
乾癬	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
小水疱性皮疹	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
皮膚変色	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
乾皮症	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
血管障害	47 (42.0)	48 (44.9)	83 (39.7)	131 (41.5)
No reasonable possibility	30 (26.8)	34 (31.8)	66 (31.6)	100 (31.6)
Reasonable possibility	17 (15.2)	14 (13.1)	17 (8.1)	31 (9.8)
巨細胞性動脈炎	35 (31.3)	28 (26.2)	48 (23.0)	76 (24.1)
No reasonable possibility	24 (21.4)	17 (15.9)	38 (18.2)	55 (17.4)
Reasonable possibility	11 (9.8)	11 (10.3)	10 (4.8)	21 (6.6)
高血圧	13 (11.6)	16 (15.0)	28 (13.4)	44 (13.9)
No reasonable possibility	10 (8.9)	13 (12.1)	27 (12.9)	40 (12.7)
Reasonable possibility	3 (2.7)	3 (2.8)	1 (0.5)	4 (1.3)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
血管障害 (Cont.)				
血腫	5 (4.5)	2 (1.9)	4 (1.9)	6 (1.9)
No reasonable possibility	5 (4.5)	2 (1.9)	4 (1.9)	6 (1.9)
深部静脈血栓症	2 (1.8)	1 (0.9)	4 (1.9)	5 (1.6)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
Reasonable possibility	2 (1.8)	0	4 (1.9)	4 (1.3)
静脈瘤	0	0	3 (1.4)	3 (0.9)
No reasonable possibility	0	0	3 (1.4)	3 (0.9)
起立性低血圧	2 (1.8)	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	2 (1.8)	1 (0.9)	1 (0.5)	2 (0.6)
間欠性跛行	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
No reasonable possibility	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)

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Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
血管障害 (Cont.)				
末梢冷感	1 (0.9)	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
Reasonable possibility	1 (0.9)	0	0	0
リンパうっ滞	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
表在性静脈血栓症	0	2 (1.9)	0	2 (0.6)
No reasonable possibility	0	2 (1.9)	0	2 (0.6)
白衣性高血圧	0	0	2 (1.0)	2 (0.6)
No reasonable possibility	0	0	2 (1.0)	2 (0.6)
動脈硬化症	1 (0.9)	1 (0.9)	0	1 (0.3)
No reasonable possibility	1 (0.9)	0	0	0
Reasonable possibility	0	1 (0.9)	0	1 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
血管障害 (Cont.)				
大動脈解離	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
大動脈狭窄	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
大動脈血栓症	0	0	1 (0.5)	1 (0.3)
Reasonable possibility	0	0	1 (0.5)	1 (0.3)
動脈出血	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
本態性高血圧症	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
血管障害 (Cont.)				
ほてり	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
高血圧クリーゼ	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
低血圧	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
リンパ浮腫	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
大血管障害	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
血管障害 (Cont.)				
末梢動脈閉塞性疾患	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
末梢血管塞栓症	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)
レイノー現象	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
血栓性静脈炎	0	1 (0.9)	0	1 (0.3)
No reasonable possibility	0	1 (0.9)	0	1 (0.3)
静脈瘤性静脈炎	0	0	1 (0.5)	1 (0.3)
No reasonable possibility	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.6.1

Subjects with Treatment-Emergent Adverse Events
by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
血管障害 (Cont.)				
末梢動脈狭窄	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0
末梢静脈疾患	1 (0.9)	0	0	0
No reasonable possibility	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

表4

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
Any adverse event	396 (548.0)	264 (363.6)	874 (509.9)	1138 (466.4)
No Reasonable Possibility	353 (488.5)	232 (319.5)	729 (425.3)	961 (393.9)
Reasonable Possibility	43 (59.5)	32 (44.1)	145 (84.6)	177 (72.5)
血液およびリンパ系障害	2 (2.8)	5 (6.9)	17 (9.9)	22 (9.0)
No Reasonable Possibility	2 (2.8)	4 (5.5)	14 (8.2)	18 (7.4)
Reasonable Possibility	0	1 (1.4)	3 (1.8)	4 (1.6)
貧血	1 (1.4)	3 (4.1)	8 (4.7)	11 (4.5)
No Reasonable Possibility	1 (1.4)	2 (2.8)	6 (3.5)	8 (3.3)
Reasonable Possibility	0	1 (1.4)	2 (1.2)	3 (1.2)
鉄欠乏性貧血	0	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	0	1 (1.4)	1 (0.6)	2 (0.8)
正色素性正球性貧血	0	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
血液およびリンパ系障害 (Cont.)				
内出血発生の増加傾向	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
骨髄浮腫	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
好酸球増加症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
白血球増加症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
リンパ球減少症	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
血液およびリンパ系障害 (Cont.)				
好中球増加症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
血小板増加症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
心臓障害	8 (11.1)	3 (4.1)	20 (11.7)	23 (9.4)
No Reasonable Possibility	8 (11.1)	3 (4.1)	18 (10.5)	21 (8.6)
Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
動悸	2 (2.8)	1 (1.4)	3 (1.8)	4 (1.6)
No Reasonable Possibility	2 (2.8)	1 (1.4)	3 (1.8)	4 (1.6)
心不全	1 (1.4)	0	4 (2.3)	4 (1.6)
No Reasonable Possibility	1 (1.4)	0	3 (1.8)	3 (1.2)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
心臓障害 (Cont.)				
心房細動	2 (2.8)	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	2 (2.8)	0	2 (1.2)	2 (0.8)
冠動脈硬化症	0	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
狭心症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
心房頻脈	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
冠動脈疾患	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
心臓障害 (Cont.)				
冠動脈入口部狭窄	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
僧帽弁石灰化	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
僧帽弁閉鎖不全症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
心筋虚血	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
心嚢液貯留	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
心臓障害 (Cont.)				
洞性徐脈	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
頻脈	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
三尖弁閉鎖不全症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
大動脈弁疾患	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
右脚ブロック	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
心臓障害 (Cont.)				
洞性頻脈	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
先天性、家族性および遺伝性障害	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
歯牙形成不全	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
耳および迷路障害	3 (4.2)	5 (6.9)	15 (8.8)	20 (8.2)
No Reasonable Possibility	3 (4.2)	5 (6.9)	14 (8.2)	19 (7.8)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
回転性めまい	1 (1.4)	2 (2.8)	7 (4.1)	9 (3.7)
No Reasonable Possibility	1 (1.4)	2 (2.8)	6 (3.5)	8 (3.3)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
耳および迷路障害 (Cont.)				
耳鳴	2 (2.8)	2 (2.8)	2 (1.2)	4 (1.6)
No Reasonable Possibility	2 (2.8)	2 (2.8)	2 (1.2)	4 (1.6)
耳痛	0	0	4 (2.3)	4 (1.6)
No Reasonable Possibility	0	0	4 (2.3)	4 (1.6)
耳不快感	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
聴力低下	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
頭位性回転性めまい	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
内分泌障害	3 (4.2)	2 (2.8)	3 (1.8)	5 (2.0)
No Reasonable Possibility	3 (4.2)	2 (2.8)	3 (1.8)	5 (2.0)
クッシング様症状	0	1 (1.4)	2 (1.2)	3 (1.2)
No Reasonable Possibility	0	1 (1.4)	2 (1.2)	3 (1.2)
クッシング症候群	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
甲状腺腫瘤	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
甲状腺腫	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
内分泌障害 (Cont.)				
中毒性結節性甲状腺腫	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
眼障害	24 (33.2)	11 (15.2)	45 (26.3)	56 (23.0)
No Reasonable Possibility	19 (26.3)	11 (15.2)	43 (25.1)	54 (22.1)
Reasonable Possibility	5 (6.9)	0	2 (1.2)	2 (0.8)
白内障	4 (5.5)	2 (2.8)	8 (4.7)	10 (4.1)
No Reasonable Possibility	3 (4.2)	2 (2.8)	8 (4.7)	10 (4.1)
Reasonable Possibility	1 (1.4)	0	0	0
眼瞼炎	0	0	5 (2.9)	5 (2.0)
No Reasonable Possibility	0	0	4 (2.3)	4 (1.6)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
結膜出血	0	1 (1.4)	3 (1.8)	4 (1.6)
No Reasonable Possibility	0	1 (1.4)	3 (1.8)	4 (1.6)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
眼障害 (Cont.)				
ドライアイ	2 (2.8)	1 (1.4)	2 (1.2)	3 (1.2)
No Reasonable Possibility	2 (2.8)	1 (1.4)	2 (1.2)	3 (1.2)
加齢黄斑変性	0	2 (2.8)	1 (0.6)	3 (1.2)
No Reasonable Possibility	0	2 (2.8)	1 (0.6)	3 (1.2)
硝子体浮遊物	2 (2.8)	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	2 (2.8)	1 (1.4)	1 (0.6)	2 (0.8)
眼痛	1 (1.4)	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	1 (1.4)	0	2 (1.2)	2 (0.8)
霰粒腫	0	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
眼障害 (Cont.)				
眼部腫脹	0	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	0	1 (1.4)	1 (0.6)	2 (0.8)
硝子体剥離	3 (4.2)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
Reasonable Possibility	2 (2.8)	0	0	0
霧視	2 (2.8)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	2 (2.8)	0	1 (0.6)	1 (0.4)
眼の異物感	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
緑内障	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
眼障害 (Cont.)				
黄斑変性	1 (1.4)	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	1 (1.4)	1 (1.4)	0	1 (0.4)
開放隅角緑内障	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	1 (1.4)	0	0	0
視力障害	1 (1.4)	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	1 (1.4)	1 (1.4)	0	1 (0.4)
角膜浮腫	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
複視	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
眼障害 (Cont.)				
眼出血	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
眼の炎症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
眼刺激	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
遠視	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
眼充血	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
眼障害 (Cont.)				
高眼圧症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
視神経乳頭出血	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
眼窩浮腫	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
眼窩周囲痛	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
羞明	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
眼障害 (Cont.)				
光視症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
老視	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
眼瞼腫脹	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
視野欠損	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
アレルギー性結膜炎	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
眼障害 (Cont.)				
眼部不快感	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
虚血性視神経症	1 (1.4)	0	0	0
Reasonable Possibility	1 (1.4)	0	0	0
網膜裂孔	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
視力低下	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
胃腸障害	32 (44.3)	32 (44.1)	70 (40.8)	102 (41.8)
No Reasonable Possibility	31 (42.9)	28 (38.6)	59 (34.4)	87 (35.7)
Reasonable Possibility	1 (1.4)	4 (5.5)	11 (6.4)	15 (6.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (Cont.)				
悪心	2 (2.8)	6 (8.3)	7 (4.1)	13 (5.3)
No Reasonable Possibility	2 (2.8)	5 (6.9)	6 (3.5)	11 (4.5)
Reasonable Possibility	0	1 (1.4)	1 (0.6)	2 (0.8)
下痢	0	4 (5.5)	9 (5.3)	13 (5.3)
No Reasonable Possibility	0	4 (5.5)	8 (4.7)	12 (4.9)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
上腹部痛	3 (4.2)	0	9 (5.3)	9 (3.7)
No Reasonable Possibility	2 (2.8)	0	6 (3.5)	6 (2.5)
Reasonable Possibility	1 (1.4)	0	3 (1.8)	3 (1.2)
便秘	3 (4.2)	4 (5.5)	5 (2.9)	9 (3.7)
No Reasonable Possibility	3 (4.2)	4 (5.5)	4 (2.3)	8 (3.3)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
嘔吐	0	5 (6.9)	3 (1.8)	8 (3.3)
No Reasonable Possibility	0	5 (6.9)	2 (1.2)	7 (2.9)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (Cont.)				
消化不良	1 (1.4)	0	6 (3.5)	6 (2.5)
No Reasonable Possibility	1 (1.4)	0	5 (2.9)	5 (2.0)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
胃食道逆流性疾患	1 (1.4)	0	5 (2.9)	5 (2.0)
No Reasonable Possibility	1 (1.4)	0	5 (2.9)	5 (2.0)
口腔内潰瘍形成	0	0	4 (2.3)	4 (1.6)
No Reasonable Possibility	0	0	3 (1.8)	3 (1.2)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
腹痛	3 (4.2)	1 (1.4)	2 (1.2)	3 (1.2)
No Reasonable Possibility	3 (4.2)	1 (1.4)	2 (1.2)	3 (1.2)
胃炎	3 (4.2)	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	3 (4.2)	1 (1.4)	1 (0.6)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (Cont.)				
腹部膨満	1 (1.4)	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	1 (1.4)	0	2 (1.2)	2 (0.8)
下腹部痛	1 (1.4)	2 (2.8)	0	2 (0.8)
No Reasonable Possibility	1 (1.4)	2 (2.8)	0	2 (0.8)
アフタ性潰瘍	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
鼠径ヘルニア	0	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	0	1 (1.4)	1 (0.6)	2 (0.8)
大腸ポリープ	2 (2.8)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	2 (2.8)	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (Cont.)				
齲歯	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
腸憩室	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
口内乾燥	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
排便回数増加	1 (1.4)	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	0	0
Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
裂孔ヘルニア	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (Cont.)				
口内炎	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	0	0
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
歯痛	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
裂肛	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
虚血性大腸炎	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
憩室	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (Cont.)				
嚥下障害	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
鼓腸	0	1 (1.4)	0	1 (0.4)
Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
食中毒	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
歯肉障害	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
歯肉痛	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (Cont.)				
過敏性腸症候群	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
口唇腫脹	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
嚥下痛	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
食道炎	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
膵炎	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (Cont.)				
臍ヘルニア	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
慢性胃炎	2 (2.8)	0	0	0
No Reasonable Possibility	2 (2.8)	0	0	0
膵嚢胞	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
直腸出血	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
一般・全身障害および投与部位の状態	20 (27.7)	14 (19.3)	48 (28.0)	62 (25.4)
No Reasonable Possibility	19 (26.3)	13 (17.9)	44 (25.7)	57 (23.4)
Reasonable Possibility	1 (1.4)	1 (1.4)	4 (2.3)	5 (2.0)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
一般・全身障害および投与部位の状態 (Cont.)				
疲労	4 (5.5)	3 (4.1)	10 (5.8)	13 (5.3)
No Reasonable Possibility	4 (5.5)	3 (4.1)	8 (4.7)	11 (4.5)
Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
末梢性浮腫	3 (4.2)	2 (2.8)	7 (4.1)	9 (3.7)
No Reasonable Possibility	3 (4.2)	2 (2.8)	7 (4.1)	9 (3.7)
胸痛	0	2 (2.8)	6 (3.5)	8 (3.3)
No Reasonable Possibility	0	2 (2.8)	5 (2.9)	7 (2.9)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
発熱	3 (4.2)	1 (1.4)	3 (1.8)	4 (1.6)
No Reasonable Possibility	3 (4.2)	0	3 (1.8)	3 (1.2)
Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
インフルエンザ様疾患	1 (1.4)	0	3 (1.8)	3 (1.2)
No Reasonable Possibility	1 (1.4)	0	3 (1.8)	3 (1.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
一般・全身障害および投与部位の状態 (Cont.)				
疼痛	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
No Reasonable Possibility	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
末梢腫脹	1 (1.4)	0	3 (1.8)	3 (1.2)
No Reasonable Possibility	1 (1.4)	0	3 (1.8)	3 (1.2)
顔面腫脹	1 (1.4)	2 (2.8)	1 (0.6)	3 (1.2)
No Reasonable Possibility	0	2 (2.8)	1 (0.6)	3 (1.2)
Reasonable Possibility	1 (1.4)	0	0	0
無力症	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
歩行障害	1 (1.4)	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	1 (1.4)	0	2 (1.2)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
一般・全身障害および投与部位の状態 (Cont.)				
浮腫	0	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
倦怠感	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
医薬品副作用	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
胸部不快感	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
顔面浮腫	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
一般・全身障害および投与部位の状態 (Cont.)				
冷感	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
注射部位疼痛	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
小結節	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
非心臓性胸痛	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
評価不能の事象	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
一般・全身障害および投与部位の状態 (Cont.)				
乾燥症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
疾患前駆期	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
不明確な障害	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
腫脹	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
肝胆道系障害	2 (2.8)	2 (2.8)	1 (0.6)	3 (1.2)
No Reasonable Possibility	2 (2.8)	1 (1.4)	1 (0.6)	2 (0.8)
Reasonable Possibility	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
肝胆道系障害 (Cont.)				
脂肪肝	1 (1.4)	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	1 (1.4)	1 (1.4)	0	1 (0.4)
胆石症	0	1 (1.4)	0	1 (0.4)
Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
肝腫大	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
肝病変	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
免疫系障害	0	2 (2.8)	4 (2.3)	6 (2.5)
No Reasonable Possibility	0	2 (2.8)	3 (1.8)	5 (2.0)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
免疫系障害 (Cont.)				
季節性アレルギー	0	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
薬物過敏症	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
過敏症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
低γグロブリン血症	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
4型過敏症	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症	75 (103.8)	55 (75.8)	164 (95.7)	219 (89.8)
No Reasonable Possibility	52 (72.0)	35 (48.2)	105 (61.3)	140 (57.4)
Reasonable Possibility	23 (31.8)	20 (27.5)	59 (34.4)	79 (32.4)
COVID-19	12 (16.6)	9 (12.4)	29 (16.9)	38 (15.6)
No Reasonable Possibility	10 (13.8)	9 (12.4)	27 (15.8)	36 (14.8)
Reasonable Possibility	2 (2.8)	0	2 (1.2)	2 (0.8)
尿路感染	16 (22.1)	9 (12.4)	13 (7.6)	22 (9.0)
No Reasonable Possibility	12 (16.6)	4 (5.5)	8 (4.7)	12 (4.9)
Reasonable Possibility	4 (5.5)	5 (6.9)	5 (2.9)	10 (4.1)
上咽頭炎	7 (9.7)	8 (11.0)	14 (8.2)	22 (9.0)
No Reasonable Possibility	6 (8.3)	6 (8.3)	11 (6.4)	17 (7.0)
Reasonable Possibility	1 (1.4)	2 (2.8)	3 (1.8)	5 (2.0)
上気道感染	7 (9.7)	1 (1.4)	10 (5.8)	11 (4.5)
No Reasonable Possibility	7 (9.7)	1 (1.4)	4 (2.3)	5 (2.0)
Reasonable Possibility	0	0	6 (3.5)	6 (2.5)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
膀胱炎	2 (2.8)	1 (1.4)	10 (5.8)	11 (4.5)
No Reasonable Possibility	1 (1.4)	0	5 (2.9)	5 (2.0)
Reasonable Possibility	1 (1.4)	1 (1.4)	5 (2.9)	6 (2.5)
口腔ヘルペス	1 (1.4)	0	11 (6.4)	11 (4.5)
No Reasonable Possibility	1 (1.4)	0	2 (1.2)	2 (0.8)
Reasonable Possibility	0	0	9 (5.3)	9 (3.7)
帯状疱疹	2 (2.8)	3 (4.1)	5 (2.9)	8 (3.3)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	2 (2.8)	3 (4.1)	4 (2.3)	7 (2.9)
肺炎	2 (2.8)	3 (4.1)	4 (2.3)	7 (2.9)
No Reasonable Possibility	2 (2.8)	2 (2.8)	2 (1.2)	4 (1.6)
Reasonable Possibility	0	1 (1.4)	2 (1.2)	3 (1.2)
副鼻腔炎	2 (2.8)	2 (2.8)	5 (2.9)	7 (2.9)
No Reasonable Possibility	0	1 (1.4)	4 (2.3)	5 (2.0)
Reasonable Possibility	2 (2.8)	1 (1.4)	1 (0.6)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
気道感染	1 (1.4)	2 (2.8)	4 (2.3)	6 (2.5)
No Reasonable Possibility	1 (1.4)	1 (1.4)	3 (1.8)	4 (1.6)
Reasonable Possibility	0	1 (1.4)	1 (0.6)	2 (0.8)
口腔カンジダ症	0	1 (1.4)	4 (2.3)	5 (2.0)
No Reasonable Possibility	0	0	3 (1.8)	3 (1.2)
Reasonable Possibility	0	1 (1.4)	1 (0.6)	2 (0.8)
潜伏結核	1 (1.4)	2 (2.8)	2 (1.2)	4 (1.6)
No Reasonable Possibility	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
Reasonable Possibility	0	1 (1.4)	1 (0.6)	2 (0.8)
咽頭炎	1 (1.4)	2 (2.8)	2 (1.2)	4 (1.6)
No Reasonable Possibility	0	1 (1.4)	2 (1.2)	3 (1.2)
Reasonable Possibility	1 (1.4)	1 (1.4)	0	1 (0.4)
歯肉炎	0	1 (1.4)	3 (1.8)	4 (1.6)
No Reasonable Possibility	0	0	3 (1.8)	3 (1.2)
Reasonable Possibility	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
鼻炎	0	1 (1.4)	3 (1.8)	4 (1.6)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
Reasonable Possibility	0	1 (1.4)	1 (0.6)	2 (0.8)
爪囲炎	2 (2.8)	0	3 (1.8)	3 (1.2)
Reasonable Possibility	2 (2.8)	0	3 (1.8)	3 (1.2)
結膜炎	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
No Reasonable Possibility	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
インフルエンザ	1 (1.4)	0	3 (1.8)	3 (1.2)
No Reasonable Possibility	1 (1.4)	0	2 (1.2)	2 (0.8)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
歯感染	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
No Reasonable Possibility	0	1 (1.4)	2 (1.2)	3 (1.2)
Reasonable Possibility	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
気管支炎	0	0	3 (1.8)	3 (1.2)
No Reasonable Possibility	0	0	3 (1.8)	3 (1.2)
ウイルス感染	0	1 (1.4)	2 (1.2)	3 (1.2)
No Reasonable Possibility	0	1 (1.4)	2 (1.2)	3 (1.2)
皮膚真菌感染	1 (1.4)	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	1 (1.4)	0	2 (1.2)	2 (0.8)
創傷感染	1 (1.4)	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
耳感染	0	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	0	1 (1.4)	1 (0.6)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
毛包炎	0	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
下気道感染	0	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
RSウイルス感染	0	2 (2.8)	0	2 (0.8)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
皮膚感染	0	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
気管気管支炎	0	0	2 (1.2)	2 (0.8)
Reasonable Possibility	0	0	2 (1.2)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
胃腸炎	3 (4.2)	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	2 (2.8)	1 (1.4)	0	1 (0.4)
Reasonable Possibility	1 (1.4)	0	0	0
単純ヘルペス	3 (4.2)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	2 (2.8)	0	0	0
Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
蜂巣炎	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	1 (1.4)	0	0	0
足部白癬	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
歯膿瘍	1 (1.4)	0	1 (0.6)	1 (0.4)
Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
急性副鼻腔炎	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
アデノウイルス結膜炎	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
憩室炎	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
眼感染	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
真菌性足感染	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
麦粒腫	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
食道カンジダ症	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
爪真菌症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
眼帯状疱疹	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
慢性中耳炎	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
術後創感染	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
ウイルス性気道感染	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
サルモネラ症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
唾液腺炎	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
ウイルス性上気道感染	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
ブドウ球菌性創感染	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
アスペルギルス感染	1 (1.4)	0	0	0
Reasonable Possibility	1 (1.4)	0	0	0
大腸菌性尿路感染	1 (1.4)	0	0	0
Reasonable Possibility	1 (1.4)	0	0	0
口腔感染	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
細菌性尿路感染	1 (1.4)	0	0	0
Reasonable Possibility	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
尿路性敗血症	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
傷害、中毒および処置合併症	15 (20.8)	11 (15.2)	44 (25.7)	55 (22.5)
No Reasonable Possibility	15 (20.8)	11 (15.2)	42 (24.5)	53 (21.7)
Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
転倒	3 (4.2)	1 (1.4)	8 (4.7)	9 (3.7)
No Reasonable Possibility	3 (4.2)	1 (1.4)	8 (4.7)	9 (3.7)
挫傷	1 (1.4)	3 (4.1)	6 (3.5)	9 (3.7)
No Reasonable Possibility	1 (1.4)	3 (4.1)	5 (2.9)	8 (3.3)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
骨挫傷	1 (1.4)	0	3 (1.8)	3 (1.2)
No Reasonable Possibility	1 (1.4)	0	3 (1.8)	3 (1.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
傷害、中毒および処置合併症 (Cont.)				
靱帯捻挫	0	0	3 (1.8)	3 (1.2)
No Reasonable Possibility	0	0	3 (1.8)	3 (1.2)
関節脱臼	0	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
処置による疼痛	0	2 (2.8)	0	2 (0.8)
No Reasonable Possibility	0	2 (2.8)	0	2 (0.8)
肋骨骨折	0	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
創傷	0	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	0	1 (1.4)	1 (0.6)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
傷害、中毒および処置合併症 (Cont.)				
節足動物咬傷	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
足骨折	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
肉離れ	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
皮膚裂傷	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	0	0
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
軟部組織損傷	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
傷害、中毒および処置合併症 (Cont.)				
脊椎圧迫骨折	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
ストレス骨折	1 (1.4)	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	1 (1.4)	1 (1.4)	0	1 (0.4)
術後貧血	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
足関節部骨折	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
剥離骨折	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
傷害、中毒および処置合併症 (Cont.)				
上顎炎	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
免疫反応	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
下肢骨折	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
術後創合併症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
処置による悪心	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
傷害、中毒および処置合併症 (Cont.)				
処置による気胸	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
植皮生着不全	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
縫合関連合併症	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
腱断裂	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
熱傷	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
傷害、中毒および処置合併症 (Cont.)				
胸椎骨折	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
歯牙破折	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
手首関節骨折	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
低温による損傷	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
歯科修復不成功	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
傷害、中毒および処置合併症 (Cont.)				
肩甲骨骨折	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
臨床検査	23 (31.8)	1 (1.4)	34 (19.8)	35 (14.3)
No Reasonable Possibility	21 (29.1)	1 (1.4)	17 (9.9)	18 (7.4)
Reasonable Possibility	2 (2.8)	0	17 (9.9)	17 (7.0)
血中クレアチンホスホキナーゼ増加	0	0	8 (4.7)	8 (3.3)
Reasonable Possibility	0	0	8 (4.7)	8 (3.3)
体重増加	2 (2.8)	1 (1.4)	3 (1.8)	4 (1.6)
No Reasonable Possibility	2 (2.8)	1 (1.4)	3 (1.8)	4 (1.6)
アラニンアミノトランスフェラーゼ増加	0	0	3 (1.8)	3 (1.2)
Reasonable Possibility	0	0	3 (1.8)	3 (1.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
臨床検査 (Cont.)				
血沈亢進	2 (2.8)	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	2 (2.8)	0	2 (1.2)	2 (0.8)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	2 (1.2)	2 (0.8)
Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
血中クレアチニン増加	4 (5.5)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	4 (5.5)	0	1 (0.6)	1 (0.4)
眼圧上昇	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
血中トリグリセリド増加	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
臨床検査 (Cont.)				
体温上昇	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
心雑音	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
B型肝炎ウイルス検査陽性	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
高比重リポ蛋白増加	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
脂質増加	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
臨床検査 (Cont.)				
肝機能検査異常	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
尿中亜硝酸塩陽性	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
便潜血陽性	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
血小板数増加	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
尿中赤血球陽性	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
臨床検査 (Cont.)				
トロポニンT増加	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
ビタミンB12減少	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
白血球数減少	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
ヘモグロビン減少	2 (2.8)	0	0	0
No Reasonable Possibility	2 (2.8)	0	0	0
体重減少	2 (2.8)	0	0	0
No Reasonable Possibility	2 (2.8)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
臨床検査 (Cont.)				
血中アルカリホスファターゼ増加	1 (1.4)	0	0	0
Reasonable Possibility	1 (1.4)	0	0	0
血中コレステロール増加	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
血中ブドウ糖増加	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
血中尿素増加	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
血中尿酸増加	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
臨床検査 (Cont.)				
Γ-グルタミルトランスフェラーゼ増加	1 (1.4)	0	0	0
Reasonable Possibility	1 (1.4)	0	0	0
ヘマトクリット減少	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
前立腺特異性抗原増加	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
赤血球数減少	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
腎機能検査異常	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
代謝および栄養障害	9 (12.5)	7 (9.6)	25 (14.6)	32 (13.1)
No Reasonable Possibility	9 (12.5)	7 (9.6)	20 (11.7)	27 (11.1)
Reasonable Possibility	0	0	5 (2.9)	5 (2.0)
高コレステロール血症	0	2 (2.8)	5 (2.9)	7 (2.9)
No Reasonable Possibility	0	2 (2.8)	4 (2.3)	6 (2.5)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
低カリウム血症	3 (4.2)	1 (1.4)	4 (2.3)	5 (2.0)
No Reasonable Possibility	3 (4.2)	1 (1.4)	4 (2.3)	5 (2.0)
低ナトリウム血症	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
No Reasonable Possibility	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
脂質異常症	0	1 (1.4)	2 (1.2)	3 (1.2)
No Reasonable Possibility	0	1 (1.4)	1 (0.6)	2 (0.8)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
代謝および栄養障害 (Cont.)				
ステロイド糖尿病	1 (1.4)	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	1 (1.4)	0	2 (1.2)	2 (0.8)
食欲減退	1 (1.4)	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	1 (1.4)	1 (1.4)	0	1 (0.4)
糖尿病	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	0	0
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
体液貯留	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
高血糖	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
代謝および栄養障害 (Cont.)				
高脂血症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
高尿酸血症	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
低カルシウム血症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
低クロール血症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
低血糖	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
代謝および栄養障害 (Cont.)				
低蛋白血症	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
脂肪腫症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
ビタミンD欠乏	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
葉酸欠乏	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
鉄欠乏	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害	67 (92.7)	34 (46.8)	141 (82.3)	175 (71.7)
No Reasonable Possibility	66 (91.3)	34 (46.8)	139 (81.1)	173 (70.9)
Reasonable Possibility	1 (1.4)	0	2 (1.2)	2 (0.8)
関節痛	15 (20.8)	3 (4.1)	24 (14.0)	27 (11.1)
No Reasonable Possibility	15 (20.8)	3 (4.1)	24 (14.0)	27 (11.1)
背部痛	9 (12.5)	3 (4.1)	21 (12.3)	24 (9.8)
No Reasonable Possibility	9 (12.5)	3 (4.1)	21 (12.3)	24 (9.8)
四肢痛	4 (5.5)	1 (1.4)	16 (9.3)	17 (7.0)
No Reasonable Possibility	4 (5.5)	1 (1.4)	16 (9.3)	17 (7.0)
変形性関節症	4 (5.5)	1 (1.4)	12 (7.0)	13 (5.3)
No Reasonable Possibility	4 (5.5)	1 (1.4)	12 (7.0)	13 (5.3)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
筋肉痛	2 (2.8)	3 (4.1)	6 (3.5)	9 (3.7)
No Reasonable Possibility	2 (2.8)	3 (4.1)	6 (3.5)	9 (3.7)
筋痙縮	4 (5.5)	1 (1.4)	7 (4.1)	8 (3.3)
No Reasonable Possibility	3 (4.2)	1 (1.4)	7 (4.1)	8 (3.3)
Reasonable Possibility	1 (1.4)	0	0	0
骨粗鬆症	3 (4.2)	1 (1.4)	5 (2.9)	6 (2.5)
No Reasonable Possibility	3 (4.2)	1 (1.4)	5 (2.9)	6 (2.5)
頚部痛	4 (5.5)	0	5 (2.9)	5 (2.0)
No Reasonable Possibility	4 (5.5)	0	5 (2.9)	5 (2.0)
顎痛	0	3 (4.1)	2 (1.2)	5 (2.0)
No Reasonable Possibility	0	3 (4.1)	2 (1.2)	5 (2.0)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
線維筋痛	0	2 (2.8)	2 (1.2)	4 (1.6)
No Reasonable Possibility	0	2 (2.8)	1 (0.6)	3 (1.2)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
椎間板突出	3 (4.2)	1 (1.4)	2 (1.2)	3 (1.2)
No Reasonable Possibility	3 (4.2)	1 (1.4)	2 (1.2)	3 (1.2)
筋力低下	2 (2.8)	1 (1.4)	2 (1.2)	3 (1.2)
No Reasonable Possibility	2 (2.8)	1 (1.4)	2 (1.2)	3 (1.2)
筋骨格系胸痛	2 (2.8)	1 (1.4)	2 (1.2)	3 (1.2)
No Reasonable Possibility	2 (2.8)	1 (1.4)	2 (1.2)	3 (1.2)
腱障害	1 (1.4)	2 (2.8)	1 (0.6)	3 (1.2)
No Reasonable Possibility	1 (1.4)	2 (2.8)	1 (0.6)	3 (1.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
滑液包炎	0	0	3 (1.8)	3 (1.2)
No Reasonable Possibility	0	0	3 (1.8)	3 (1.2)
骨減少症	0	0	3 (1.8)	3 (1.2)
No Reasonable Possibility	0	0	3 (1.8)	3 (1.2)
大転子疼痛症候群	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
肩回旋筋腱板症候群	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
脊椎痛	1 (1.4)	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	1 (1.4)	0	2 (1.2)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
筋骨格痛	0	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
ミオパチー	0	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	0	1 (1.4)	1 (0.6)	2 (0.8)
腱炎	0	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
弾発指	0	2 (2.8)	0	2 (0.8)
No Reasonable Possibility	0	2 (2.8)	0	2 (0.8)
筋骨格硬直	3 (4.2)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	3 (4.2)	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
関節可動域低下	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
腰部脊柱管狭窄症	1 (1.4)	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	1 (1.4)	1 (1.4)	0	1 (0.4)
リウマチ性多発筋痛	1 (1.4)	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	1 (1.4)	1 (1.4)	0	1 (0.4)
シェーグレン症候群	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
滑液嚢腫	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
狭窄性腱鞘炎	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
関節炎	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
頚部脊柱管狭窄症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
側腹部痛	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
単径部痛	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
関節滲出液	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
関節腫脹	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
半月板変性	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
筋骨格障害	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
骨端症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
関節周囲炎	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
足底筋膜炎	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
肩甲帯痛	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
脊柱管狭窄症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
脊椎滑液嚢腫	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
顎関節症候群	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
腱痛	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
腱鞘炎	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
椎間孔狭窄	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
関節障害	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
椎間板障害	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	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)	4 (5.5)	4 (5.5)	17 (9.9)	21 (8.6)
No Reasonable Possibility	4 (5.5)	4 (5.5)	14 (8.2)	18 (7.4)
Reasonable Possibility	0	0	3 (1.8)	3 (1.2)
皮膚有棘細胞癌	0	0	5 (2.9)	5 (2.0)
No Reasonable Possibility	0	0	3 (1.8)	3 (1.2)
Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
脂漏性角化症	0	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
基底細胞癌	2 (2.8)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	2 (2.8)	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
副腎腺腫	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
良性毛包腫瘍	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
悪性黒子	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
脂肪腫	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
肺腺癌	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
メラノサイト性母斑	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
骨髄異形成症候群	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
粘液腫	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
皮膚の新生物	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
甲状腺乳頭癌	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
前立腺癌	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
前立腺腺腫	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
皮膚乳頭腫	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
血管筋脂肪腫	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
神経線維腫	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害	30 (41.5)	32 (44.1)	76 (44.3)	108 (44.3)
No Reasonable Possibility	28 (38.7)	31 (42.7)	74 (43.2)	105 (43.0)
Reasonable Possibility	2 (2.8)	1 (1.4)	2 (1.2)	3 (1.2)
頭痛	7 (9.7)	11 (15.2)	26 (15.2)	37 (15.2)
No Reasonable Possibility	7 (9.7)	11 (15.2)	25 (14.6)	36 (14.8)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
坐骨神経痛	1 (1.4)	3 (4.1)	4 (2.3)	7 (2.9)
No Reasonable Possibility	1 (1.4)	3 (4.1)	4 (2.3)	7 (2.9)
浮動性めまい	6 (8.3)	2 (2.8)	4 (2.3)	6 (2.5)
No Reasonable Possibility	5 (6.9)	2 (2.8)	4 (2.3)	6 (2.5)
Reasonable Possibility	1 (1.4)	0	0	0
錯感覚	1 (1.4)	2 (2.8)	2 (1.2)	4 (1.6)
No Reasonable Possibility	1 (1.4)	2 (2.8)	2 (1.2)	4 (1.6)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
感覚鈍麻	0	0	4 (2.3)	4 (1.6)
No Reasonable Possibility	0	0	4 (2.3)	4 (1.6)
後頭神経痛	0	0	4 (2.3)	4 (1.6)
No Reasonable Possibility	0	0	4 (2.3)	4 (1.6)
緊張性頭痛	0	2 (2.8)	2 (1.2)	4 (1.6)
No Reasonable Possibility	0	2 (2.8)	2 (1.2)	4 (1.6)
灼熱感	0	1 (1.4)	2 (1.2)	3 (1.2)
No Reasonable Possibility	0	1 (1.4)	2 (1.2)	3 (1.2)
手根管症候群	0	0	3 (1.8)	3 (1.2)
No Reasonable Possibility	0	0	3 (1.8)	3 (1.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
失神寸前の状態	0	0	3 (1.8)	3 (1.2)
No Reasonable Possibility	0	0	3 (1.8)	3 (1.2)
神経根障害	0	0	3 (1.8)	3 (1.2)
No Reasonable Possibility	0	0	3 (1.8)	3 (1.2)
頚動脈狭窄	0	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
記憶障害	0	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	0	1 (1.4)	1 (0.6)	2 (0.8)
ヘルペス後神経痛	0	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
偽性根症候群	0	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	0	1 (1.4)	1 (0.6)	2 (0.8)
下肢静止不能症候群	0	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
失神	2 (2.8)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	2 (2.8)	0	1 (0.6)	1 (0.4)
振戦	2 (2.8)	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	1 (1.4)	1 (1.4)	0	1 (0.4)
Reasonable Possibility	1 (1.4)	0	0	0
腰髄神経根障害	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
健忘	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
無嗅覚	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
頚腕症候群	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
注意力障害	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
労作性めまい	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
ジストニア	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
電気ショック様感覚	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
味覚減退	0	1 (1.4)	0	1 (0.4)
Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
脳圧低下	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
不随意性筋収縮	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
神経痛性筋萎縮症	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
精神運動亢進	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
4分の1盲	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
一過性失語症	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
一過性脳虚血発作	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
トンネル状視野	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
椎骨動脈狭窄	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
平衡障害	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
ブレインフォグ	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
脳アミロイド血管障害	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
脳脊髄瘻	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
異常感覚	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
片頭痛	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
神経痛	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
末梢性ニューロパチー	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
視神経炎	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
多発ニューロパチー	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
精神障害	7 (9.7)	4 (5.5)	9 (5.3)	13 (5.3)
No Reasonable Possibility	7 (9.7)	2 (2.8)	9 (5.3)	11 (4.5)
Reasonable Possibility	0	2 (2.8)	0	2 (0.8)
不眠症	2 (2.8)	0	3 (1.8)	3 (1.2)
No Reasonable Possibility	2 (2.8)	0	3 (1.8)	3 (1.2)
不安	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
No Reasonable Possibility	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
精神障害 (Cont.)				
抑うつ気分	0	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
神経過敏	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
歯ぎしり	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
錯乱状態	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
リビドー減退	0	1 (1.4)	0	1 (0.4)
Reasonable Possibility	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
精神障害 (Cont.)				
落ち着きのなさ	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
譫妄	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
躁病	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
混合性不安抑うつ障害	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
腎および尿路障害	11 (15.2)	2 (2.8)	7 (4.1)	9 (3.7)
No Reasonable Possibility	11 (15.2)	2 (2.8)	7 (4.1)	9 (3.7)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
腎および尿路障害 (Cont.)				
頻尿	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
No Reasonable Possibility	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
腎損傷	0	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
血尿	3 (4.2)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	3 (4.2)	0	1 (0.6)	1 (0.4)
腎結石症	1 (1.4)	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	1 (1.4)	1 (1.4)	0	1 (0.4)
夜間頻尿	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
腎および尿路障害 (Cont.)				
尿道狭窄	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
急性腎障害	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
緊張性膀胱	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
蛋白尿	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
腎仙痛	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
腎および尿路障害 (Cont.)				
腎嚢胞	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
尿失禁	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
生殖系および乳房障害	2 (2.8)	3 (4.1)	7 (4.1)	10 (4.1)
No Reasonable Possibility	2 (2.8)	3 (4.1)	6 (3.5)	9 (3.7)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
勃起不全	0	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	0	1 (1.4)	1 (0.6)	2 (0.8)
乳房腫瘤	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
生殖系および乳房障害 (Cont.)				
乳房痛	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
膀胱瘤	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
乳頭痛	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
骨盤痛	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
前立腺腫大	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
生殖系および乳房障害 (Cont.)				
外陰腟灼熱感	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
外陰腟乾燥	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
亀頭包皮炎	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
外陰腟そう痒症	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
呼吸器、胸郭および縦隔障害	11 (15.2)	9 (12.4)	32 (18.7)	41 (16.8)
No Reasonable Possibility	11 (15.2)	9 (12.4)	23 (13.4)	32 (13.1)
Reasonable Possibility	0	0	9 (5.3)	9 (3.7)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
呼吸器、胸郭および縦隔障害 (Cont.)				
咳嗽	5 (6.9)	3 (4.1)	10 (5.8)	13 (5.3)
No Reasonable Possibility	5 (6.9)	3 (4.1)	7 (4.1)	10 (4.1)
Reasonable Possibility	0	0	3 (1.8)	3 (1.2)
口腔咽頭痛	1 (1.4)	1 (1.4)	3 (1.8)	4 (1.6)
No Reasonable Possibility	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
喘息	0	0	4 (2.3)	4 (1.6)
No Reasonable Possibility	0	0	3 (1.8)	3 (1.2)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
呼吸困難	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
No Reasonable Possibility	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
鼻出血	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
呼吸器、胸郭および縦隔障害 (Cont.)				
鼻漏	1 (1.4)	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	1 (1.4)	0	2 (1.2)	2 (0.8)
肺腫瘤	0	2 (2.8)	0	2 (0.8)
No Reasonable Possibility	0	2 (2.8)	0	2 (0.8)
慢性気管支炎	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
気管支痙攣	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
下咽頭癒着	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
呼吸器、胸郭および縦隔障害 (Cont.)				
鼻閉	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
起坐呼吸	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
胸水	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
湿性咳嗽	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
肺塞栓症	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
呼吸器、胸郭および縦隔障害 (Cont.)				
呼吸障害	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
アレルギー性鼻炎	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
咽喉刺激感	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
労作性呼吸困難	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
咳払い	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害	19 (26.3)	9 (12.4)	48 (28.0)	57 (23.4)
No Reasonable Possibility	15 (20.8)	8 (11.0)	35 (20.4)	43 (17.6)
Reasonable Possibility	4 (5.5)	1 (1.4)	13 (7.6)	14 (5.7)
発疹	2 (2.8)	2 (2.8)	8 (4.7)	10 (4.1)
No Reasonable Possibility	2 (2.8)	2 (2.8)	6 (3.5)	8 (3.3)
Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
ざ瘡	0	0	6 (3.5)	6 (2.5)
No Reasonable Possibility	0	0	4 (2.3)	4 (1.6)
Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
寝汗	1 (1.4)	2 (2.8)	1 (0.6)	3 (1.2)
No Reasonable Possibility	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
脱毛症	0	0	3 (1.8)	3 (1.2)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
多汗症	0	1 (1.4)	2 (1.2)	3 (1.2)
No Reasonable Possibility	0	1 (1.4)	1 (0.6)	2 (0.8)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
皮膚潰瘍	2 (2.8)	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	2 (2.8)	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
皮膚乾燥	1 (1.4)	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
紅斑	1 (1.4)	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
Reasonable Possibility	1 (1.4)	0	0	0
光線角化症	0	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
接触皮膚炎	0	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
斑状丘疹状皮疹	0	1 (1.4)	1 (0.6)	2 (0.8)
No Reasonable Possibility	0	1 (1.4)	1 (0.6)	2 (0.8)
酒さ	0	0	2 (1.2)	2 (0.8)
No Reasonable Possibility	0	0	2 (1.2)	2 (0.8)
過角化	1 (1.4)	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	1 (1.4)	1 (1.4)	0	1 (0.4)
円形脱毛症	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
皮膚嚢腫	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
皮膚炎	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
びまん性脱毛症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
湿疹	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
毛髪成長異常	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
男性型多毛症	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
汗疹	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
爪変色	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
爪破損	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
皮膚疼痛	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
口囲皮膚炎	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
痂皮	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
皮膚硬結	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
皮膚病変	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
うっ滞性皮膚炎	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
黄色皮膚	0	0	1 (0.6)	1 (0.4)
Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
水疱	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
冷汗	1 (1.4)	0	0	0
Reasonable Possibility	1 (1.4)	0	0	0
アレルギー性皮膚炎	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
斑状出血	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
丘疹	1 (1.4)	0	0	0
Reasonable Possibility	1 (1.4)	0	0	0
類天疱瘡	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
痒疹	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
そう痒症	1 (1.4)	0	0	0
Reasonable Possibility	1 (1.4)	0	0	0
乾癬	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
斑状皮疹	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
脂漏性皮膚炎	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
血管障害	29 (40.1)	16 (22.0)	47 (27.4)	63 (25.8)
No Reasonable Possibility	25 (34.6)	15 (20.7)	39 (22.8)	54 (22.1)
Reasonable Possibility	4 (5.5)	1 (1.4)	8 (4.7)	9 (3.7)
高血圧	5 (6.9)	7 (9.6)	20 (11.7)	27 (11.1)
No Reasonable Possibility	4 (5.5)	7 (9.6)	17 (9.9)	24 (9.8)
Reasonable Possibility	1 (1.4)	0	3 (1.8)	3 (1.2)
巨細胞性動脈炎	13 (18.0)	6 (8.3)	20 (11.7)	26 (10.7)
No Reasonable Possibility	11 (15.2)	5 (6.9)	15 (8.8)	20 (8.2)
Reasonable Possibility	2 (2.8)	1 (1.4)	5 (2.9)	6 (2.5)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
血管障害 (Cont.)				
血腫	3 (4.2)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	3 (4.2)	0	1 (0.6)	1 (0.4)
間欠性跛行	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
レイノー現象	1 (1.4)	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	1 (1.4)	1 (1.4)	0	1 (0.4)
静脈瘤	1 (1.4)	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	1 (1.4)	0	1 (0.6)	1 (0.4)
動脈出血	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
血管障害 (Cont.)				
リンパ浮腫	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
リンパうっ滞	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
起立性低血圧	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)
血栓性静脈炎	0	1 (1.4)	0	1 (0.4)
No Reasonable Possibility	0	1 (1.4)	0	1 (0.4)
白衣性高血圧	0	0	1 (0.6)	1 (0.4)
No Reasonable Possibility	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.6.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Relationship to Upadacitinib (or Matching Placebo) - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Relationship	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
血管障害 (Cont.)				
大動脈瘤	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
大動脈炎	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
動脈硬化症	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0
末梢冷感	1 (1.4)	0	0	0
Reasonable Possibility	1 (1.4)	0	0	0
末梢静脈疾患	1 (1.4)	0	0	0
No Reasonable Possibility	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

表5

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ABT-494 (GIANT CELL ARTERITIS)
STUDY M16-852 (CUTOFF 06FEB2024)
R&D/23/2455 - CLINICAL/STATISTICAL

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
Any adverse event	106 (94.6)	102 (95.3)	202 (96.7)	304 (96.2)
Grade 1	18 (16.1)	18 (16.8)	22 (10.5)	40 (12.7)
Grade 2	57 (50.9)	64 (59.8)	115 (55.0)	179 (56.6)
Grade 3	27 (24.1)	19 (17.8)	55 (26.3)	74 (23.4)
Grade 4	2 (1.8)	1 (0.9)	8 (3.8)	9 (2.8)
Grade 5	2 (1.8)	0	2 (1.0)	2 (0.6)
血液およびリンパ系障害	6 (5.4)	4 (3.7)	19 (9.1)	23 (7.3)
Grade 1	3 (2.7)	2 (1.9)	13 (6.2)	15 (4.7)
Grade 2	2 (1.8)	1 (0.9)	6 (2.9)	7 (2.2)
Grade 3	1 (0.9)	1 (0.9)	0	1 (0.3)
貧血	2 (1.8)	3 (2.8)	9 (4.3)	12 (3.8)
Grade 1	1 (0.9)	1 (0.9)	6 (2.9)	7 (2.2)
Grade 2	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
Grade 3	0	1 (0.9)	0	1 (0.3)
内出血発生の増加傾向	1 (0.9)	1 (0.9)	4 (1.9)	5 (1.6)
Grade 1	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
鉄欠乏性貧血	0	0	2 (1.0)	2 (0.6)
Grade 2	0	0	2 (1.0)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
血液およびリンパ系障害 (Cont.)				
血小板増加症	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	2 (1.0)	2 (0.6)
大赤血球症	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)
好酸球増加症	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
白血球増加症	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
リンパ球増加症	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
血液およびリンパ系障害 (Cont.)				
リンパ球減少症	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
好中球増加症	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
白血球減少症	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
好中球減少症	1 (0.9)	0	0	0
Grade 3	1 (0.9)	0	0	0
心臓障害	15 (13.4)	10 (9.3)	23 (11.0)	33 (10.4)
Grade 1	5 (4.5)	5 (4.7)	7 (3.3)	12 (3.8)
Grade 2	8 (7.1)	3 (2.8)	9 (4.3)	12 (3.8)
Grade 3	2 (1.8)	2 (1.9)	7 (3.3)	9 (2.8)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
心臓障害 (Cont.)				
動悸	2 (1.8)	2 (1.9)	4 (1.9)	6 (1.9)
Grade 1	1 (0.9)	2 (1.9)	2 (1.0)	4 (1.3)
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
心房細動	2 (1.8)	0	4 (1.9)	4 (1.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	2 (1.8)	0	1 (0.5)	1 (0.3)
Grade 3	0	0	2 (1.0)	2 (0.6)
心不全	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 3	0	1 (0.9)	1 (0.5)	2 (0.6)
うっ血性心不全	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 3	0	0	1 (0.5)	1 (0.3)
三尖弁閉鎖不全症	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
心臓障害 (Cont.)				
高血圧性心筋症	0	2 (1.9)	0	2 (0.6)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
冠動脈硬化症	2 (1.8)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	0	0
僧帽弁閉鎖不全症	2 (1.8)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
頻脈	2 (1.8)	0	1 (0.5)	1 (0.3)
Grade 2	2 (1.8)	0	1 (0.5)	1 (0.3)
第一度房室ブロック	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
心臓障害 (Cont.)				
大動脈弁石灰化	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
大動脈弁狭窄	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
心房頻脈	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
心臓弁膜疾患	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
肺性心	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
心臓障害 (Cont.)				
冠動脈疾患	0	1 (0.9)	0	1 (0.3)
Grade 3	0	1 (0.9)	0	1 (0.3)
冠動脈入口部狭窄	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
拡張機能障害	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
期外収縮	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
高血圧性心疾患	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
心臓障害 (Cont.)				
虚血性心筋症	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
左室肥大	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
右室不全	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
洞性徐脈	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
洞性頻脈	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
心臓障害 (Cont.)				
狭心症	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
大動脈弁疾患	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
大動脈弁閉鎖不全症	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
右脚ブロック	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
線維性心内膜炎	1 (0.9)	0	0	0
Grade 3	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
心臓障害 (Cont.)				
心筋虚血	1 (0.9)	0	0	0
Grade 3	1 (0.9)	0	0	0
洞性不整脈	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
心室性期外収縮	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
先天性、家族性および遺伝性障害	2 (1.8)	1 (0.9)	0	1 (0.3)
Grade 1	2 (1.8)	0	0	0
Grade 2	0	1 (0.9)	0	1 (0.3)
歯牙形成不全	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
先天性、家族性および遺伝性障害 (Cont.)				
心房中隔欠損症	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
播種状表在性光線性汗孔角化症	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
耳および迷路障害	4 (3.6)	9 (8.4)	15 (7.2)	24 (7.6)
Grade 1	3 (2.7)	7 (6.5)	12 (5.7)	19 (6.0)
Grade 2	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
Grade 3	0	1 (0.9)	0	1 (0.3)
回転性めまい	2 (1.8)	4 (3.7)	7 (3.3)	11 (3.5)
Grade 1	1 (0.9)	3 (2.8)	5 (2.4)	8 (2.5)
Grade 2	1 (0.9)	0	2 (1.0)	2 (0.6)
Grade 3	0	1 (0.9)	0	1 (0.3)
耳鳴	2 (1.8)	3 (2.8)	5 (2.4)	8 (2.5)
Grade 1	2 (1.8)	3 (2.8)	5 (2.4)	8 (2.5)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
耳および迷路障害 (Cont.)				
耳痛	0	0	5 (2.4)	5 (1.6)
Grade 1	0	0	4 (1.9)	4 (1.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
感音性難聴	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
耳不快感	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
聴力低下	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
内分泌障害	5 (4.5)	9 (8.4)	9 (4.3)	18 (5.7)
Grade 1	5 (4.5)	7 (6.5)	7 (3.3)	14 (4.4)
Grade 2	0	2 (1.9)	2 (1.0)	4 (1.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
内分泌障害 (Cont.)				
クッシング様症状	0	5 (4.7)	4 (1.9)	9 (2.8)
Grade 1	0	4 (3.7)	3 (1.4)	7 (2.2)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
甲状腺腫瘤	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
Grade 1	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
クッシング症候群	2 (1.8)	0	2 (1.0)	2 (0.6)
Grade 1	2 (1.8)	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
甲状腺腫	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
甲状腺機能亢進症	0	2 (1.9)	0	2 (0.6)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
内分泌障害 (Cont.)				
副腎抑制	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
眼障害	22 (19.6)	21 (19.6)	56 (26.8)	77 (24.4)
Grade 1	15 (13.4)	10 (9.3)	36 (17.2)	46 (14.6)
Grade 2	7 (6.3)	10 (9.3)	14 (6.7)	24 (7.6)
Grade 3	0	1 (0.9)	5 (2.4)	6 (1.9)
Grade 4	0	0	1 (0.5)	1 (0.3)
白内障	2 (1.8)	6 (5.6)	10 (4.8)	16 (5.1)
Grade 1	2 (1.8)	0	5 (2.4)	5 (1.6)
Grade 2	0	6 (5.6)	5 (2.4)	11 (3.5)
霧視	4 (3.6)	5 (4.7)	6 (2.9)	11 (3.5)
Grade 1	4 (3.6)	4 (3.7)	5 (2.4)	9 (2.8)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
ドライアイ	3 (2.7)	2 (1.9)	8 (3.8)	10 (3.2)
Grade 1	2 (1.8)	1 (0.9)	5 (2.4)	6 (1.9)
Grade 2	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
眼障害 (Cont.)				
結膜出血	1 (0.9)	1 (0.9)	5 (2.4)	6 (1.9)
Grade 1	0	1 (0.9)	4 (1.9)	5 (1.6)
Grade 2	1 (0.9)	0	0	0
Grade 3	0	0	1 (0.5)	1 (0.3)
眼瞼炎	1 (0.9)	2 (1.9)	3 (1.4)	5 (1.6)
Grade 1	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
眼痛	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
Grade 1	1 (0.9)	0	3 (1.4)	3 (0.9)
Grade 2	0	1 (0.9)	0	1 (0.3)
緑内障	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 3	0	0	1 (0.5)	1 (0.3)
硝子体浮遊物	3 (2.7)	1 (0.9)	2 (1.0)	3 (0.9)
Grade 1	3 (2.7)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
眼障害 (Cont.)				
高眼圧症	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 1	0	1 (0.9)	2 (1.0)	3 (0.9)
眼部不快感	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	1 (0.9)	0	0	0
霰粒腫	0	0	2 (1.0)	2 (0.6)
Grade 2	0	0	2 (1.0)	2 (0.6)
複視	0	0	2 (1.0)	2 (0.6)
Grade 3	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	1 (0.5)	1 (0.3)
眼の炎症	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	2 (1.0)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
眼障害 (Cont.)				
眼部腫脹	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	1 (0.5)	2 (0.6)
眼の異物感	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	2 (1.0)	2 (0.6)
光視症	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
視野欠損	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
視力障害	2 (1.8)	0	1 (0.5)	1 (0.3)
Grade 1	2 (1.8)	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
眼障害 (Cont.)				
硝子体剥離	2 (1.8)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	0	0
眼刺激	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
視力低下	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)
加齢黄斑変性	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
眼瞼痙攣	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
眼障害 (Cont.)				
角膜浮腫	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
眼出血	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
眼瞼下垂	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
遠視	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
黄斑変性	0	1 (0.9)	0	1 (0.3)
Grade 3	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
眼障害 (Cont.)				
黄斑浮腫	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
眼充血	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
開放隅角緑内障	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
視神経萎縮	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
視神経乳頭出血	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
眼障害 (Cont.)				
眼窩浮腫	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
眼窩周囲痛	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
羞明	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
老視	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
網膜剥離	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
眼障害 (Cont.)				
網膜出血	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
網膜裂孔	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
眼瞼腫脹	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
流涙増加	2 (1.8)	0	0	0
Grade 1	2 (1.8)	0	0	0
アレルギー性結膜炎	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
眼障害 (Cont.)				
散瞳	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
眼窩脂肪ヘルニア	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
後嚢部混濁	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
胃腸障害	37 (33.0)	31 (29.0)	93 (44.5)	124 (39.2)
Grade 1	13 (11.6)	17 (15.9)	53 (25.4)	70 (22.2)
Grade 2	21 (18.8)	12 (11.2)	35 (16.7)	47 (14.9)
Grade 3	2 (1.8)	2 (1.9)	5 (2.4)	7 (2.2)
Grade 5	1 (0.9)	0	0	0
下痢	12 (10.7)	5 (4.7)	18 (8.6)	23 (7.3)
Grade 1	6 (5.4)	4 (3.7)	13 (6.2)	17 (5.4)
Grade 2	6 (5.4)	1 (0.9)	3 (1.4)	4 (1.3)
Grade 3	0	0	2 (1.0)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
便秘	2 (1.8)	8 (7.5)	11 (5.3)	19 (6.0)
Grade 1	0	4 (3.7)	4 (1.9)	8 (2.5)
Grade 2	2 (1.8)	4 (3.7)	7 (3.3)	11 (3.5)
悪心	4 (3.6)	6 (5.6)	11 (5.3)	17 (5.4)
Grade 1	1 (0.9)	6 (5.6)	8 (3.8)	14 (4.4)
Grade 2	3 (2.7)	0	2 (1.0)	2 (0.6)
Grade 3	0	0	1 (0.5)	1 (0.3)
消化不良	3 (2.7)	2 (1.9)	10 (4.8)	12 (3.8)
Grade 1	1 (0.9)	2 (1.9)	6 (2.9)	8 (2.5)
Grade 2	2 (1.8)	0	4 (1.9)	4 (1.3)
上腹部痛	5 (4.5)	0	11 (5.3)	11 (3.5)
Grade 1	3 (2.7)	0	7 (3.3)	7 (2.2)
Grade 2	2 (1.8)	0	4 (1.9)	4 (1.3)
腹痛	4 (3.6)	1 (0.9)	8 (3.8)	9 (2.8)
Grade 1	3 (2.7)	1 (0.9)	7 (3.3)	8 (2.5)
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
胃食道逆流性疾患	2 (1.8)	0	9 (4.3)	9 (2.8)
Grade 1	1 (0.9)	0	4 (1.9)	4 (1.3)
Grade 2	1 (0.9)	0	5 (2.4)	5 (1.6)
歯痛	2 (1.8)	0	7 (3.3)	7 (2.2)
Grade 1	2 (1.8)	0	2 (1.0)	2 (0.6)
Grade 2	0	0	5 (2.4)	5 (1.6)
嘔吐	1 (0.9)	2 (1.9)	5 (2.4)	7 (2.2)
Grade 1	0	1 (0.9)	4 (1.9)	5 (1.6)
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 3	0	1 (0.9)	0	1 (0.3)
下腹部痛	2 (1.8)	2 (1.9)	3 (1.4)	5 (1.6)
Grade 1	2 (1.8)	1 (0.9)	2 (1.0)	3 (0.9)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
アフタ性潰瘍	1 (0.9)	1 (0.9)	4 (1.9)	5 (1.6)
Grade 1	0	0	3 (1.4)	3 (0.9)
Grade 2	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
腹部膨満	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
Grade 1	0	1 (0.9)	3 (1.4)	4 (1.3)
Grade 2	1 (0.9)	0	0	0
口内乾燥	1 (0.9)	2 (1.9)	2 (1.0)	4 (1.3)
Grade 1	1 (0.9)	2 (1.9)	2 (1.0)	4 (1.3)
嚥下障害	0	2 (1.9)	1 (0.5)	3 (0.9)
Grade 1	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	0	1 (0.9)	0	1 (0.3)
歯肉痛	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 1	0	1 (0.9)	2 (1.0)	3 (0.9)
痔核	0	0	3 (1.4)	3 (0.9)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	2 (1.0)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
口腔内潰瘍形成	0	0	3 (1.4)	3 (0.9)
Grade 1	0	0	2 (1.0)	2 (0.6)
Grade 2	0	0	1 (0.5)	1 (0.3)
大腸ポリープ	3 (2.7)	0	2 (1.0)	2 (0.6)
Grade 1	0	0	2 (1.0)	2 (0.6)
Grade 2	3 (2.7)	0	0	0
胃炎	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
腸憩室	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
齲歯	1 (0.9)	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 3	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
鼓腸	1 (0.9)	1 (0.9)	0	1 (0.3)
Grade 1	1 (0.9)	1 (0.9)	0	1 (0.3)
排便回数増加	1 (0.9)	1 (0.9)	0	1 (0.3)
Grade 1	1 (0.9)	0	0	0
Grade 2	0	1 (0.9)	0	1 (0.3)
膵嚢胞	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	0	0
裂肛	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
口唇炎	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
虚血性大腸炎	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
潰瘍性大腸炎	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
十二指腸炎	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
十二指腸胃逆流	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
消化器痛	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
歯肉障害	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
痔出血	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
歯の知覚過敏	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
鼠径ヘルニア	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
口唇腫脹	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
腰ヘルニア	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
マロリー・ワイス症候群	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
非感染性歯肉炎	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
膵臓障害	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
膵炎	0	1 (0.9)	0	1 (0.3)
Grade 3	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
慢性膵炎	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
唾液腺痛	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
口内炎	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
舌不快感	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
舌潰瘍	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
歯の障害	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
腹部不快感	2 (1.8)	0	0	0
Grade 1	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
急性膵炎	2 (1.8)	0	0	0
Grade 3	1 (0.9)	0	0	0
Grade 5	1 (0.9)	0	0	0
慢性胃炎	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
大腸炎	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (Cont.)				
血便排泄	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
歯状態不良	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
直腸出血	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
一般・全身障害および投与部位の状態	21 (18.8)	21 (19.6)	73 (34.9)	94 (29.7)
Grade 1	14 (12.5)	16 (15.0)	42 (20.1)	58 (18.4)
Grade 2	5 (4.5)	5 (4.7)	27 (12.9)	32 (10.1)
Grade 3	2 (1.8)	0	3 (1.4)	3 (0.9)
Grade 5	0	0	1 (0.5)	1 (0.3)
疲労	6 (5.4)	4 (3.7)	19 (9.1)	23 (7.3)
Grade 1	4 (3.6)	3 (2.8)	15 (7.2)	18 (5.7)
Grade 2	2 (1.8)	1 (0.9)	4 (1.9)	5 (1.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
末梢性浮腫	3 (2.7)	7 (6.5)	16 (7.7)	23 (7.3)
Grade 1	0	5 (4.7)	9 (4.3)	14 (4.4)
Grade 2	1 (0.9)	2 (1.9)	6 (2.9)	8 (2.5)
Grade 3	2 (1.8)	0	1 (0.5)	1 (0.3)
発熱	2 (1.8)	4 (3.7)	9 (4.3)	13 (4.1)
Grade 1	1 (0.9)	4 (3.7)	8 (3.8)	12 (3.8)
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
胸痛	3 (2.7)	2 (1.9)	7 (3.3)	9 (2.8)
Grade 1	3 (2.7)	1 (0.9)	3 (1.4)	4 (1.3)
Grade 2	0	1 (0.9)	4 (1.9)	5 (1.6)
末梢腫脹	3 (2.7)	0	5 (2.4)	5 (1.6)
Grade 1	2 (1.8)	0	3 (1.4)	3 (0.9)
Grade 2	1 (0.9)	0	2 (1.0)	2 (0.6)
倦怠感	1 (0.9)	0	5 (2.4)	5 (1.6)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 2	0	0	4 (1.9)	4 (1.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
無力症	1 (0.9)	0	3 (1.4)	3 (0.9)
Grade 1	1 (0.9)	0	2 (1.0)	2 (0.6)
Grade 3	0	0	1 (0.5)	1 (0.3)
顔面腫脹	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
Grade 1	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	0	0	1 (0.5)	1 (0.3)
インフルエンザ様疾患	2 (1.8)	0	2 (1.0)	2 (0.6)
Grade 1	2 (1.8)	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
疼痛	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	1 (0.9)	0	0	0
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
胸部不快感	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	2 (1.0)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
悪寒	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	1 (0.5)	2 (0.6)
浮腫	0	0	2 (1.0)	2 (0.6)
Grade 2	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
非心臓性胸痛	2 (1.8)	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	2 (1.8)	0	0	0
歩行障害	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	0	0
Grade 3	0	0	1 (0.5)	1 (0.3)
不明確な障害	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	0	0
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
注射部位疼痛	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	0	0
医薬品副作用	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
Death	0	0	1 (0.5)	1 (0.3)
Grade 5	0	0	1 (0.5)	1 (0.3)
不快感	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
顔面浮腫	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
脂肪組織増加	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
冷感	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
熱感	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
小結節	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
治療非遵守	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
評価不能の事象	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
ワクチン接種部位疼痛	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
乾燥症	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
疾患前駆期	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
体調不良	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
腫脹	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
肝胆道系障害	6 (5.4)	1 (0.9)	6 (2.9)	7 (2.2)
Grade 1	2 (1.8)	0	3 (1.4)	3 (0.9)
Grade 2	1 (0.9)	0	3 (1.4)	3 (0.9)
Grade 3	3 (2.7)	1 (0.9)	0	1 (0.3)
肝細胞融解	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	0	0
Grade 2	0	0	1 (0.5)	1 (0.3)
肝病変	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	0	0
Grade 2	0	0	1 (0.5)	1 (0.3)
胆道ジスキネジア	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

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Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
肝胆道系障害 (Cont.)				
肝嚢胞	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
肝機能異常	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
脂肪肝	0	1 (0.9)	0	1 (0.3)
Grade 3	0	1 (0.9)	0	1 (0.3)
肝腫大	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
胆管嚢胞	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
肝胆道系障害 (Cont.)				
硬化性胆管炎	1 (0.9)	0	0	0
Grade 3	1 (0.9)	0	0	0
慢性胆嚢炎	1 (0.9)	0	0	0
Grade 3	1 (0.9)	0	0	0
胆石症	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
薬物性肝障害	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
胆嚢ポリープ	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
肝胆道系障害 (Cont.)				
急性肝炎	1 (0.9)	0	0	0
Grade 3	1 (0.9)	0	0	0
免疫系障害	1 (0.9)	1 (0.9)	7 (3.3)	8 (2.5)
Grade 1	1 (0.9)	0	4 (1.9)	4 (1.3)
Grade 2	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 3	0	0	1 (0.5)	1 (0.3)
季節性アレルギー	0	0	3 (1.4)	3 (0.9)
Grade 1	0	0	2 (1.0)	2 (0.6)
Grade 2	0	0	1 (0.5)	1 (0.3)
薬物過敏症	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
食物アレルギー	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
免疫系障害 (Cont.)				
低γグロブリン血症	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
サルコイドーシス	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
4型過敏症	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
アナフィラキシー様反応	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
感染症および寄生虫症	66 (58.9)	61 (57.0)	132 (63.2)	193 (61.1)
Grade 1	21 (18.8)	15 (14.0)	35 (16.7)	50 (15.8)
Grade 2	35 (31.3)	39 (36.4)	83 (39.7)	122 (38.6)
Grade 3	7 (6.3)	7 (6.5)	11 (5.3)	18 (5.7)
Grade 4	2 (1.8)	0	2 (1.0)	2 (0.6)
Grade 5	1 (0.9)	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
COVID-19	12 (10.7)	12 (11.2)	28 (13.4)	40 (12.7)
Grade 1	10 (8.9)	8 (7.5)	16 (7.7)	24 (7.6)
Grade 2	2 (1.8)	4 (3.7)	11 (5.3)	15 (4.7)
Grade 5	0	0	1 (0.5)	1 (0.3)
尿路感染	18 (16.1)	15 (14.0)	21 (10.0)	36 (11.4)
Grade 1	2 (1.8)	0	5 (2.4)	5 (1.6)
Grade 2	14 (12.5)	13 (12.1)	16 (7.7)	29 (9.2)
Grade 3	2 (1.8)	2 (1.9)	0	2 (0.6)
上咽頭炎	13 (11.6)	6 (5.6)	18 (8.6)	24 (7.6)
Grade 1	8 (7.1)	3 (2.8)	13 (6.2)	16 (5.1)
Grade 2	5 (4.5)	3 (2.8)	5 (2.4)	8 (2.5)
膀胱炎	3 (2.7)	5 (4.7)	15 (7.2)	20 (6.3)
Grade 1	0	1 (0.9)	3 (1.4)	4 (1.3)
Grade 2	3 (2.7)	4 (3.7)	11 (5.3)	15 (4.7)
Grade 3	0	0	1 (0.5)	1 (0.3)
上気道感染	8 (7.1)	8 (7.5)	11 (5.3)	19 (6.0)
Grade 1	3 (2.7)	5 (4.7)	4 (1.9)	9 (2.8)
Grade 2	5 (4.5)	3 (2.8)	6 (2.9)	9 (2.8)
Grade 3	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
口腔ヘルペス	4 (3.6)	3 (2.8)	8 (3.8)	11 (3.5)
Grade 1	4 (3.6)	2 (1.9)	1 (0.5)	3 (0.9)
Grade 2	0	1 (0.9)	7 (3.3)	8 (2.5)
帯状疱疹	3 (2.7)	3 (2.8)	8 (3.8)	11 (3.5)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	3 (2.7)	3 (2.8)	7 (3.3)	10 (3.2)
口腔カンジダ症	2 (1.8)	5 (4.7)	6 (2.9)	11 (3.5)
Grade 1	1 (0.9)	3 (2.8)	2 (1.0)	5 (1.6)
Grade 2	1 (0.9)	2 (1.9)	4 (1.9)	6 (1.9)
気管支炎	1 (0.9)	0	8 (3.8)	8 (2.5)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	7 (3.3)	7 (2.2)
インフルエンザ	1 (0.9)	3 (2.8)	4 (1.9)	7 (2.2)
Grade 1	1 (0.9)	1 (0.9)	4 (1.9)	5 (1.6)
Grade 2	0	2 (1.9)	0	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
肺炎	5 (4.5)	5 (4.7)	1 (0.5)	6 (1.9)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 2	2 (1.8)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 3	2 (1.8)	3 (2.8)	0	3 (0.9)
Grade 4	1 (0.9)	0	0	0
麦粒腫	1 (0.9)	1 (0.9)	5 (2.4)	6 (1.9)
Grade 1	1 (0.9)	0	2 (1.0)	2 (0.6)
Grade 2	0	1 (0.9)	3 (1.4)	4 (1.3)
鼻炎	1 (0.9)	1 (0.9)	5 (2.4)	6 (1.9)
Grade 1	1 (0.9)	1 (0.9)	4 (1.9)	5 (1.6)
Grade 2	0	0	1 (0.5)	1 (0.3)
結膜炎	4 (3.6)	1 (0.9)	4 (1.9)	5 (1.6)
Grade 1	2 (1.8)	1 (0.9)	2 (1.0)	3 (0.9)
Grade 2	2 (1.8)	0	2 (1.0)	2 (0.6)
胃腸炎	4 (3.6)	2 (1.9)	3 (1.4)	5 (1.6)
Grade 1	3 (2.7)	1 (0.9)	3 (1.4)	4 (1.3)
Grade 2	1 (0.9)	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
副鼻腔炎	1 (0.9)	2 (1.9)	3 (1.4)	5 (1.6)
Grade 2	1 (0.9)	2 (1.9)	3 (1.4)	5 (1.6)
爪真菌症	0	2 (1.9)	3 (1.4)	5 (1.6)
Grade 1	0	0	3 (1.4)	3 (0.9)
Grade 2	0	1 (0.9)	0	1 (0.3)
Grade 3	0	1 (0.9)	0	1 (0.3)
気道感染	0	1 (0.9)	4 (1.9)	5 (1.6)
Grade 2	0	1 (0.9)	3 (1.4)	4 (1.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
歯感染	3 (2.7)	3 (2.8)	1 (0.5)	4 (1.3)
Grade 1	2 (1.8)	1 (0.9)	0	1 (0.3)
Grade 2	1 (0.9)	2 (1.9)	1 (0.5)	3 (0.9)
咽頭炎	1 (0.9)	3 (2.8)	1 (0.5)	4 (1.3)
Grade 1	0	3 (2.8)	1 (0.5)	4 (1.3)
Grade 2	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
毛包炎	0	1 (0.9)	3 (1.4)	4 (1.3)
Grade 1	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	0	0	2 (1.0)	2 (0.6)
下気道感染	0	0	4 (1.9)	4 (1.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	3 (1.4)	3 (0.9)
爪囲炎	2 (1.8)	1 (0.9)	2 (1.0)	3 (0.9)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
皮膚真菌感染	1 (0.9)	2 (1.9)	1 (0.5)	3 (0.9)
Grade 1	1 (0.9)	0	0	0
Grade 2	0	2 (1.9)	1 (0.5)	3 (0.9)
耳感染	0	2 (1.9)	1 (0.5)	3 (0.9)
Grade 2	0	2 (1.9)	1 (0.5)	3 (0.9)

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Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
歯肉炎	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
足部白癬	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	1 (0.9)	0	0	0
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
感染性滑液包炎	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
COVID-19肺炎	0	0	2 (1.0)	2 (0.6)
Grade 2	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
丹毒	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)

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Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
消化管感染	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
眼帯状疱疹	0	0	2 (1.0)	2 (0.6)
Grade 3	0	0	2 (1.0)	2 (0.6)
口腔真菌感染	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
RSウイルス感染	0	2 (1.9)	0	2 (0.6)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 3	0	1 (0.9)	0	1 (0.3)
歯膿瘍	0	0	2 (1.0)	2 (0.6)
Grade 2	0	0	2 (1.0)	2 (0.6)

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Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
ウイルス感染	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
ウイルス性上気道感染	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	1 (0.5)	2 (0.6)
大腸菌性尿路感染	2 (1.8)	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 3	1 (0.9)	0	0	0
単純ヘルペス	2 (1.8)	0	1 (0.5)	1 (0.3)
Grade 2	2 (1.8)	0	1 (0.5)	1 (0.3)
カンジダ感染	1 (0.9)	1 (0.9)	0	1 (0.3)
Grade 2	1 (0.9)	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
潜伏結核	1 (0.9)	1 (0.9)	0	1 (0.3)
Grade 1	1 (0.9)	0	0	0
Grade 2	0	1 (0.9)	0	1 (0.3)
食道カンジダ症	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)
創傷感染	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 3	1 (0.9)	0	1 (0.5)	1 (0.3)
急性副鼻腔炎	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
アデノウイルス結膜炎	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
無症候性細菌尿	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
蜂巣炎	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
大腸菌性膀胱炎	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
皮膚糸状菌症	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
医療機器関連感染	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
憩室炎	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
遊走性紅斑	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
眼感染	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
熱性感染症	0	1 (0.9)	0	1 (0.3)
Grade 3	0	1 (0.9)	0	1 (0.3)
クロストリジウム菌性胃腸炎	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
ウイルス性胃腸炎	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
陰部単純ヘルペス	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
泌尿生殖器感染	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
耳帯状疱疹	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
椎間板炎	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
限局性感染	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
中耳炎	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
慢性中耳炎	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
ニューモシスチス・イロベチイ肺炎	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	1 (0.5)	1 (0.3)
シュードモナス性肺炎	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
シュードモナス性菌血症	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	1 (0.5)	1 (0.3)
歯髄炎	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
ウイルス性気道感染	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
サルモネラ症	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
レンサ球菌性化膿性関節炎	0	1 (0.9)	0	1 (0.3)
Grade 3	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
唾液腺炎	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
皮膚感染	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
軟部組織感染	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
頭部白癬	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
真菌性舌感染	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
気管気管支炎	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
膣感染	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
ウイルス性咽頭炎	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
口腔感染	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
骨髄炎	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
外耳炎	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
細菌性肺炎	1 (0.9)	0	0	0
Grade 3	1 (0.9)	0	0	0
敗血症	1 (0.9)	0	0	0
Grade 5	1 (0.9)	0	0	0
ブドウ球菌性敗血症	1 (0.9)	0	0	0
Grade 3	1 (0.9)	0	0	0
重複感染	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (Cont.)				
細菌性尿路感染	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
尿路性敗血症	1 (0.9)	0	0	0
Grade 4	1 (0.9)	0	0	0
傷害、中毒および処置合併症	24 (21.4)	22 (20.6)	40 (19.1)	62 (19.6)
Grade 1	8 (7.1)	11 (10.3)	20 (9.6)	31 (9.8)
Grade 2	13 (11.6)	9 (8.4)	15 (7.2)	24 (7.6)
Grade 3	3 (2.7)	1 (0.9)	5 (2.4)	6 (1.9)
Grade 4	0	1 (0.9)	0	1 (0.3)
転倒	5 (4.5)	4 (3.7)	8 (3.8)	12 (3.8)
Grade 1	3 (2.7)	3 (2.8)	5 (2.4)	8 (2.5)
Grade 2	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 3	1 (0.9)	0	2 (1.0)	2 (0.6)
挫傷	2 (1.8)	5 (4.7)	7 (3.3)	12 (3.8)
Grade 1	0	4 (3.7)	6 (2.9)	10 (3.2)
Grade 2	2 (1.8)	1 (0.9)	1 (0.5)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
皮膚裂傷	3 (2.7)	0	6 (2.9)	6 (1.9)
Grade 1	1 (0.9)	0	3 (1.4)	3 (0.9)
Grade 2	1 (0.9)	0	3 (1.4)	3 (0.9)
Grade 3	1 (0.9)	0	0	0
脊椎圧迫骨折	2 (1.8)	1 (0.9)	5 (2.4)	6 (1.9)
Grade 1	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 2	2 (1.8)	0	1 (0.5)	1 (0.3)
Grade 3	0	0	2 (1.0)	2 (0.6)
皮膚擦過傷	0	3 (2.8)	1 (0.5)	4 (1.3)
Grade 1	0	3 (2.8)	0	3 (0.9)
Grade 2	0	0	1 (0.5)	1 (0.3)
腱断裂	0	3 (2.8)	1 (0.5)	4 (1.3)
Grade 1	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	0	2 (1.9)	0	2 (0.6)
靭帯捻挫	3 (2.7)	0	2 (1.0)	2 (0.6)
Grade 1	1 (0.9)	0	2 (1.0)	2 (0.6)
Grade 2	2 (1.8)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
肉離れ	2 (1.8)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	1 (0.9)	0	1 (0.3)
頭部損傷	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 2	1 (0.9)	0	0	0
Grade 3	0	0	1 (0.5)	1 (0.3)
関節脱臼	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	2 (1.0)	2 (0.6)
膝蓋骨骨折	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	0	0	1 (0.5)	1 (0.3)
Grade 3	0	1 (0.9)	0	1 (0.3)
処置による疼痛	0	2 (1.9)	0	2 (0.6)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
肋骨骨折	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
脊椎骨折	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	0	0	1 (0.5)	1 (0.3)
Grade 3	0	1 (0.9)	0	1 (0.3)
腱損傷	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
足骨折	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	0	0
Grade 3	0	0	1 (0.5)	1 (0.3)
四肢損傷	1 (0.9)	1 (0.9)	0	1 (0.3)
Grade 2	1 (0.9)	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
皮膚創傷	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	0	0
ストレス骨折	1 (0.9)	1 (0.9)	0	1 (0.3)
Grade 1	1 (0.9)	0	0	0
Grade 2	0	1 (0.9)	0	1 (0.3)
節足動物刺傷	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
剥離骨折	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
第1度熱傷	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
白内障手術合併症	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
頭蓋顔面骨折	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
上顎炎	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
股関節部骨折	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
上腕骨骨折	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
腸脛靱帯症候群	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
免疫反応	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
下肢骨折	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
腰椎骨折	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
処置後出血	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
術後創合併症	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
交通事故	0	1 (0.9)	0	1 (0.3)
Grade 4	0	1 (0.9)	0	1 (0.3)
軟部組織損傷	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
熱傷	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
胸椎骨折	0	1 (0.9)	0	1 (0.3)
Grade 3	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
歯の完全脱臼	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
上肢骨折	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
手首関節骨折	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
節足動物咬傷	3 (2.7)	0	0	0
Grade 1	3 (2.7)	0	0	0
骨挫傷	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
脳振盪	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
歯科修復不成功	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
顔面損傷	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
注入に伴う反応	1 (0.9)	0	0	0
Grade 3	1 (0.9)	0	0	0
筋断裂	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (Cont.)				
橈骨骨折	1 (0.9)	0	0	0
Grade 3	1 (0.9)	0	0	0
反応性胃障害	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
肩甲骨骨折	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
創傷	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
臨床検査	19 (17.0)	13 (12.1)	35 (16.7)	48 (15.2)
Grade 1	9 (8.0)	9 (8.4)	20 (9.6)	29 (9.2)
Grade 2	9 (8.0)	4 (3.7)	12 (5.7)	16 (5.1)
Grade 3	1 (0.9)	0	3 (1.4)	3 (0.9)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
臨床検査 (Cont.)				
体重増加	4 (3.6)	6 (5.6)	6 (2.9)	12 (3.8)
Grade 1	2 (1.8)	6 (5.6)	4 (1.9)	10 (3.2)
Grade 2	2 (1.8)	0	2 (1.0)	2 (0.6)
血中クレアチンホスホキナーゼ増加	0	0	6 (2.9)	6 (1.9)
Grade 1	0	0	4 (1.9)	4 (1.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
血中コレステロール増加	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
Grade 1	0	0	2 (1.0)	2 (0.6)
Grade 2	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
ヘモグロビン減少	1 (0.9)	0	3 (1.4)	3 (0.9)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
アラニンアミノトランスフェラーゼ増加	0	0	3 (1.4)	3 (0.9)
Grade 1	0	0	2 (1.0)	2 (0.6)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
臨床検査 (Cont.)				
リンパ球数減少	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
血沈亢進	2 (1.8)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	1 (0.9)	0	1 (0.3)
血中クレアチニン増加	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	1 (0.9)	0	0	0
肝機能検査異常	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
トランスアミナーゼ上昇	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
臨床検査 (Cont.)				
体重減少	2 (1.8)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	0	0
血中カリウム減少	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	0	0
Grade 3	0	0	1 (0.5)	1 (0.3)
眼圧上昇	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	0	0
Grade 2	0	0	1 (0.5)	1 (0.3)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
血中ビリルビン増加	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
臨床検査 (Cont.)				
血中ブドウ糖増加	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
血中鉄減少	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
血中ナトリウム減少	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
血中トリグリセリド増加	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
C-反応性蛋白増加	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
臨床検査 (Cont.)				
心雑音	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
B型肝炎ウイルス検査陽性	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
平均赤血球容積増加	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
モノクローナル免疫グロブリン増加	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
尿中亜硝酸塩陽性	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
臨床検査 (Cont.)				
壁細胞抗体陽性	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
尿中赤血球陽性	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
トロポニンT増加	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
血中アルカリホスファターゼ増加	1 (0.9)	0	0	0
Grade 3	1 (0.9)	0	0	0
骨密度異常	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
臨床検査 (Cont.)				
心電図QT延長	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
エプスタイン・バーウイルス抗体陽性	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
Γ-グルタミルトランスフェラーゼ増加	1 (0.9)	0	0	0
Grade 3	1 (0.9)	0	0	0
肝機能検査値上昇	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
前立腺特異性抗原増加	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
臨床検査 (Cont.)				
腎機能検査異常	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
尿中白血球陽性	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
代謝および栄養障害	16 (14.3)	11 (10.3)	28 (13.4)	39 (12.3)
Grade 1	6 (5.4)	5 (4.7)	14 (6.7)	19 (6.0)
Grade 2	10 (8.9)	5 (4.7)	13 (6.2)	18 (5.7)
Grade 3	0	1 (0.9)	1 (0.5)	2 (0.6)
低カリウム血症	1 (0.9)	2 (1.9)	5 (2.4)	7 (2.2)
Grade 1	0	0	2 (1.0)	2 (0.6)
Grade 2	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
Grade 3	0	1 (0.9)	1 (0.5)	2 (0.6)
糖尿病	4 (3.6)	1 (0.9)	4 (1.9)	5 (1.6)
Grade 1	2 (1.8)	0	1 (0.5)	1 (0.3)
Grade 2	2 (1.8)	1 (0.9)	3 (1.4)	4 (1.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
代謝および栄養障害 (Cont.)				
脂質異常症	1 (0.9)	2 (1.9)	3 (1.4)	5 (1.6)
Grade 1	1 (0.9)	2 (1.9)	1 (0.5)	3 (0.9)
Grade 2	0	0	2 (1.0)	2 (0.6)
ステロイド糖尿病	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
Grade 1	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
低ナトリウム血症	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 3	0	1 (0.9)	0	1 (0.3)
高コレステロール血症	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
高脂血症	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 1	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
代謝および栄養障害 (Cont.)				
体液貯留	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
2型糖尿病	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
食欲減退	2 (1.8)	1 (0.9)	0	1 (0.3)
Grade 1	1 (0.9)	1 (0.9)	0	1 (0.3)
Grade 2	1 (0.9)	0	0	0
高血糖	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)
高尿酸血症	1 (0.9)	1 (0.9)	0	1 (0.3)
Grade 1	1 (0.9)	0	0	0
Grade 2	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
代謝および栄養障害 (Cont.)				
脂肪腫症	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)
高クロール血性アシドーシス	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
脱水	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
食物不耐性	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
痛風	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
代謝および栄養障害 (Cont.)				
低カルシウム血症	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
低クロール血症	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
低血糖	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
低蛋白血症	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
食欲亢進	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
代謝および栄養障害 (Cont.)				
鉄欠乏	3 (2.7)	0	0	0
Grade 1	1 (0.9)	0	0	0
Grade 2	2 (1.8)	0	0	0
中心性肥満	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
葉酸欠乏	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
低マグネシウム血症	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
ビタミンD欠乏	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害	56 (50.0)	45 (42.1)	108 (51.7)	153 (48.4)
Grade 1	27 (24.1)	21 (19.6)	52 (24.9)	73 (23.1)
Grade 2	24 (21.4)	22 (20.6)	50 (23.9)	72 (22.8)
Grade 3	5 (4.5)	2 (1.9)	6 (2.9)	8 (2.5)
関節痛	15 (13.4)	7 (6.5)	29 (13.9)	36 (11.4)
Grade 1	11 (9.8)	4 (3.7)	17 (8.1)	21 (6.6)
Grade 2	4 (3.6)	3 (2.8)	12 (5.7)	15 (4.7)
背部痛	15 (13.4)	6 (5.6)	25 (12.0)	31 (9.8)
Grade 1	4 (3.6)	4 (3.7)	11 (5.3)	15 (4.7)
Grade 2	10 (8.9)	2 (1.9)	14 (6.7)	16 (5.1)
Grade 3	1 (0.9)	0	0	0
筋痙縮	8 (7.1)	6 (5.6)	13 (6.2)	19 (6.0)
Grade 1	3 (2.7)	4 (3.7)	8 (3.8)	12 (3.8)
Grade 2	5 (4.5)	2 (1.9)	5 (2.4)	7 (2.2)
四肢痛	6 (5.4)	4 (3.7)	15 (7.2)	19 (6.0)
Grade 1	5 (4.5)	4 (3.7)	9 (4.3)	13 (4.1)
Grade 2	1 (0.9)	0	6 (2.9)	6 (1.9)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
筋肉痛	5 (4.5)	7 (6.5)	9 (4.3)	16 (5.1)
Grade 1	4 (3.6)	5 (4.7)	5 (2.4)	10 (3.2)
Grade 2	1 (0.9)	2 (1.9)	3 (1.4)	5 (1.6)
Grade 3	0	0	1 (0.5)	1 (0.3)
変形性関節症	5 (4.5)	3 (2.8)	13 (6.2)	16 (5.1)
Grade 1	2 (1.8)	2 (1.9)	6 (2.9)	8 (2.5)
Grade 2	2 (1.8)	1 (0.9)	5 (2.4)	6 (1.9)
Grade 3	1 (0.9)	0	2 (1.0)	2 (0.6)
骨粗鬆症	3 (2.7)	3 (2.8)	7 (3.3)	10 (3.2)
Grade 1	1 (0.9)	0	2 (1.0)	2 (0.6)
Grade 2	1 (0.9)	3 (2.8)	4 (1.9)	7 (2.2)
Grade 3	1 (0.9)	0	1 (0.5)	1 (0.3)
筋骨格系胸痛	1 (0.9)	1 (0.9)	5 (2.4)	6 (1.9)
Grade 1	1 (0.9)	1 (0.9)	4 (1.9)	5 (1.6)
Grade 2	0	0	1 (0.5)	1 (0.3)
ミオパチー	2 (1.8)	1 (0.9)	4 (1.9)	5 (1.6)
Grade 1	1 (0.9)	0	2 (1.0)	2 (0.6)
Grade 2	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
腱障害	2 (1.8)	4 (3.7)	1 (0.5)	5 (1.6)
Grade 1	2 (1.8)	1 (0.9)	0	1 (0.3)
Grade 2	0	3 (2.8)	1 (0.5)	4 (1.3)
筋力低下	1 (0.9)	3 (2.8)	2 (1.0)	5 (1.6)
Grade 1	1 (0.9)	3 (2.8)	2 (1.0)	5 (1.6)
頚部痛	6 (5.4)	1 (0.9)	3 (1.4)	4 (1.3)
Grade 1	3 (2.7)	0	2 (1.0)	2 (0.6)
Grade 2	3 (2.7)	1 (0.9)	1 (0.5)	2 (0.6)
椎間板突出	4 (3.6)	2 (1.9)	2 (1.0)	4 (1.3)
Grade 1	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	2 (1.8)	0	1 (0.5)	1 (0.3)
Grade 3	1 (0.9)	1 (0.9)	0	1 (0.3)
大転子疼痛症候群	3 (2.7)	2 (1.9)	2 (1.0)	4 (1.3)
Grade 1	3 (2.7)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
滑液包炎	2 (1.8)	1 (0.9)	3 (1.4)	4 (1.3)
Grade 1	2 (1.8)	0	2 (1.0)	2 (0.6)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
関節腫脹	1 (0.9)	0	4 (1.9)	4 (1.3)
Grade 1	1 (0.9)	0	3 (1.4)	3 (0.9)
Grade 2	0	0	1 (0.5)	1 (0.3)
顎痛	1 (0.9)	2 (1.9)	2 (1.0)	4 (1.3)
Grade 1	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 2	1 (0.9)	1 (0.9)	0	1 (0.3)
筋骨格硬直	0	0	4 (1.9)	4 (1.3)
Grade 1	0	0	4 (1.9)	4 (1.3)
顎関節症候群	0	2 (1.9)	2 (1.0)	4 (1.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	2 (1.9)	1 (0.5)	3 (0.9)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
腱炎	0	1 (0.9)	3 (1.4)	4 (1.3)
Grade 1	0	0	2 (1.0)	2 (0.6)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
リウマチ性多発筋痛	5 (4.5)	1 (0.9)	2 (1.0)	3 (0.9)
Grade 1	2 (1.8)	0	0	0
Grade 2	2 (1.8)	1 (0.9)	2 (1.0)	3 (0.9)
Grade 3	1 (0.9)	0	0	0
骨減少症	2 (1.8)	0	3 (1.4)	3 (0.9)
Grade 1	2 (1.8)	0	2 (1.0)	2 (0.6)
Grade 2	0	0	1 (0.5)	1 (0.3)
線維筋痛	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
腰部脊柱管狭窄症	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 2	0	0	2 (1.0)	2 (0.6)
Grade 3	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
肩回旋筋腱板症候群	3 (2.7)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	3 (2.7)	0	1 (0.5)	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
関節炎	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	1 (0.9)	0	0	0
シェーグレン症候群	1 (0.9)	0	2 (1.0)	2 (0.6)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
脊椎痛	1 (0.9)	0	2 (1.0)	2 (0.6)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
側腹部痛	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
骨端症	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
変形性脊椎症	0	2 (1.9)	0	2 (0.6)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
椎間孔狭窄	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
滑液嚢腫	2 (1.8)	1 (0.9)	0	1 (0.3)
Grade 1	1 (0.9)	1 (0.9)	0	1 (0.3)
Grade 2	1 (0.9)	0	0	0
関節可動域低下	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
腱痛	1 (0.9)	1 (0.9)	0	1 (0.3)
Grade 1	1 (0.9)	1 (0.9)	0	1 (0.3)
頚部脊柱管狭窄症	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
椎間関節症候群	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
指変形	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
単径部痛	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
顎関節クリッキング	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
顎障害	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
関節滲出液	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
関節雑音	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
半月板変性	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
筋不快感	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
筋骨格不快感	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
筋骨格障害	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
膝蓋大腿関節痛症候群	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
関節周囲炎	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
足底筋膜炎	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
乾癬性関節症	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
肩甲帯痛	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
軟部組織腫瘤	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
脊柱管狭窄症	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
脊椎滑液嚢腫	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
腱鞘炎	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
弾発指	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
関節障害	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
椎間板障害	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
筋骨格系および結合組織障害 (Cont.)				
関節硬直	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
筋肉疲労	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
筋骨格痛	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
関節リウマチ	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
手関節変形	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	7 (6.3)	6 (5.6)	16 (7.7)	22 (7.0)
Grade 1	3 (2.7)	3 (2.8)	6 (2.9)	9 (2.8)
Grade 2	3 (2.7)	2 (1.9)	6 (2.9)	8 (2.5)
Grade 3	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
Grade 4	0	0	1 (0.5)	1 (0.3)
皮膚有棘細胞癌	0	1 (0.9)	3 (1.4)	4 (1.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
Grade 3	0	1 (0.9)	1 (0.5)	2 (0.6)
基底細胞癌	2 (1.8)	0	2 (1.0)	2 (0.6)
Grade 2	2 (1.8)	0	2 (1.0)	2 (0.6)
結腸直腸腺腫	0	2 (1.9)	0	2 (0.6)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
メラノサイト性母斑	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	2 (1.0)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
脂漏性角化症	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	2 (1.0)	2 (0.6)
皮膚乳頭腫	0	2 (1.9)	0	2 (0.6)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
副腎腺腫	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
線維腫	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
良性毛包腫瘍	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
悪性黒子	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
脂肪腫	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
ファーター膨大部の悪性新生物	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
皮膚の新生物	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
肺扁平上皮癌	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
舌の悪性新生物、病期不明	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
血管筋脂肪腫	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
血管腫	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
膵管内乳頭粘液性腫瘍	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
神経線維腫	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
前立腺癌	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
遠隔転移を伴う扁桃癌	1 (0.9)	0	0	0
Grade 3	1 (0.9)	0	0	0
神経系障害	32 (28.6)	39 (36.4)	81 (38.8)	120 (38.0)
Grade 1	17 (15.2)	21 (19.6)	46 (22.0)	67 (21.2)
Grade 2	11 (9.8)	16 (15.0)	27 (12.9)	43 (13.6)
Grade 3	4 (3.6)	2 (1.9)	7 (3.3)	9 (2.8)
Grade 4	0	0	1 (0.5)	1 (0.3)
頭痛	13 (11.6)	16 (15.0)	34 (16.3)	50 (15.8)
Grade 1	12 (10.7)	8 (7.5)	20 (9.6)	28 (8.9)
Grade 2	1 (0.9)	7 (6.5)	11 (5.3)	18 (5.7)
Grade 3	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 4	0	0	1 (0.5)	1 (0.3)
浮動性めまい	6 (5.4)	6 (5.6)	10 (4.8)	16 (5.1)
Grade 1	6 (5.4)	5 (4.7)	9 (4.3)	14 (4.4)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
坐骨神経痛	0	3 (2.8)	6 (2.9)	9 (2.8)
Grade 1	0	0	5 (2.4)	5 (1.6)
Grade 2	0	2 (1.9)	0	2 (0.6)
Grade 3	0	1 (0.9)	1 (0.5)	2 (0.6)
味覚不全	1 (0.9)	3 (2.8)	3 (1.4)	6 (1.9)
Grade 1	1 (0.9)	3 (2.8)	3 (1.4)	6 (1.9)
錯感覚	1 (0.9)	2 (1.9)	4 (1.9)	6 (1.9)
Grade 1	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
失神	4 (3.6)	1 (0.9)	4 (1.9)	5 (1.6)
Grade 1	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	1 (0.9)	0	2 (1.0)	2 (0.6)
Grade 3	2 (1.8)	0	1 (0.5)	1 (0.3)
緊張性頭痛	0	1 (0.9)	4 (1.9)	5 (1.6)
Grade 1	0	1 (0.9)	3 (1.4)	4 (1.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
手根管症候群	0	0	4 (1.9)	4 (1.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	3 (1.4)	3 (0.9)
傾眠	0	2 (1.9)	2 (1.0)	4 (1.3)
Grade 1	0	2 (1.9)	1 (0.5)	3 (0.9)
Grade 3	0	0	1 (0.5)	1 (0.3)
振戦	5 (4.5)	2 (1.9)	1 (0.5)	3 (0.9)
Grade 1	4 (3.6)	2 (1.9)	1 (0.5)	3 (0.9)
Grade 2	1 (0.9)	0	0	0
片頭痛	2 (1.8)	2 (1.9)	1 (0.5)	3 (0.9)
Grade 1	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	1 (0.9)	1 (0.9)	0	1 (0.3)
記憶障害	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
Grade 1	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 2	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
ヘルペス後神経痛	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
Grade 2	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
後頭神経痛	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 1	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	0	0	1 (0.5)	1 (0.3)
偽性根症候群	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 2	0	1 (0.9)	2 (1.0)	3 (0.9)
下肢静止不能症候群	0	0	3 (1.4)	3 (0.9)
Grade 1	0	0	3 (1.4)	3 (0.9)
感覚鈍麻	1 (0.9)	0	2 (1.0)	2 (0.6)
Grade 1	0	0	2 (1.0)	2 (0.6)
Grade 2	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
末梢性ニューロパチー	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	1 (0.9)	1 (0.9)	0	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
健忘	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
灼熱感	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
体位性めまい	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	2 (1.0)	2 (0.6)
頭部不快感	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
神経根障害	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
味覚障害	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	2 (1.0)	2 (0.6)
一過性脳虚血発作	0	2 (1.9)	0	2 (0.6)
Grade 2	0	2 (1.9)	0	2 (0.6)
平衡障害	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)
ブレインフォグ	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
腰髄神経根障害	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	0	0
Grade 3	0	0	1 (0.5)	1 (0.3)
無嗅覚	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
反射消失	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
頚動脈狭窄	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
小脳性運動失調	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
頚腕症候群	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
注意力障害	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
労作性めまい	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
ジストニア	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
電気ショック様感覚	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
味覚減退	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
肋間神経痛	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
脳圧低下	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
単神経炎	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
不随意性筋収縮	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
神経圧迫	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
嗅覚錯誤	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
梨状筋症候群	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
失神寸前の状態	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
精神運動亢進	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
4分の1盲	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
副鼻腔炎に伴う頭痛	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
一過性失語症	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
トンネル状視野	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
椎骨動脈狭窄	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
神経痛	2 (1.8)	0	0	0
Grade 2	2 (1.8)	0	0	0
脳アミロイド血管障害	1 (0.9)	0	0	0
Grade 3	1 (0.9)	0	0	0
脳梗塞	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
脳脊髄癆	1 (0.9)	0	0	0
Grade 3	1 (0.9)	0	0	0
脳卒中	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0

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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害 (Cont.)				
認知障害	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
脱髄	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
異常感覚	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
多発ニューロパチー	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
精神障害	13 (11.6)	8 (7.5)	20 (9.6)	28 (8.9)
Grade 1	6 (5.4)	5 (4.7)	10 (4.8)	15 (4.7)
Grade 2	7 (6.3)	3 (2.8)	8 (3.8)	11 (3.5)
Grade 3	0	0	2 (1.0)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
精神障害 (Cont.)				
不眠症	5 (4.5)	3 (2.8)	4 (1.9)	7 (2.2)
Grade 1	2 (1.8)	2 (1.9)	3 (1.4)	5 (1.6)
Grade 2	3 (2.7)	1 (0.9)	1 (0.5)	2 (0.6)
うつ病	1 (0.9)	2 (1.9)	3 (1.4)	5 (1.6)
Grade 1	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
不安	1 (0.9)	0	3 (1.4)	3 (0.9)
Grade 1	0	0	2 (1.0)	2 (0.6)
Grade 2	1 (0.9)	0	0	0
Grade 3	0	0	1 (0.5)	1 (0.3)
錯乱状態	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
抑うつ気分	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
精神障害 (Cont.)				
落ち着きのなさ	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	1 (0.5)	2 (0.6)
睡眠障害	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	1 (0.5)	2 (0.6)
物質誘発性精神病性障害	0	0	2 (1.0)	2 (0.6)
Grade 2	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
神経過敏	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	0	0
Grade 2	0	0	1 (0.5)	1 (0.3)
歯ぎしり	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
精神障害 (Cont.)				
燃え尽き症候群	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
リビドー減退	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
人格変化	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
譫妄	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
初期不眠症	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
精神障害 (Cont.)				
躁病	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
混合性不安抑うつ障害	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
気分動揺	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
睡眠の質低下	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
腎および尿路障害	13 (11.6)	5 (4.7)	19 (9.1)	24 (7.6)
Grade 1	6 (5.4)	4 (3.7)	13 (6.2)	17 (5.4)
Grade 2	6 (5.4)	1 (0.9)	4 (1.9)	5 (1.6)
Grade 3	1 (0.9)	0	2 (1.0)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
腎および尿路障害 (Cont.)				
血尿	4 (3.6)	0	4 (1.9)	4 (1.3)
Grade 1	3 (2.7)	0	4 (1.9)	4 (1.3)
Grade 2	1 (0.9)	0	0	0
頻尿	1 (0.9)	2 (1.9)	2 (1.0)	4 (1.3)
Grade 1	1 (0.9)	2 (1.9)	2 (1.0)	4 (1.3)
排尿困難	1 (0.9)	0	3 (1.4)	3 (0.9)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	2 (1.0)	2 (0.6)
急性腎障害	3 (2.7)	0	2 (1.0)	2 (0.6)
Grade 1	2 (1.8)	0	1 (0.5)	1 (0.3)
Grade 3	1 (0.9)	0	1 (0.5)	1 (0.3)
腎結石症	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
腎および尿路障害 (Cont.)				
尿失禁	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	1 (0.9)	0	0	0
緊張性膀胱	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
尿意切迫	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	0	0
腎嚢胞	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)
慢性腎臓病	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
腎および尿路障害 (Cont.)				
腎炎	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
夜間頻尿	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
腎不全	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
腎機能障害	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
腎損傷	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
腎および尿路障害 (Cont.)				
蛋白尿	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
腎仙痛	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
生殖系および乳房障害	4 (3.6)	1 (0.9)	8 (3.8)	9 (2.8)
Grade 1	4 (3.6)	0	5 (2.4)	5 (1.6)
Grade 2	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 3	0	0	1 (0.5)	1 (0.3)
良性前立腺肥大症	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
乳房痛	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
生殖系および乳房障害 (Cont.)				
乳房腫瘤	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
子宮頚部上皮異形成	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
膀胱瘤	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
乳頭痛	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
前立腺障害	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
生殖系および乳房障害 (Cont.)				
外陰腟乾燥	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
骨盤痛	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
前立腺腫大	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
外陰腟そう痒症	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
呼吸器、胸郭および縦隔障害	14 (12.5)	20 (18.7)	49 (23.4)	69 (21.8)
Grade 1	9 (8.0)	14 (13.1)	29 (13.9)	43 (13.6)
Grade 2	3 (2.7)	4 (3.7)	14 (6.7)	18 (5.7)
Grade 3	2 (1.8)	2 (1.9)	6 (2.9)	8 (2.5)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)				
咳嗽	4 (3.6)	5 (4.7)	14 (6.7)	19 (6.0)
Grade 1	2 (1.8)	3 (2.8)	11 (5.3)	14 (4.4)
Grade 2	2 (1.8)	2 (1.9)	3 (1.4)	5 (1.6)
口腔咽頭痛	1 (0.9)	4 (3.7)	6 (2.9)	10 (3.2)
Grade 1	1 (0.9)	3 (2.8)	5 (2.4)	8 (2.5)
Grade 2	0	1 (0.9)	1 (0.5)	2 (0.6)
呼吸困難	5 (4.5)	1 (0.9)	7 (3.3)	8 (2.5)
Grade 1	4 (3.6)	1 (0.9)	5 (2.4)	6 (1.9)
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
肺塞栓症	2 (1.8)	2 (1.9)	6 (2.9)	8 (2.5)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
Grade 3	2 (1.8)	1 (0.9)	5 (2.4)	6 (1.9)
喘息	0	1 (0.9)	4 (1.9)	5 (1.6)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 3	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)				
労作性呼吸困難	2 (1.8)	2 (1.9)	2 (1.0)	4 (1.3)
Grade 1	2 (1.8)	2 (1.9)	2 (1.0)	4 (1.3)
鼻出血	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
Grade 1	1 (0.9)	0	3 (1.4)	3 (0.9)
Grade 2	0	1 (0.9)	0	1 (0.3)
慢性閉塞性肺疾患	0	0	3 (1.4)	3 (0.9)
Grade 2	0	0	3 (1.4)	3 (0.9)
鼻漏	1 (0.9)	0	2 (1.0)	2 (0.6)
Grade 1	1 (0.9)	0	2 (1.0)	2 (0.6)
発声障害	0	2 (1.9)	0	2 (0.6)
Grade 1	0	2 (1.9)	0	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)				
湿性咳嗽	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	2 (1.0)	2 (0.6)
肺腫瘤	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	2 (1.0)	2 (0.6)
急性呼吸不全	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
無気肺	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
気管支拡張症	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)				
慢性気管支炎	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
気管支痙攣	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
血胸	0	1 (0.9)	0	1 (0.3)
Grade 3	0	1 (0.9)	0	1 (0.3)
下咽頭癒着	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
上気道分泌増加	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)				
肺障害	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
起坐呼吸	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
ラ音	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
アレルギー性鼻炎	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
咽喉刺激感	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)				
咳払い	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
皮膚および皮下組織障害	26 (23.2)	20 (18.7)	57 (27.3)	77 (24.4)
Grade 1	16 (14.3)	15 (14.0)	40 (19.1)	55 (17.4)
Grade 2	10 (8.9)	5 (4.7)	17 (8.1)	22 (7.0)
発疹	3 (2.7)	3 (2.8)	11 (5.3)	14 (4.4)
Grade 1	2 (1.8)	2 (1.9)	8 (3.8)	10 (3.2)
Grade 2	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
多汗症	3 (2.7)	3 (2.8)	5 (2.4)	8 (2.5)
Grade 1	2 (1.8)	3 (2.8)	4 (1.9)	7 (2.2)
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
ざ瘡	1 (0.9)	0	7 (3.3)	7 (2.2)
Grade 1	1 (0.9)	0	6 (2.9)	6 (1.9)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
皮膚乾燥	0	0	6 (2.9)	6 (1.9)
Grade 1	0	0	3 (1.4)	3 (0.9)
Grade 2	0	0	3 (1.4)	3 (0.9)
脱毛症	3 (2.7)	0	5 (2.4)	5 (1.6)
Grade 1	3 (2.7)	0	5 (2.4)	5 (1.6)
紅斑	1 (0.9)	0	4 (1.9)	4 (1.3)
Grade 1	1 (0.9)	0	3 (1.4)	3 (0.9)
Grade 2	0	0	1 (0.5)	1 (0.3)
寝汗	1 (0.9)	2 (1.9)	1 (0.5)	3 (0.9)
Grade 1	1 (0.9)	2 (1.9)	1 (0.5)	3 (0.9)
口囲皮膚炎	1 (0.9)	0	3 (1.4)	3 (0.9)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	2 (1.0)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
酒さ	1 (0.9)	0	3 (1.4)	3 (0.9)
Grade 1	0	0	2 (1.0)	2 (0.6)
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
皮膚病変	0	1 (0.9)	2 (1.0)	3 (0.9)
Grade 1	0	1 (0.9)	2 (1.0)	3 (0.9)
そう痒症	2 (1.8)	0	2 (1.0)	2 (0.6)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
皮膚炎	1 (0.9)	0	2 (1.0)	2 (0.6)
Grade 1	1 (0.9)	0	0	0
Grade 2	0	0	2 (1.0)	2 (0.6)
接触皮膚炎	1 (0.9)	0	2 (1.0)	2 (0.6)
Grade 1	0	0	2 (1.0)	2 (0.6)
Grade 2	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
皮膚疼痛	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
皮膚潰瘍	1 (0.9)	0	2 (1.0)	2 (0.6)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
びまん性脱毛症	0	2 (1.9)	0	2 (0.6)
Grade 1	0	2 (1.9)	0	2 (0.6)
湿疹	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	1 (0.5)	2 (0.6)
男性型多毛症	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	2 (1.0)	2 (0.6)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
斑状丘疹状皮疹	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
脂漏性皮膚炎	3 (2.7)	0	1 (0.5)	1 (0.3)
Grade 1	2 (1.8)	0	0	0
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
脂肪肥大症	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	1 (0.9)	0	0	0
斑状皮疹	1 (0.9)	1 (0.9)	0	1 (0.3)
Grade 1	1 (0.9)	1 (0.9)	0	1 (0.3)
光線角化症	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
円形脱毛症	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
汎発性脱毛症	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
アンドロゲン性脱毛症	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
血管浮腫	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
腕橈骨筋そう痒症	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
ざ瘡様皮膚炎	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
皮膚症	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
毛髪成長異常	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
爪変色	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
爪破損	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
陰茎潰瘍形成	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
光線性皮膚症	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
紅斑性皮疹	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
痂皮	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
皮膚亀裂	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
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Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
皮膚色素過剰	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)
皮膚硬結	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
皮膚刺激	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
皮膚軟化	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
皮膚腫瘤	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
うっ滞性皮膚炎	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
黄色皮膚	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
水疱	2 (1.8)	0	0	0
Grade 1	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
冷汗	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
アレルギー性皮膚炎	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
斑状出血	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
過角化	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
硬化性苔癬	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
後天性リポジストロフィー	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
網状皮斑	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	UPA Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
神経皮膚炎	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
丘疹	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
類天疱瘡	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
乾癬	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
小水疱性皮疹	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害 (Cont.)				
皮膚変色	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
乾皮症	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	0	0
血管障害	47 (42.0)	48 (44.9)	83 (39.7)	131 (41.5)
Grade 1	14 (12.5)	9 (8.4)	26 (12.4)	35 (11.1)
Grade 2	25 (22.3)	34 (31.8)	45 (21.5)	79 (25.0)
Grade 3	8 (7.1)	5 (4.7)	8 (3.8)	13 (4.1)
Grade 4	0	0	4 (1.9)	4 (1.3)
巨細胞性動脈炎	35 (31.3)	28 (26.2)	48 (23.0)	76 (24.1)
Grade 1	10 (8.9)	2 (1.9)	10 (4.8)	12 (3.8)
Grade 2	18 (16.1)	24 (22.4)	33 (15.8)	57 (18.0)
Grade 3	7 (6.3)	2 (1.9)	4 (1.9)	6 (1.9)
Grade 4	0	0	1 (0.5)	1 (0.3)
高血圧	13 (11.6)	16 (15.0)	28 (13.4)	44 (13.9)
Grade 1	7 (6.3)	5 (4.7)	9 (4.3)	14 (4.4)
Grade 2	5 (4.5)	10 (9.3)	19 (9.1)	29 (9.2)
Grade 3	1 (0.9)	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
血管障害 (Cont.)				
血腫	5 (4.5)	2 (1.9)	4 (1.9)	6 (1.9)
Grade 1	4 (3.6)	2 (1.9)	3 (1.4)	5 (1.6)
Grade 2	1 (0.9)	0	0	0
Grade 4	0	0	1 (0.5)	1 (0.3)
深部静脈血栓症	2 (1.8)	1 (0.9)	4 (1.9)	5 (1.6)
Grade 1	1 (0.9)	0	0	0
Grade 2	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 3	0	1 (0.9)	3 (1.4)	4 (1.3)
静脈瘤	0	0	3 (1.4)	3 (0.9)
Grade 1	0	0	2 (1.0)	2 (0.6)
Grade 2	0	0	1 (0.5)	1 (0.3)
起立性低血圧	2 (1.8)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	0	1 (0.5)	1 (0.3)
Grade 2	2 (1.8)	1 (0.9)	0	1 (0.3)
間欠性跛行	1 (0.9)	1 (0.9)	1 (0.5)	2 (0.6)
Grade 1	0	1 (0.9)	1 (0.5)	2 (0.6)
Grade 2	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
血管障害 (Cont.)				
末梢冷感	1 (0.9)	0	2 (1.0)	2 (0.6)
Grade 1	1 (0.9)	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
リンパうっ滞	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	2 (1.0)	2 (0.6)
表在性静脈血栓症	0	2 (1.9)	0	2 (0.6)
Grade 2	0	2 (1.9)	0	2 (0.6)
白衣性高血圧	0	0	2 (1.0)	2 (0.6)
Grade 1	0	0	2 (1.0)	2 (0.6)
動脈硬化症	1 (0.9)	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
Grade 2	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
血管障害 (Cont.)				
大動脈解離	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	1 (0.5)	1 (0.3)
大動脈狭窄	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
大動脈血栓症	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	1 (0.5)	1 (0.3)
動脈出血	0	1 (0.9)	0	1 (0.3)
Grade 3	0	1 (0.9)	0	1 (0.3)
本態性高血圧症	0	1 (0.9)	0	1 (0.3)
Grade 2	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
血管障害 (Cont.)				
ほてり	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
高血圧クリーゼ	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)
低血圧	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)
リンパ浮腫	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
大血管障害	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
血管障害 (Cont.)				
末梢動脈閉塞性疾患	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
末梢血管塞栓症	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	1 (0.5)	1 (0.3)
レイノー現象	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
血栓性静脈炎	0	1 (0.9)	0	1 (0.3)
Grade 1	0	1 (0.9)	0	1 (0.3)
静脈瘤性静脈炎	0	0	1 (0.5)	1 (0.3)
Grade 2	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.5.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Maximum Toxicity in Period 1 (SS1)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
血管障害 (Cont.)				
末梢動脈狭窄	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0
末梢静脈疾患	1 (0.9)	0	0	0
Grade 1	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

表6

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ABT-494 (GIANT CELL ARTERITIS)
STUDY M16-852 (CUTOFF 06FEB2024)
R&D/23/2455 - CLINICAL/STATISTICAL

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
Any adverse event	396 (548.0)	264 (363.6)	874 (509.9)	1138 (466.4)
Grade 1	212 (293.4)	132 (181.8)	465 (271.3)	597 (244.7)
Grade 2	160 (221.4)	111 (152.9)	367 (214.1)	478 (195.9)
Grade 3	23 (31.8)	21 (28.9)	38 (22.2)	59 (24.2)
Grade 4	1 (1.4)	0	4 (2.3)	4 (1.6)
血液およびリンパ系障害	2 (2.8)	5 (6.9)	17 (9.9)	22 (9.0)
Grade 1	2 (2.8)	1 (1.4)	11 (6.4)	12 (4.9)
Grade 2	0	3 (4.1)	5 (2.9)	8 (3.3)
Grade 3	0	1 (1.4)	1 (0.6)	2 (0.8)
貧血	1 (1.4)	3 (4.1)	8 (4.7)	11 (4.5)
Grade 1	1 (1.4)	0	6 (3.5)	6 (2.5)
Grade 2	0	2 (2.8)	2 (1.2)	4 (1.6)
Grade 3	0	1 (1.4)	0	1 (0.4)
鉄欠乏性貧血	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 2	0	1 (1.4)	1 (0.6)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
血液およびリンパ系障害 (Cont.)				
正色素性正球性貧血	0	0	2 (1.2)	2 (0.8)
Grade 1	0	0	2 (1.2)	2 (0.8)
内出血発生の増加傾向	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	0	0
Grade 2	0	0	1 (0.6)	1 (0.4)
骨髄浮腫	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)
好酸球増加症	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
血液およびリンパ系障害 (Cont.)				
白血球増加症	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
リンパ球減少症	0	0	1 (0.6)	1 (0.4)
Grade 3	0	0	1 (0.6)	1 (0.4)
好中球増加症	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
血小板増加症	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
心臓障害	8 (11.1)	3 (4.1)	20 (11.7)	23 (9.4)
Grade 1	2 (2.8)	1 (1.4)	8 (4.7)	9 (3.7)
Grade 2	6 (8.3)	1 (1.4)	6 (3.5)	7 (2.9)
Grade 3	0	1 (1.4)	6 (3.5)	7 (2.9)
動悸	2 (2.8)	1 (1.4)	3 (1.8)	4 (1.6)
Grade 1	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
Grade 2	1 (1.4)	0	1 (0.6)	1 (0.4)
心不全	1 (1.4)	0	4 (2.3)	4 (1.6)
Grade 2	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 3	0	0	2 (1.2)	2 (0.8)
心房細動	2 (2.8)	0	2 (1.2)	2 (0.8)
Grade 2	2 (2.8)	0	0	0
Grade 3	0	0	2 (1.2)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
心臓障害 (Cont.)				
冠動脈硬化症	0	0	2 (1.2)	2 (0.8)
Grade 1	0	0	2 (1.2)	2 (0.8)
狭心症	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
心房頻脈	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
冠動脈疾患	0	1 (1.4)	0	1 (0.4)
Grade 3	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
心臓障害 (Cont.)				
冠動脈入口部狭窄	0	0	1 (0.6)	1 (0.4)
Grade 3	0	0	1 (0.6)	1 (0.4)
僧帽弁石灰化	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
僧帽弁閉鎖不全症	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
心筋虚血	0	0	1 (0.6)	1 (0.4)
Grade 3	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
心臓障害 (Cont.)				
心嚢液貯留	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
洞性徐脈	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)
頻脈	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
三尖弁閉鎖不全症	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
心臓障害 (Cont.)				
大動脈弁疾患	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
右脚ブロック	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
洞性頻脈	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
先天性、家族性および遺伝性障害	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
先天性、家族性および遺伝性障害 (Cont.)				
歯牙形成不全	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)
耳および迷路障害	3 (4.2)	5 (6.9)	15 (8.8)	20 (8.2)
Grade 1	3 (4.2)	4 (5.5)	13 (7.6)	17 (7.0)
Grade 2	0	0	2 (1.2)	2 (0.8)
Grade 3	0	1 (1.4)	0	1 (0.4)
回転性めまい	1 (1.4)	2 (2.8)	7 (4.1)	9 (3.7)
Grade 1	1 (1.4)	1 (1.4)	6 (3.5)	7 (2.9)
Grade 2	0	0	1 (0.6)	1 (0.4)
Grade 3	0	1 (1.4)	0	1 (0.4)
耳鳴	2 (2.8)	2 (2.8)	2 (1.2)	4 (1.6)
Grade 1	2 (2.8)	2 (2.8)	2 (1.2)	4 (1.6)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
耳および迷路障害 (Cont.)				
耳痛	0	0	4 (2.3)	4 (1.6)
Grade 1	0	0	3 (1.8)	3 (1.2)
Grade 2	0	0	1 (0.6)	1 (0.4)
耳不快感	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
聴力低下	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)
頭位性回転性めまい	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
内分泌障害	3 (4.2)	2 (2.8)	3 (1.8)	5 (2.0)
Grade 1	2 (2.8)	2 (2.8)	3 (1.8)	5 (2.0)
Grade 3	1 (1.4)	0	0	0
クッシング様症状	0	1 (1.4)	2 (1.2)	3 (1.2)
Grade 1	0	1 (1.4)	2 (1.2)	3 (1.2)
クッシング症候群	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	1 (0.6)	1 (0.4)
甲状腺腫瘤	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
内分泌障害 (Cont.)				
甲状腺腫	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
中毒性結節性甲状腺腫	1 (1.4)	0	0	0
Grade 3	1 (1.4)	0	0	0
眼障害	24 (33.2)	11 (15.2)	45 (26.3)	56 (23.0)
Grade 1	14 (19.4)	6 (8.3)	27 (15.8)	33 (13.5)
Grade 2	10 (13.8)	4 (5.5)	17 (9.9)	21 (8.6)
Grade 3	0	1 (1.4)	0	1 (0.4)
Grade 4	0	0	1 (0.6)	1 (0.4)
白内障	4 (5.5)	2 (2.8)	8 (4.7)	10 (4.1)
Grade 1	1 (1.4)	0	5 (2.9)	5 (2.0)
Grade 2	3 (4.2)	2 (2.8)	3 (1.8)	5 (2.0)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
眼障害 (Cont.)				
眼瞼炎	0	0	5 (2.9)	5 (2.0)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	4 (2.3)	4 (1.6)
結膜出血	0	1 (1.4)	3 (1.8)	4 (1.6)
Grade 1	0	1 (1.4)	3 (1.8)	4 (1.6)
ドライアイ	2 (2.8)	1 (1.4)	2 (1.2)	3 (1.2)
Grade 1	2 (2.8)	1 (1.4)	1 (0.6)	2 (0.8)
Grade 2	0	0	1 (0.6)	1 (0.4)
加齢黄斑変性	0	2 (2.8)	1 (0.6)	3 (1.2)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	0	2 (2.8)	0	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
眼障害 (Cont.)				
硝子体浮遊物	2 (2.8)	1 (1.4)	1 (0.6)	2 (0.8)
Grade 1	2 (2.8)	1 (1.4)	0	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
眼痛	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 1	1 (1.4)	0	2 (1.2)	2 (0.8)
霰粒腫	0	0	2 (1.2)	2 (0.8)
Grade 2	0	0	2 (1.2)	2 (0.8)
眼部腫脹	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 1	0	1 (1.4)	1 (0.6)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
眼障害 (Cont.)				
硝子体剥離	3 (4.2)	0	1 (0.6)	1 (0.4)
Grade 1	2 (2.8)	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	0	0
霧視	2 (2.8)	0	1 (0.6)	1 (0.4)
Grade 1	2 (2.8)	0	1 (0.6)	1 (0.4)
眼の異物感	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	1 (0.6)	1 (0.4)
緑内障	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
眼障害 (Cont.)				
黄斑変性	1 (1.4)	1 (1.4)	0	1 (0.4)
Grade 2	1 (1.4)	0	0	0
Grade 3	0	1 (1.4)	0	1 (0.4)
開放隅角緑内障	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	0	0
視力障害	1 (1.4)	1 (1.4)	0	1 (0.4)
Grade 1	1 (1.4)	1 (1.4)	0	1 (0.4)
角膜浮腫	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
眼障害 (Cont.)				
複視	0	0	1 (0.6)	1 (0.4)
Grade 4	0	0	1 (0.6)	1 (0.4)
眼出血	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
眼の炎症	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
眼刺激	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
眼障害 (Cont.)				
遠視	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
眼充血	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
高眼圧症	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
視神経乳頭出血	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
眼障害 (Cont.)				
眼窩浮腫	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
眼窩周囲痛	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)
羞明	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
光視症	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
眼障害 (Cont.)				
老視	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
眼瞼腫脹	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
視野欠損	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
アレルギー性結膜炎	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
眼障害 (Cont.)				
眼部不快感	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
虚血性視神経症	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
網膜裂孔	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
視力低下	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害	32 (44.3)	32 (44.1)	70 (40.8)	102 (41.8)
Grade 1	19 (26.3)	19 (26.2)	38 (22.2)	57 (23.4)
Grade 2	11 (15.2)	11 (15.2)	29 (16.9)	40 (16.4)
Grade 3	2 (2.8)	2 (2.8)	3 (1.8)	5 (2.0)
悪心	2 (2.8)	6 (8.3)	7 (4.1)	13 (5.3)
Grade 1	1 (1.4)	6 (8.3)	4 (2.3)	10 (4.1)
Grade 2	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 3	0	0	1 (0.6)	1 (0.4)
下痢	0	4 (5.5)	9 (5.3)	13 (5.3)
Grade 1	0	3 (4.1)	5 (2.9)	8 (3.3)
Grade 2	0	1 (1.4)	3 (1.8)	4 (1.6)
Grade 3	0	0	1 (0.6)	1 (0.4)
上腹部痛	3 (4.2)	0	9 (5.3)	9 (3.7)
Grade 1	3 (4.2)	0	6 (3.5)	6 (2.5)
Grade 2	0	0	3 (1.8)	3 (1.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (Cont.)				
便秘	3 (4.2)	4 (5.5)	5 (2.9)	9 (3.7)
Grade 1	0	2 (2.8)	1 (0.6)	3 (1.2)
Grade 2	3 (4.2)	2 (2.8)	4 (2.3)	6 (2.5)
嘔吐	0	5 (6.9)	3 (1.8)	8 (3.3)
Grade 1	0	3 (4.1)	2 (1.2)	5 (2.0)
Grade 2	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 3	0	1 (1.4)	0	1 (0.4)
消化不良	1 (1.4)	0	6 (3.5)	6 (2.5)
Grade 1	1 (1.4)	0	3 (1.8)	3 (1.2)
Grade 2	0	0	3 (1.8)	3 (1.2)
胃食道逆流性疾患	1 (1.4)	0	5 (2.9)	5 (2.0)
Grade 1	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 2	0	0	3 (1.8)	3 (1.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (Cont.)				
口腔内潰瘍形成	0	0	4 (2.3)	4 (1.6)
Grade 1	0	0	2 (1.2)	2 (0.8)
Grade 2	0	0	2 (1.2)	2 (0.8)
腹痛	3 (4.2)	1 (1.4)	2 (1.2)	3 (1.2)
Grade 1	2 (2.8)	1 (1.4)	0	1 (0.4)
Grade 2	1 (1.4)	0	2 (1.2)	2 (0.8)
胃炎	3 (4.2)	1 (1.4)	1 (0.6)	2 (0.8)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	2 (2.8)	1 (1.4)	0	1 (0.4)
Grade 3	1 (1.4)	0	0	0
腹部膨満	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 1	0	0	2 (1.2)	2 (0.8)
Grade 2	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (Cont.)				
下腹部痛	1 (1.4)	2 (2.8)	0	2 (0.8)
Grade 1	1 (1.4)	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)
アフタ性潰瘍	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	1 (1.4)	0	1 (0.4)
鼠径ヘルニア	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 1	0	1 (1.4)	0	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
大腸ポリープ	2 (2.8)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (Cont.)				
齲歯	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
Grade 3	1 (1.4)	0	0	0
腸憩室	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	0	0
Grade 2	0	0	1 (0.6)	1 (0.4)
口内乾燥	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	1 (0.6)	1 (0.4)
排便回数増加	1 (1.4)	1 (1.4)	0	1 (0.4)
Grade 1	1 (1.4)	0	0	0
Grade 2	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (Cont.)				
裂孔ヘルニア	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	1 (0.6)	1 (0.4)
口内炎	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	0	0
Grade 2	0	0	1 (0.6)	1 (0.4)
歯痛	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	1 (0.6)	1 (0.4)
裂肛	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (Cont.)				
虚血性大腸炎	0	0	1 (0.6)	1 (0.4)
Grade 3	0	0	1 (0.6)	1 (0.4)
憩室	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)
嚥下障害	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
鼓腸	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (Cont.)				
食中毒	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
歯肉障害	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)
歯肉痛	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
過敏性腸症候群	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (Cont.)				
口唇腫脹	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)
嚥下痛	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
食道炎	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
膵炎	0	1 (1.4)	0	1 (0.4)
Grade 3	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
胃腸障害 (Cont.)				
臍ヘルニア	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)
慢性胃炎	2 (2.8)	0	0	0
Grade 1	2 (2.8)	0	0	0
膵嚢胞	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
直腸出血	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
一般・全身障害および投与部位の状態	20 (27.7)	14 (19.3)	48 (28.0)	62 (25.4)
Grade 1	15 (20.8)	9 (12.4)	25 (14.6)	34 (13.9)
Grade 2	3 (4.2)	5 (6.9)	21 (12.3)	26 (10.7)
Grade 3	2 (2.8)	0	2 (1.2)	2 (0.8)
疲労	4 (5.5)	3 (4.1)	10 (5.8)	13 (5.3)
Grade 1	2 (2.8)	2 (2.8)	6 (3.5)	8 (3.3)
Grade 2	2 (2.8)	1 (1.4)	4 (2.3)	5 (2.0)
末梢性浮腫	3 (4.2)	2 (2.8)	7 (4.1)	9 (3.7)
Grade 1	1 (1.4)	2 (2.8)	4 (2.3)	6 (2.5)
Grade 2	0	0	3 (1.8)	3 (1.2)
Grade 3	2 (2.8)	0	0	0
胸痛	0	2 (2.8)	6 (3.5)	8 (3.3)
Grade 1	0	1 (1.4)	4 (2.3)	5 (2.0)
Grade 2	0	1 (1.4)	2 (1.2)	3 (1.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
一般・全身障害および投与部位の状態 (Cont.)				
発熱	3 (4.2)	1 (1.4)	3 (1.8)	4 (1.6)
Grade 1	3 (4.2)	0	1 (0.6)	1 (0.4)
Grade 2	0	1 (1.4)	2 (1.2)	3 (1.2)
インフルエンザ様疾患	1 (1.4)	0	3 (1.8)	3 (1.2)
Grade 1	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 2	0	0	1 (0.6)	1 (0.4)
疼痛	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
Grade 1	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 2	0	1 (1.4)	1 (0.6)	2 (0.8)
末梢腫脹	1 (1.4)	0	3 (1.8)	3 (1.2)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	2 (1.2)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
一般・全身障害および投与部位の状態 (Cont.)				
顔面腫脹	1 (1.4)	2 (2.8)	1 (0.6)	3 (1.2)
Grade 1	1 (1.4)	2 (2.8)	0	2 (0.8)
Grade 2	0	0	1 (0.6)	1 (0.4)
無力症	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
Grade 1	1 (1.4)	0	0	0
Grade 2	0	1 (1.4)	0	1 (0.4)
Grade 3	0	0	1 (0.6)	1 (0.4)
歩行障害	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 1	1 (1.4)	0	0	0
Grade 2	0	0	1 (0.6)	1 (0.4)
Grade 3	0	0	1 (0.6)	1 (0.4)
浮腫	0	0	2 (1.2)	2 (0.8)
Grade 2	0	0	2 (1.2)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
一般・全身障害および投与部位の状態 (Cont.)				
倦怠感	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	1 (0.6)	1 (0.4)
医薬品副作用	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
胸部不快感	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
顔面浮腫	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
一般・全身障害および投与部位の状態 (Cont.)				
冷感	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
注射部位疼痛	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
小結節	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)
非心臓性胸痛	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
一般・全身障害および投与部位の状態 (Cont.)				
評価不能の事象	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
乾燥症	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
疾患前駆期	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
不明確な障害	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
一般・全身障害および投与部位の状態 (Cont.)				
腫脹	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
肝胆道系障害	2 (2.8)	2 (2.8)	1 (0.6)	3 (1.2)
Grade 1	2 (2.8)	1 (1.4)	0	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
Grade 3	0	1 (1.4)	0	1 (0.4)
脂肪肝	1 (1.4)	1 (1.4)	0	1 (0.4)
Grade 1	1 (1.4)	0	0	0
Grade 3	0	1 (1.4)	0	1 (0.4)
胆石症	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
肝胆道系障害 (Cont.)				
肝腫大	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
肝病変	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
免疫系障害	0	2 (2.8)	4 (2.3)	6 (2.5)
Grade 1	0	1 (1.4)	3 (1.8)	4 (1.6)
Grade 2	0	1 (1.4)	1 (0.6)	2 (0.8)
季節性アレルギー	0	0	2 (1.2)	2 (0.8)
Grade 1	0	0	2 (1.2)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
免疫系障害 (Cont.)				
薬物過敏症	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)
過敏症	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
低γグロブリン血症	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
4型過敏症	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症	75 (103.8)	55 (75.8)	164 (95.7)	219 (89.8)
Grade 1	27 (37.4)	19 (26.2)	57 (33.3)	76 (31.1)
Grade 2	43 (59.5)	32 (44.1)	100 (58.3)	132 (54.1)
Grade 3	4 (5.5)	4 (5.5)	6 (3.5)	10 (4.1)
Grade 4	1 (1.4)	0	1 (0.6)	1 (0.4)
COVID-19	12 (16.6)	9 (12.4)	29 (16.9)	38 (15.6)
Grade 1	6 (8.3)	5 (6.9)	15 (8.8)	20 (8.2)
Grade 2	6 (8.3)	4 (5.5)	14 (8.2)	18 (7.4)
尿路感染	16 (22.1)	9 (12.4)	13 (7.6)	22 (9.0)
Grade 1	3 (4.2)	0	5 (2.9)	5 (2.0)
Grade 2	12 (16.6)	9 (12.4)	8 (4.7)	17 (7.0)
Grade 3	1 (1.4)	0	0	0
上咽頭炎	7 (9.7)	8 (11.0)	14 (8.2)	22 (9.0)
Grade 1	5 (6.9)	4 (5.5)	7 (4.1)	11 (4.5)
Grade 2	2 (2.8)	4 (5.5)	7 (4.1)	11 (4.5)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
上気道感染	7 (9.7)	1 (1.4)	10 (5.8)	11 (4.5)
Grade 1	4 (5.5)	0	2 (1.2)	2 (0.8)
Grade 2	3 (4.2)	1 (1.4)	7 (4.1)	8 (3.3)
Grade 3	0	0	1 (0.6)	1 (0.4)
膀胱炎	2 (2.8)	1 (1.4)	10 (5.8)	11 (4.5)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	2 (2.8)	1 (1.4)	8 (4.7)	9 (3.7)
Grade 3	0	0	1 (0.6)	1 (0.4)
口腔ヘルペス	1 (1.4)	0	11 (6.4)	11 (4.5)
Grade 1	1 (1.4)	0	5 (2.9)	5 (2.0)
Grade 2	0	0	6 (3.5)	6 (2.5)
帯状疱疹	2 (2.8)	3 (4.1)	5 (2.9)	8 (3.3)
Grade 1	0	1 (1.4)	0	1 (0.4)
Grade 2	2 (2.8)	2 (2.8)	5 (2.9)	7 (2.9)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
肺炎	2 (2.8)	3 (4.1)	4 (2.3)	7 (2.9)
Grade 1	0	1 (1.4)	0	1 (0.4)
Grade 2	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 3	1 (1.4)	2 (2.8)	1 (0.6)	3 (1.2)
Grade 4	0	0	1 (0.6)	1 (0.4)
副鼻腔炎	2 (2.8)	2 (2.8)	5 (2.9)	7 (2.9)
Grade 1	0	1 (1.4)	0	1 (0.4)
Grade 2	2 (2.8)	1 (1.4)	5 (2.9)	6 (2.5)
気道感染	1 (1.4)	2 (2.8)	4 (2.3)	6 (2.5)
Grade 1	0	1 (1.4)	0	1 (0.4)
Grade 2	1 (1.4)	1 (1.4)	4 (2.3)	5 (2.0)
口腔カンジダ症	0	1 (1.4)	4 (2.3)	5 (2.0)
Grade 1	0	0	3 (1.8)	3 (1.2)
Grade 2	0	1 (1.4)	1 (0.6)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
潜伏結核	1 (1.4)	2 (2.8)	2 (1.2)	4 (1.6)
Grade 1	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 2	0	2 (2.8)	1 (0.6)	3 (1.2)
咽頭炎	1 (1.4)	2 (2.8)	2 (1.2)	4 (1.6)
Grade 1	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 2	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
歯肉炎	0	1 (1.4)	3 (1.8)	4 (1.6)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	0	1 (1.4)	2 (1.2)	3 (1.2)
鼻炎	0	1 (1.4)	3 (1.8)	4 (1.6)
Grade 1	0	1 (1.4)	2 (1.2)	3 (1.2)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
爪囲炎	2 (2.8)	0	3 (1.8)	3 (1.2)
Grade 1	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 2	1 (1.4)	0	1 (0.6)	1 (0.4)
結膜炎	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
Grade 1	0	1 (1.4)	0	1 (0.4)
Grade 2	1 (1.4)	0	2 (1.2)	2 (0.8)
インフルエンザ	1 (1.4)	0	3 (1.8)	3 (1.2)
Grade 1	0	0	2 (1.2)	2 (0.8)
Grade 2	1 (1.4)	0	1 (0.6)	1 (0.4)
歯感染	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
Grade 1	1 (1.4)	1 (1.4)	0	1 (0.4)
Grade 2	0	0	2 (1.2)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
気管支炎	0	0	3 (1.8)	3 (1.2)
Grade 2	0	0	3 (1.8)	3 (1.2)
ウイルス感染	0	1 (1.4)	2 (1.2)	3 (1.2)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	0	1 (1.4)	1 (0.6)	2 (0.8)
皮膚真菌感染	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 1	1 (1.4)	0	0	0
Grade 2	0	0	2 (1.2)	2 (0.8)
創傷感染	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 2	0	0	1 (0.6)	1 (0.4)
Grade 3	1 (1.4)	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
耳感染	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 2	0	1 (1.4)	1 (0.6)	2 (0.8)
毛包炎	0	0	2 (1.2)	2 (0.8)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
下気道感染	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 2	0	1 (1.4)	1 (0.6)	2 (0.8)
RSウイルス感染	0	2 (2.8)	0	2 (0.8)
Grade 1	0	1 (1.4)	0	1 (0.4)
Grade 3	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
皮膚感染	0	0	2 (1.2)	2 (0.8)
Grade 2	0	0	2 (1.2)	2 (0.8)
気管気管支炎	0	0	2 (1.2)	2 (0.8)
Grade 1	0	0	2 (1.2)	2 (0.8)
胃腸炎	3 (4.2)	1 (1.4)	0	1 (0.4)
Grade 1	2 (2.8)	1 (1.4)	0	1 (0.4)
Grade 2	1 (1.4)	0	0	0
単純ヘルペス	3 (4.2)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 2	2 (2.8)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
蜂巣炎	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	1 (0.6)	1 (0.4)
足部白癬	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	0	0
Grade 2	0	0	1 (0.6)	1 (0.4)
歯膿瘍	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	1 (0.6)	1 (0.4)
急性副鼻腔炎	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
アデノウイルス結膜炎	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
憩室炎	0	1 (1.4)	0	1 (0.4)
Grade 3	0	1 (1.4)	0	1 (0.4)
眼感染	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
真菌性足感染	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
麦粒腫	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
食道カンジダ症	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
爪真菌症	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
眼帯状疱疹	0	0	1 (0.6)	1 (0.4)
Grade 3	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
慢性中耳炎	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
術後創感染	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
ウイルス性気道感染	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
サルモネラ症	0	0	1 (0.6)	1 (0.4)
Grade 3	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
唾液腺炎	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
ウイルス性上気道感染	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)
ブドウ球菌性創感染	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
アスペルギルス感染	1 (1.4)	0	0	0
Grade 3	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
大腸菌性尿路感染	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
口腔感染	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
細菌性尿路感染	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
尿路性敗血症	1 (1.4)	0	0	0
Grade 4	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
傷害、中毒および処置合併症	15 (20.8)	11 (15.2)	44 (25.7)	55 (22.5)
Grade 1	8 (11.1)	7 (9.6)	22 (12.8)	29 (11.9)
Grade 2	7 (9.7)	3 (4.1)	19 (11.1)	22 (9.0)
Grade 3	0	1 (1.4)	2 (1.2)	3 (1.2)
Grade 4	0	0	1 (0.6)	1 (0.4)
転倒	3 (4.2)	1 (1.4)	8 (4.7)	9 (3.7)
Grade 1	3 (4.2)	1 (1.4)	5 (2.9)	6 (2.5)
Grade 2	0	0	2 (1.2)	2 (0.8)
Grade 3	0	0	1 (0.6)	1 (0.4)
挫傷	1 (1.4)	3 (4.1)	6 (3.5)	9 (3.7)
Grade 1	1 (1.4)	2 (2.8)	5 (2.9)	7 (2.9)
Grade 2	0	1 (1.4)	1 (0.6)	2 (0.8)
骨挫傷	1 (1.4)	0	3 (1.8)	3 (1.2)
Grade 1	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 2	0	0	2 (1.2)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
傷害、中毒および処置合併症 (Cont.)				
靱帯捻挫	0	0	3 (1.8)	3 (1.2)
Grade 1	0	0	2 (1.2)	2 (0.8)
Grade 2	0	0	1 (0.6)	1 (0.4)
関節脱臼	0	0	2 (1.2)	2 (0.8)
Grade 1	0	0	2 (1.2)	2 (0.8)
処置による疼痛	0	2 (2.8)	0	2 (0.8)
Grade 1	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)
肋骨骨折	0	0	2 (1.2)	2 (0.8)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
傷害、中毒および処置合併症 (Cont.)				
創傷	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 1	0	1 (1.4)	0	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
節足動物咬傷	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	0	0
Grade 2	0	0	1 (0.6)	1 (0.4)
足骨折	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	0	0
Grade 4	0	0	1 (0.6)	1 (0.4)
肉離れ	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
傷害、中毒および処置合併症 (Cont.)				
皮膚裂傷	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	0	0
軟部組織損傷	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	1 (0.6)	1 (0.4)
脊椎圧迫骨折	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	0	0
Grade 3	0	0	1 (0.6)	1 (0.4)
ストレス骨折	1 (1.4)	1 (1.4)	0	1 (0.4)
Grade 1	1 (1.4)	0	0	0
Grade 2	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
傷害、中毒および処置合併症 (Cont.)				
術後貧血	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
足関節部骨折	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)
剥離骨折	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
上顆炎	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
傷害、中毒および処置合併症 (Cont.)				
免疫反応	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
下肢骨折	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
術後創合併症	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
処置による悪心	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
傷害、中毒および処置合併症 (Cont.)				
処置による気胸	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
植皮生着不全	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
縫合関連合併症	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)
腱断裂	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
傷害、中毒および処置合併症 (Cont.)				
熱傷	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
胸椎骨折	0	1 (1.4)	0	1 (0.4)
Grade 3	0	1 (1.4)	0	1 (0.4)
歯牙破折	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
手首関節骨折	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
傷害、中毒および処置合併症 (Cont.)				
低温による損傷	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
歯科修復不成功	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
肩甲骨骨折	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
臨床検査	23 (31.8)	1 (1.4)	34 (19.8)	35 (14.3)
Grade 1	13 (18.0)	1 (1.4)	19 (11.1)	20 (8.2)
Grade 2	7 (9.7)	0	13 (7.6)	13 (5.3)
Grade 3	3 (4.2)	0	2 (1.2)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
臨床検査 (Cont.)				
血中クレアチンホスホキナーゼ増加	0	0	8 (4.7)	8 (3.3)
Grade 1	0	0	4 (2.3)	4 (1.6)
Grade 2	0	0	3 (1.8)	3 (1.2)
Grade 3	0	0	1 (0.6)	1 (0.4)
体重増加	2 (2.8)	1 (1.4)	3 (1.8)	4 (1.6)
Grade 1	2 (2.8)	1 (1.4)	3 (1.8)	4 (1.6)
アラニンアミノトランスフェラーゼ増加	0	0	3 (1.8)	3 (1.2)
Grade 1	0	0	2 (1.2)	2 (0.8)
Grade 2	0	0	1 (0.6)	1 (0.4)
血沈亢進	2 (2.8)	0	2 (1.2)	2 (0.8)
Grade 1	2 (2.8)	0	2 (1.2)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
臨床検査 (Cont.)				
アスパラギン酸アミノトランスフェラーゼ増加	0	0	2 (1.2)	2 (0.8)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
血中クレアチニン増加	4 (5.5)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 2	3 (4.2)	0	0	0
眼圧上昇	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	0	0
Grade 2	0	0	1 (0.6)	1 (0.4)
血中トリグリセリド増加	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
臨床検査 (Cont.)				
体温上昇	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
心雑音	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
B型肝炎ウイルス検査陽性	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
高比重リポ蛋白増加	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
臨床検査 (Cont.)				
脂質増加	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
肝機能検査異常	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
尿中亜硝酸塩陽性	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
便潜血陽性	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
臨床検査 (Cont.)				
血小板数増加	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
尿中赤血球陽性	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
トロポニンT増加	0	0	1 (0.6)	1 (0.4)
Grade 3	0	0	1 (0.6)	1 (0.4)
ビタミンB12減少	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
臨床検査 (Cont.)				
白血球数減少	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
ヘモグロビン減少	2 (2.8)	0	0	0
Grade 1	1 (1.4)	0	0	0
Grade 3	1 (1.4)	0	0	0
体重減少	2 (2.8)	0	0	0
Grade 1	2 (2.8)	0	0	0
血中アルカリホスファターゼ増加	1 (1.4)	0	0	0
Grade 3	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
臨床検査 (Cont.)				
血中コレステロール増加	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
血中ブドウ糖増加	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
血中尿素増加	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
血中尿酸増加	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
臨床検査 (Cont.)				
Γ-グルタミルトランスフェラーゼ増加	1 (1.4)	0	0	0
Grade 3	1 (1.4)	0	0	0
ヘマトクリット減少	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
前立腺特異性抗原増加	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
赤血球数減少	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
臨床検査 (Cont.)				
腎機能検査異常	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
代謝および栄養障害	9 (12.5)	7 (9.6)	25 (14.6)	32 (13.1)
Grade 1	4 (5.5)	3 (4.1)	14 (8.2)	17 (7.0)
Grade 2	4 (5.5)	2 (2.8)	11 (6.4)	13 (5.3)
Grade 3	1 (1.4)	2 (2.8)	0	2 (0.8)
高コレステロール血症	0	2 (2.8)	5 (2.9)	7 (2.9)
Grade 1	0	1 (1.4)	2 (1.2)	3 (1.2)
Grade 2	0	1 (1.4)	3 (1.8)	4 (1.6)
低カリウム血症	3 (4.2)	1 (1.4)	4 (2.3)	5 (2.0)
Grade 1	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 2	2 (2.8)	0	2 (1.2)	2 (0.8)
Grade 3	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
代謝および栄養障害 (Cont.)				
低ナトリウム血症	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
Grade 3	1 (1.4)	1 (1.4)	0	1 (0.4)
脂質異常症	0	1 (1.4)	2 (1.2)	3 (1.2)
Grade 1	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 2	0	0	1 (0.6)	1 (0.4)
ステロイド糖尿病	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	1 (0.6)	1 (0.4)
食欲減退	1 (1.4)	1 (1.4)	0	1 (0.4)
Grade 1	1 (1.4)	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
代謝および栄養障害 (Cont.)				
糖尿病	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	1 (0.6)	1 (0.4)
体液貯留	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
高血糖	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
高脂血症	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
代謝および栄養障害 (Cont.)				
高尿酸血症	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)
低カルシウム血症	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
低クロール血症	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
低血糖	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
代謝および栄養障害 (Cont.)				
低蛋白血症	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
脂肪腫症	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
ビタミンD欠乏	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
葉酸欠乏	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
代謝および栄養障害 (Cont.)				
鉄欠乏	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
筋骨格系および結合組織障害	67 (92.7)	34 (46.8)	141 (82.3)	175 (71.7)
Grade 1	38 (52.6)	20 (27.5)	81 (47.3)	101 (41.4)
Grade 2	25 (34.6)	12 (16.5)	55 (32.1)	67 (27.5)
Grade 3	4 (5.5)	2 (2.8)	5 (2.9)	7 (2.9)
関節痛	15 (20.8)	3 (4.1)	24 (14.0)	27 (11.1)
Grade 1	10 (13.8)	1 (1.4)	13 (7.6)	14 (5.7)
Grade 2	5 (6.9)	2 (2.8)	11 (6.4)	13 (5.3)
背部痛	9 (12.5)	3 (4.1)	21 (12.3)	24 (9.8)
Grade 1	3 (4.2)	3 (4.1)	10 (5.8)	13 (5.3)
Grade 2	6 (8.3)	0	11 (6.4)	11 (4.5)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
四肢痛	4 (5.5)	1 (1.4)	16 (9.3)	17 (7.0)
Grade 1	3 (4.2)	1 (1.4)	12 (7.0)	13 (5.3)
Grade 2	1 (1.4)	0	3 (1.8)	3 (1.2)
Grade 3	0	0	1 (0.6)	1 (0.4)
変形性関節症	4 (5.5)	1 (1.4)	12 (7.0)	13 (5.3)
Grade 1	2 (2.8)	1 (1.4)	6 (3.5)	7 (2.9)
Grade 2	1 (1.4)	0	4 (2.3)	4 (1.6)
Grade 3	1 (1.4)	0	2 (1.2)	2 (0.8)
筋肉痛	2 (2.8)	3 (4.1)	6 (3.5)	9 (3.7)
Grade 1	1 (1.4)	3 (4.1)	5 (2.9)	8 (3.3)
Grade 2	1 (1.4)	0	1 (0.6)	1 (0.4)
筋痙縮	4 (5.5)	1 (1.4)	7 (4.1)	8 (3.3)
Grade 1	2 (2.8)	1 (1.4)	7 (4.1)	8 (3.3)
Grade 2	2 (2.8)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
骨粗鬆症	3 (4.2)	1 (1.4)	5 (2.9)	6 (2.5)
Grade 1	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 2	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
Grade 3	1 (1.4)	0	1 (0.6)	1 (0.4)
頚部痛	4 (5.5)	0	5 (2.9)	5 (2.0)
Grade 1	2 (2.8)	0	2 (1.2)	2 (0.8)
Grade 2	2 (2.8)	0	3 (1.8)	3 (1.2)
顎痛	0	3 (4.1)	2 (1.2)	5 (2.0)
Grade 1	0	3 (4.1)	2 (1.2)	5 (2.0)
線維筋痛	0	2 (2.8)	2 (1.2)	4 (1.6)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	0	2 (2.8)	1 (0.6)	3 (1.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
椎間板突出	3 (4.2)	1 (1.4)	2 (1.2)	3 (1.2)
Grade 1	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	0	0
Grade 3	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
筋力低下	2 (2.8)	1 (1.4)	2 (1.2)	3 (1.2)
Grade 1	2 (2.8)	1 (1.4)	2 (1.2)	3 (1.2)
筋骨格系胸痛	2 (2.8)	1 (1.4)	2 (1.2)	3 (1.2)
Grade 1	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
Grade 2	1 (1.4)	0	0	0
腱障害	1 (1.4)	2 (2.8)	1 (0.6)	3 (1.2)
Grade 1	1 (1.4)	0	0	0
Grade 2	0	2 (2.8)	1 (0.6)	3 (1.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
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PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
滑液包炎	0	0	3 (1.8)	3 (1.2)
Grade 1	0	0	2 (1.2)	2 (0.8)
Grade 2	0	0	1 (0.6)	1 (0.4)
骨減少症	0	0	3 (1.8)	3 (1.2)
Grade 1	0	0	2 (1.2)	2 (0.8)
Grade 2	0	0	1 (0.6)	1 (0.4)
大転子疼痛症候群	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
Grade 1	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
肩回旋筋腱板症候群	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
Grade 1	1 (1.4)	0	0	0
Grade 2	0	1 (1.4)	1 (0.6)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
脊椎痛	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 1	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
筋骨格痛	0	0	2 (1.2)	2 (0.8)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
ミオパチー	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 2	0	1 (1.4)	1 (0.6)	2 (0.8)
腱炎	0	0	2 (1.2)	2 (0.8)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
弾発指	0	2 (2.8)	0	2 (0.8)
Grade 1	0	2 (2.8)	0	2 (0.8)
筋骨格硬直	3 (4.2)	0	1 (0.6)	1 (0.4)
Grade 1	3 (4.2)	0	1 (0.6)	1 (0.4)
関節可動域低下	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	1 (0.6)	1 (0.4)
腰部脊柱管狭窄症	1 (1.4)	1 (1.4)	0	1 (0.4)
Grade 3	1 (1.4)	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
リウマチ性多発筋痛	1 (1.4)	1 (1.4)	0	1 (0.4)
Grade 1	1 (1.4)	0	0	0
Grade 2	0	1 (1.4)	0	1 (0.4)
シェーグレン症候群	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	0	0
Grade 2	0	0	1 (0.6)	1 (0.4)
滑液嚢腫	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	0	0
狭窄性腱鞘炎	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
関節炎	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
頚部脊柱管狭窄症	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
側腹部痛	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
単径部痛	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
関節滲出液	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
関節腫脹	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
半月板変性	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
筋骨格障害	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
骨端症	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
関節周囲炎	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
足底筋膜炎	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
肩甲帯痛	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
脊柱管狭窄症	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
脊椎滑液嚢腫	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
顎関節症候群	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)
腱痛	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)				
腱鞘炎	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
椎間孔狭窄	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)
関節障害	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
椎間板障害	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
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）	4 (5.5)	4 (5.5)	17 (9.9)	21 (8.6)
Grade 1	2 (2.8)	1 (1.4)	7 (4.1)	8 (3.3)
Grade 2	2 (2.8)	2 (2.8)	6 (3.5)	8 (3.3)
Grade 3	0	1 (1.4)	4 (2.3)	5 (2.0)
皮膚有棘細胞癌	0	0	5 (2.9)	5 (2.0)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	3 (1.8)	3 (1.2)
Grade 3	0	0	1 (0.6)	1 (0.4)
脂漏性角化症	0	0	2 (1.2)	2 (0.8)
Grade 1	0	0	2 (1.2)	2 (0.8)
基底細胞癌	2 (2.8)	0	1 (0.6)	1 (0.4)
Grade 2	2 (2.8)	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
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Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
副腎腺腫	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)
良性毛包腫瘍	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
悪性黒子	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
脂肪腫	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
肺腺癌	0	1 (1.4)	0	1 (0.4)
Grade 3	0	1 (1.4)	0	1 (0.4)
メラノサイト性母斑	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
骨髄異形成症候群	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
粘液腫	0	0	1 (0.6)	1 (0.4)
Grade 3	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
皮膚の新生物	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
甲状腺乳頭癌	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)
前立腺癌	0	0	1 (0.6)	1 (0.4)
Grade 3	0	0	1 (0.6)	1 (0.4)
前立腺腺腫	0	0	1 (0.6)	1 (0.4)
Grade 3	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
皮膚乳頭腫	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)
血管筋脂肪腫	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
神経線維腫	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
神経系障害	30 (41.5)	32 (44.1)	76 (44.3)	108 (44.3)
Grade 1	20 (27.7)	17 (23.4)	50 (29.2)	67 (27.5)
Grade 2	7 (9.7)	15 (20.7)	24 (14.0)	39 (16.0)
Grade 3	3 (4.2)	0	1 (0.6)	1 (0.4)
Grade 4	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
頭痛	7 (9.7)	11 (15.2)	26 (15.2)	37 (15.2)
Grade 1	6 (8.3)	7 (9.6)	17 (9.9)	24 (9.8)
Grade 2	1 (1.4)	4 (5.5)	8 (4.7)	12 (4.9)
Grade 4	0	0	1 (0.6)	1 (0.4)
坐骨神経痛	1 (1.4)	3 (4.1)	4 (2.3)	7 (2.9)
Grade 1	0	0	3 (1.8)	3 (1.2)
Grade 2	1 (1.4)	3 (4.1)	1 (0.6)	4 (1.6)
浮動性めまい	6 (8.3)	2 (2.8)	4 (2.3)	6 (2.5)
Grade 1	5 (6.9)	1 (1.4)	4 (2.3)	5 (2.0)
Grade 2	1 (1.4)	1 (1.4)	0	1 (0.4)
錯感覚	1 (1.4)	2 (2.8)	2 (1.2)	4 (1.6)
Grade 1	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
Grade 2	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
感覚鈍麻	0	0	4 (2.3)	4 (1.6)
Grade 1	0	0	3 (1.8)	3 (1.2)
Grade 2	0	0	1 (0.6)	1 (0.4)
後頭神経痛	0	0	4 (2.3)	4 (1.6)
Grade 1	0	0	3 (1.8)	3 (1.2)
Grade 2	0	0	1 (0.6)	1 (0.4)
緊張性頭痛	0	2 (2.8)	2 (1.2)	4 (1.6)
Grade 1	0	1 (1.4)	2 (1.2)	3 (1.2)
Grade 2	0	1 (1.4)	0	1 (0.4)
灼熱感	0	1 (1.4)	2 (1.2)	3 (1.2)
Grade 1	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
手根管症候群	0	0	3 (1.8)	3 (1.2)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	2 (1.2)	2 (0.8)
失神寸前の状態	0	0	3 (1.8)	3 (1.2)
Grade 1	0	0	2 (1.2)	2 (0.8)
Grade 2	0	0	1 (0.6)	1 (0.4)
神経根障害	0	0	3 (1.8)	3 (1.2)
Grade 1	0	0	2 (1.2)	2 (0.8)
Grade 2	0	0	1 (0.6)	1 (0.4)
頚動脈狭窄	0	0	2 (1.2)	2 (0.8)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
記憶障害	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 1	0	1 (1.4)	1 (0.6)	2 (0.8)
ヘルペス後神経痛	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 2	0	1 (1.4)	1 (0.6)	2 (0.8)
偽性根症候群	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 2	0	1 (1.4)	1 (0.6)	2 (0.8)
下肢静止不能症候群	0	0	2 (1.2)	2 (0.8)
Grade 1	0	0	2 (1.2)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
失神	2 (2.8)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 3	1 (1.4)	0	0	0
振戦	2 (2.8)	1 (1.4)	0	1 (0.4)
Grade 1	2 (2.8)	1 (1.4)	0	1 (0.4)
腰髄神経根障害	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	0	0
Grade 3	0	0	1 (0.6)	1 (0.4)
健忘	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
無嗅覚	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
頚腕症候群	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
注意力障害	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)
労作性めまい	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
ジストニア	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
電気ショック様感覚	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)
味覚減退	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)
脳圧低下	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
不随意性筋収縮	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
神経痛性筋萎縮症	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)
精神運動亢進	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
4分の1盲	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
一過性失語症	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)
一過性脳虚血発作	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)
トンネル状視野	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
椎骨動脈狭窄	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
平衡障害	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
ブレインフォグ	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
脳アミロイド血管障害	1 (1.4)	0	0	0
Grade 3	1 (1.4)	0	0	0
脳脊髄瘻	1 (1.4)	0	0	0
Grade 3	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
異常感覚	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
片頭痛	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
神経痛	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
末梢性ニューロパチー	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
神経系障害 (Cont.)				
視神経炎	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
多発ニューロパチー	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
精神障害	7 (9.7)	4 (5.5)	9 (5.3)	13 (5.3)
Grade 1	3 (4.2)	1 (1.4)	5 (2.9)	6 (2.5)
Grade 2	4 (5.5)	3 (4.1)	4 (2.3)	7 (2.9)
不眠症	2 (2.8)	0	3 (1.8)	3 (1.2)
Grade 1	1 (1.4)	0	3 (1.8)	3 (1.2)
Grade 2	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
精神障害 (Cont.)				
不安	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
抑うつ気分	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 2	0	1 (1.4)	1 (0.6)	2 (0.8)
神経過敏	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	1 (1.4)	0	0	0
Grade 2	0	0	1 (0.6)	1 (0.4)
歯ぎしり	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
精神障害 (Cont.)				
錯乱状態	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
リビドー減退	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)
落ち着きのなさ	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)
譫妄	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
精神障害 (Cont.)				
躁病	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
混合性不安抑うつ障害	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
腎および尿路障害	11 (15.2)	2 (2.8)	7 (4.1)	9 (3.7)
Grade 1	6 (8.3)	2 (2.8)	5 (2.9)	7 (2.9)
Grade 2	4 (5.5)	0	2 (1.2)	2 (0.8)
Grade 3	1 (1.4)	0	0	0
頻尿	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
Grade 1	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
腎および尿路障害 (Cont.)				
腎損傷	0	0	2 (1.2)	2 (0.8)
Grade 1	0	0	2 (1.2)	2 (0.8)
血尿	3 (4.2)	0	1 (0.6)	1 (0.4)
Grade 1	2 (2.8)	0	1 (0.6)	1 (0.4)
Grade 3	1 (1.4)	0	0	0
腎結石症	1 (1.4)	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)
Grade 2	1 (1.4)	0	0	0
夜間頻尿	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
腎および尿路障害 (Cont.)				
尿道狭窄	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
急性腎障害	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
緊張性膀胱	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
蛋白尿	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
腎および尿路障害 (Cont.)				
腎仙痛	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
腎嚢胞	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
尿失禁	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
生殖系および乳房障害	2 (2.8)	3 (4.1)	7 (4.1)	10 (4.1)
Grade 1	1 (1.4)	1 (1.4)	5 (2.9)	6 (2.5)
Grade 2	1 (1.4)	2 (2.8)	2 (1.2)	4 (1.6)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
生殖系および乳房障害 (Cont.)				
勃起不全	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 1	0	1 (1.4)	0	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
乳房腫瘤	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
乳房痛	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
膀胱瘤	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
生殖系および乳房障害 (Cont.)				
乳頭痛	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
骨盤痛	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
前立腺腫大	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
外陰腟灼熱感	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
生殖系および乳房障害 (Cont.)				
外陰腟乾燥	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)
亀頭包皮炎	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
外陰腟そう痒症	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
呼吸器、胸郭および縦隔障害	11 (15.2)	9 (12.4)	32 (18.7)	41 (16.8)
Grade 1	9 (12.5)	6 (8.3)	20 (11.7)	26 (10.7)
Grade 2	2 (2.8)	2 (2.8)	8 (4.7)	10 (4.1)
Grade 3	0	1 (1.4)	4 (2.3)	5 (2.0)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
呼吸器、胸郭および縦隔障害 (Cont.)				
咳嗽	5 (6.9)	3 (4.1)	10 (5.8)	13 (5.3)
Grade 1	3 (4.2)	2 (2.8)	9 (5.3)	11 (4.5)
Grade 2	2 (2.8)	1 (1.4)	1 (0.6)	2 (0.8)
口腔咽頭痛	1 (1.4)	1 (1.4)	3 (1.8)	4 (1.6)
Grade 1	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 2	0	1 (1.4)	1 (0.6)	2 (0.8)
喘息	0	0	4 (2.3)	4 (1.6)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	2 (1.2)	2 (0.8)
Grade 3	0	0	1 (0.6)	1 (0.4)
呼吸困難	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)
Grade 1	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
呼吸器、胸郭および縦隔障害 (Cont.)				
鼻出血	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
Grade 1	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
鼻漏	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 1	1 (1.4)	0	2 (1.2)	2 (0.8)
肺腫瘤	0	2 (2.8)	0	2 (0.8)
Grade 1	0	1 (1.4)	0	1 (0.4)
Grade 3	0	1 (1.4)	0	1 (0.4)
慢性気管支炎	0	0	1 (0.6)	1 (0.4)
Grade 3	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
呼吸器、胸郭および縦隔障害 (Cont.)				
気管支痙攣	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
下咽頭癒着	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
鼻閉	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
起坐呼吸	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
呼吸器、胸郭および縦隔障害 (Cont.)				
胸水	0	0	1 (0.6)	1 (0.4)
Grade 3	0	0	1 (0.6)	1 (0.4)
湿性咳嗽	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
肺塞栓症	0	0	1 (0.6)	1 (0.4)
Grade 3	0	0	1 (0.6)	1 (0.4)
呼吸障害	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
呼吸器、胸郭および縦隔障害 (Cont.)				
アレルギー性鼻炎	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
咽喉刺激感	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
労作性呼吸困難	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
咳払い	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害	19 (26.3)	9 (12.4)	48 (28.0)	57 (23.4)
Grade 1	12 (16.6)	6 (8.3)	34 (19.8)	40 (16.4)
Grade 2	6 (8.3)	3 (4.1)	14 (8.2)	17 (7.0)
Grade 3	1 (1.4)	0	0	0
発疹	2 (2.8)	2 (2.8)	8 (4.7)	10 (4.1)
Grade 1	2 (2.8)	1 (1.4)	5 (2.9)	6 (2.5)
Grade 2	0	1 (1.4)	3 (1.8)	4 (1.6)
ざ瘡	0	0	6 (3.5)	6 (2.5)
Grade 1	0	0	4 (2.3)	4 (1.6)
Grade 2	0	0	2 (1.2)	2 (0.8)
寝汗	1 (1.4)	2 (2.8)	1 (0.6)	3 (1.2)
Grade 1	1 (1.4)	2 (2.8)	1 (0.6)	3 (1.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
脱毛症	0	0	3 (1.8)	3 (1.2)
Grade 1	0	0	3 (1.8)	3 (1.2)
多汗症	0	1 (1.4)	2 (1.2)	3 (1.2)
Grade 1	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 2	0	0	1 (0.6)	1 (0.4)
皮膚潰瘍	2 (2.8)	0	2 (1.2)	2 (0.8)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 3	1 (1.4)	0	0	0
皮膚乾燥	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 1	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
紅斑	1 (1.4)	0	2 (1.2)	2 (0.8)
Grade 1	1 (1.4)	0	2 (1.2)	2 (0.8)
光線角化症	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)
接触皮膚炎	0	0	2 (1.2)	2 (0.8)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
斑状丘疹状皮疹	0	1 (1.4)	1 (0.6)	2 (0.8)
Grade 1	0	1 (1.4)	0	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
酒さ	0	0	2 (1.2)	2 (0.8)
Grade 1	0	0	2 (1.2)	2 (0.8)
過角化	1 (1.4)	1 (1.4)	0	1 (0.4)
Grade 1	1 (1.4)	1 (1.4)	0	1 (0.4)
円形脱毛症	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
皮膚嚢腫	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
皮膚炎	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
びまん性脱毛症	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
湿疹	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
毛髪成長異常	0	1 (1.4)	0	1 (0.4)
Grade 2	0	1 (1.4)	0	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
男性型多毛症	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
汗疹	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
爪変色	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
爪破損	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
皮膚疼痛	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
口囲皮膚炎	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
痂皮	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
皮膚硬結	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
皮膚病変	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
うっ滞性皮膚炎	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
黄色皮膚	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
水疱	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
冷汗	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
アレルギー性皮膚炎	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
斑状出血	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
丘疹	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
類天疱瘡	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
痒疹	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
そう痒症	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
乾癬	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
斑状皮疹	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
脂漏性皮膚炎	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
血管障害	29 (40.1)	16 (22.0)	47 (27.4)	63 (25.8)
Grade 1	10 (13.8)	4 (5.5)	18 (10.5)	22 (9.0)
Grade 2	18 (24.9)	9 (12.4)	27 (15.8)	36 (14.8)
Grade 3	1 (1.4)	3 (4.1)	2 (1.2)	5 (2.0)
高血圧	5 (6.9)	7 (9.6)	20 (11.7)	27 (11.1)
Grade 1	1 (1.4)	1 (1.4)	6 (3.5)	7 (2.9)
Grade 2	3 (4.2)	5 (6.9)	13 (7.6)	18 (7.4)
Grade 3	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
血管障害 (Cont.)				
巨細胞性動脈炎	13 (18.0)	6 (8.3)	20 (11.7)	26 (10.7)
Grade 1	5 (6.9)	1 (1.4)	6 (3.5)	7 (2.9)
Grade 2	8 (11.1)	4 (5.5)	13 (7.6)	17 (7.0)
Grade 3	0	1 (1.4)	1 (0.6)	2 (0.8)
血腫	3 (4.2)	0	1 (0.6)	1 (0.4)
Grade 1	2 (2.8)	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	0	0
間欠性跛行	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	0	0
レイノー現象	1 (1.4)	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)
Grade 2	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
血管障害 (Cont.)				
静脈瘤	1 (1.4)	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
Grade 2	1 (1.4)	0	0	0
動脈出血	0	1 (1.4)	0	1 (0.4)
Grade 3	0	1 (1.4)	0	1 (0.4)
リンパ浮腫	0	0	1 (0.6)	1 (0.4)
Grade 2	0	0	1 (0.6)	1 (0.4)
リンパうっ滞	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
血管障害 (Cont.)				
起立性低血圧	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
血栓性静脈炎	0	1 (1.4)	0	1 (0.4)
Grade 1	0	1 (1.4)	0	1 (0.4)
白衣性高血圧	0	0	1 (0.6)	1 (0.4)
Grade 1	0	0	1 (0.6)	1 (0.4)
大動脈瘤	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.5.2

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term and Maximum Toxicity - Long-Term (SS_LT)

MedDRA 26.1 System Organ Class Preferred Term Toxicity	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	UPA Total (N=131) (PYS=244.0) Events (E/100PY)
血管障害 (Cont.)				
大動脈炎	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
動脈硬化症	1 (1.4)	0	0	0
Grade 2	1 (1.4)	0	0	0
末梢冷感	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0
末梢静脈疾患	1 (1.4)	0	0	0
Grade 1	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
Table depicts the maximum toxicity adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

表7

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ABT-494 (GIANT CELL ARTERITIS)
STUDY M16-852 (CUTOFF 06FEB2024)
R&D/23/2455 - CLINICAL/STATISTICAL

TABLE 14.3__2.3.1

Subjects with Treatment-Emergent Adverse Events Leading to Death
by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
Any adverse event	2 (1.8)	0	2 (1.0)	2 (0.6)
胃腸障害	1 (0.9)	0	0	0
急性膵炎	1 (0.9)	0	0	0
一般・全身障害および投与部位の状態	0	0	1 (0.5)	1 (0.3)
死亡	0	0	1 (0.5)	1 (0.3)
感染症および寄生虫症	1 (0.9)	0	1 (0.5)	1 (0.3)
COVID-19	0	0	1 (0.5)	1 (0.3)
敗血症	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

表8

[redacted]20[redacted] 17:55 <[redacted]>
ABT-494 (GIANT CELL ARTERITIS)
STUDY M16-852 (CUTOFF 06FEB2024)
R&D/23/2455 - CLINICAL/STATISTICAL

TABLE 14.3__2.1.1

Subjects with Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
Any adverse event	24 (21.4)	14 (13.1)	48 (23.0)	62 (19.6)
血液およびリンパ系障害	0	1 (0.9)	0	1 (0.3)
貧血	0	1 (0.9)	0	1 (0.3)
心臓障害	2 (1.8)	1 (0.9)	5 (2.4)	6 (1.9)
心房細動	0	0	1 (0.5)	1 (0.3)
心不全	0	1 (0.9)	1 (0.5)	2 (0.6)
うっ血性心不全	0	0	2 (1.0)	2 (0.6)
線維性心内膜炎	1 (0.9)	0	0	0
僧帽弁閉鎖不全症	0	0	1 (0.5)	1 (0.3)
心筋虚血	1 (0.9)	0	0	0
三尖弁閉鎖不全症	0	0	1 (0.5)	1 (0.3)
耳および迷路障害	0	1 (0.9)	0	1 (0.3)
回転性めまい	0	1 (0.9)	0	1 (0.3)
眼障害	0	0	4 (1.9)	4 (1.3)
複視	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__2.1.1

Subjects with Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
眼障害 (cont.)				
緑内障	0	0	1 (0.5)	1 (0.3)
黄斑浮腫	0	0	1 (0.5)	1 (0.3)
網膜剥離	0	0	1 (0.5)	1 (0.3)
胃腸障害	2 (1.8)	3 (2.8)	4 (1.9)	7 (2.2)
虚血性大腸炎	0	0	1 (0.5)	1 (0.3)
潰瘍性大腸炎	0	0	1 (0.5)	1 (0.3)
下痢	0	0	1 (0.5)	1 (0.3)
マロリー・ワイス症候群	0	1 (0.9)	0	1 (0.3)
膵炎	0	1 (0.9)	0	1 (0.3)
急性膵炎	2 (1.8)	0	0	0
嘔吐	0	1 (0.9)	1 (0.5)	2 (0.6)
一般・全身障害および投与部位の状態	1 (0.9)	0	3 (1.4)	3 (0.9)
死亡	0	0	1 (0.5)	1 (0.3)
疲労	0	0	1 (0.5)	1 (0.3)
末梢性浮腫	1 (0.9)	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__2.1.1

Subjects with Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
肝胆道系障害	2 (1.8)	0	0	0
慢性胆嚢炎	1 (0.9)	0	0	0
急性肝炎	1 (0.9)	0	0	0
免疫系障害	0	0	1 (0.5)	1 (0.3)
薬物過敏症	0	0	1 (0.5)	1 (0.3)
感染症および寄生虫症	11 (9.8)	6 (5.6)	12 (5.7)	18 (5.7)
COVID-19	0	0	1 (0.5)	1 (0.3)
COVID-19肺炎	0	0	2 (1.0)	2 (0.6)
膀胱炎	0	0	1 (0.5)	1 (0.3)
医療機器関連感染	0	0	1 (0.5)	1 (0.3)
丹毒	0	1 (0.9)	0	1 (0.3)
熱性感染症	0	1 (0.9)	0	1 (0.3)
クロストリジウム菌性胃腸炎	0	0	1 (0.5)	1 (0.3)
泌尿生殖器感染	0	0	1 (0.5)	1 (0.3)
椎間板炎	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__2.1.1

Subjects with Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
感染症および寄生虫症 (cont.)				
眼帯状疱疹	0	0	2 (1.0)	2 (0.6)
ニューモシスチス・イロベチイ肺炎	0	0	1 (0.5)	1 (0.3)
肺炎	5 (4.5)	3 (2.8)	0	3 (0.9)
細菌性肺炎	1 (0.9)	0	0	0
シュードモナス性菌血症	0	0	1 (0.5)	1 (0.3)
RSウイルス感染	0	1 (0.9)	0	1 (0.3)
気道感染	0	0	1 (0.5)	1 (0.3)
サルモネラ症	0	0	1 (0.5)	1 (0.3)
敗血症	1 (0.9)	0	0	0
レンサ球菌性化膿性関節炎	0	1 (0.9)	0	1 (0.3)
ブドウ球菌性敗血症	1 (0.9)	0	0	0
尿路感染	1 (0.9)	0	0	0
尿路性敗血症	1 (0.9)	0	0	0
創傷感染	1 (0.9)	0	0	0
傷害、中毒および処置合併症	2 (1.8)	2 (1.9)	2 (1.0)	4 (1.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__2.1.1

Subjects with Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症 (cont.)				
転倒	1 (0.9)	0	1 (0.5)	1 (0.3)
頭部損傷	0	0	1 (0.5)	1 (0.3)
股関節部骨折	0	0	1 (0.5)	1 (0.3)
注入に伴う反応	1 (0.9)	0	0	0
膝蓋骨骨折	0	1 (0.9)	0	1 (0.3)
橈骨骨折	1 (0.9)	0	0	0
交通事故	0	1 (0.9)	0	1 (0.3)
脊椎骨折	0	1 (0.9)	0	1 (0.3)
胸椎骨折	0	1 (0.9)	0	1 (0.3)
臨床検査	1 (0.9)	0	1 (0.5)	1 (0.3)
血中アルカリホスファターゼ増加	1 (0.9)	0	0	0
Γ-グルタミルトランスフェラーゼ増加	1 (0.9)	0	0	0
トロポニンT増加	0	0	1 (0.5)	1 (0.3)
代謝および栄養障害	0	1 (0.9)	0	1 (0.3)
低カリウム血症	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__2.1.1

Subjects with Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
代謝および栄養障害 (cont.)				
低ナトリウム血症	0	1 (0.9)	0	1 (0.3)
筋骨格系および結合組織障害	3 (2.7)	1 (0.9)	4 (1.9)	5 (1.6)
背部痛	1 (0.9)	0	0	0
椎間板突出	1 (0.9)	0	0	0
腰部脊柱管狭窄症	0	1 (0.9)	0	1 (0.3)
半月板変性	0	0	1 (0.5)	1 (0.3)
変形性関節症	1 (0.9)	0	2 (1.0)	2 (0.6)
椎間孔狭窄	0	0	1 (0.5)	1 (0.3)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2 (1.8)	1 (0.9)	3 (1.4)	4 (1.3)
ファーター膨大部の悪性新生物	0	0	1 (0.5)	1 (0.3)
前立腺癌	1 (0.9)	0	0	0
肺扁平上皮癌	0	0	1 (0.5)	1 (0.3)
皮膚有棘細胞癌	0	1 (0.9)	0	1 (0.3)
舌の悪性新生物、病期不明	0	0	1 (0.5)	1 (0.3)
遠隔転移を伴う扁桃癌	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__2.1.1

Subjects with Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
神経系障害	5 (4.5)	1 (0.9)	3 (1.4)	4 (1.3)
小脳性運動失調	0	0	1 (0.5)	1 (0.3)
脳アミロイド血管障害	1 (0.9)	0	0	0
脳梗塞	1 (0.9)	0	0	0
脳脊髄癆	1 (0.9)	0	0	0
脳卒中	1 (0.9)	0	0	0
頭痛	0	0	1 (0.5)	1 (0.3)
4分の1盲	0	0	1 (0.5)	1 (0.3)
坐骨神経痛	0	1 (0.9)	0	1 (0.3)
失神	1 (0.9)	0	0	0
精神障害	0	0	1 (0.5)	1 (0.3)
物質誘発性精神病性障害	0	0	1 (0.5)	1 (0.3)
腎および尿路障害	1 (0.9)	0	0	0
急性腎障害	1 (0.9)	0	0	0
生殖系および乳房障害	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__2.1.1

Subjects with Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
生殖系および乳房障害 (cont.)				
子宮頚部上皮異形成	0	0	1 (0.5)	1 (0.3)
呼吸器、胸郭および縦隔障害	2 (1.8)	2 (1.9)	5 (2.4)	7 (2.2)
血胸	0	1 (0.9)	0	1 (0.3)
肺塞栓症	2 (1.8)	1 (0.9)	5 (2.4)	6 (1.9)
血管障害	2 (1.8)	1 (0.9)	10 (4.8)	11 (3.5)
大動脈解離	0	0	1 (0.5)	1 (0.3)
大動脈血栓症	0	0	1 (0.5)	1 (0.3)
動脈硬化症	1 (0.9)	0	0	0
深部静脈血栓症	0	0	3 (1.4)	3 (0.9)
巨細胞性動脈炎	1 (0.9)	1 (0.9)	3 (1.4)	4 (1.3)
血腫	0	0	1 (0.5)	1 (0.3)
末梢動脈閉塞性疾患	0	0	1 (0.5)	1 (0.3)
末梢血管塞栓症	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

表9

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ABT-494 (GIANT CELL ARTERITIS)
STUDY M16-852 (CUTOFF 06FEB2024)
R&D/23/2455 - CLINICAL/STATISTICAL

TABLE 14.3__2.1.2

Treatment-Emergent Serious Adverse Events per 100 Patient-years (PYS)
by System Organ Class and Preferred Term - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	Total (N=131) (PYS=244) Events (E/100PY)
Any adverse event	18 (24.9)	15 (20.7)	26 (15.2)	41 (16.8)
血液およびリンパ系障害	0	1 (1.4)	0	1 (0.4)
貧血	0	1 (1.4)	0	1 (0.4)
心臓障害	0	0	6 (3.5)	6 (2.5)
心房細動	0	0	2 (1.2)	2 (0.8)
心不全	0	0	2 (1.2)	2 (0.8)
僧帽弁閉鎖不全症	0	0	1 (0.6)	1 (0.4)
心筋虚血	0	0	1 (0.6)	1 (0.4)
耳および迷路障害	0	1 (1.4)	0	1 (0.4)
回転性めまい	0	1 (1.4)	0	1 (0.4)
内分泌障害	1 (1.4)	0	0	0
中毒性結節性甲状腺腫	1 (1.4)	0	0	0
眼障害	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity
date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo;
UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg;
UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__2.1.2

Treatment-Emergent Serious Adverse Events per 100 Patient-years (PYS)
by System Organ Class and Preferred Term - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	Total (N=131) (PYS=244) Events (E/100PY)
眼障害 (cont.)				
複視	0	0	1 (0.6)	1 (0.4)
胃腸障害	0	2 (2.8)	2 (1.2)	4 (1.6)
虚血性大腸炎	0	0	1 (0.6)	1 (0.4)
膵炎	0	1 (1.4)	0	1 (0.4)
嘔吐	0	1 (1.4)	1 (0.6)	2 (0.8)
一般・全身障害および投与部位の状態	1 (1.4)	0	0	0
末梢性浮腫	1 (1.4)	0	0	0
感染症および寄生虫症	5 (6.9)	3 (4.1)	5 (2.9)	8 (3.3)
アスペルギルス感染	1 (1.4)	0	0	0
膀胱炎	0	0	1 (0.6)	1 (0.4)
憩室炎	0	1 (1.4)	0	1 (0.4)
眼帯状疱疹	0	0	1 (0.6)	1 (0.4)
肺炎	1 (1.4)	1 (1.4)	2 (1.2)	3 (1.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo;
UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg;
UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__2.1.2

Treatment-Emergent Serious Adverse Events per 100 Patient-years (PYS)
by System Organ Class and Preferred Term - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	Total (N=131) (PYS=244) Events (E/100PY)
感染症および寄生虫症 (cont.)				
RSウイルス感染	0	1 (1.4)	0	1 (0.4)
サルモネラ症	0	0	1 (0.6)	1 (0.4)
尿路感染	1 (1.4)	0	0	0
尿路性敗血症	1 (1.4)	0	0	0
創傷感染	1 (1.4)	0	0	0
傷害、中毒および処置合併症	0	1 (1.4)	1 (0.6)	2 (0.8)
足骨折	0	0	1 (0.6)	1 (0.4)
胸椎骨折	0	1 (1.4)	0	1 (0.4)
臨床検査	2 (2.8)	0	1 (0.6)	1 (0.4)
血中アルカリホスファターゼ増加	1 (1.4)	0	0	0
Γ-グルタミルトランスフェラーゼ増加	1 (1.4)	0	0	0
トロポニンT増加	0	0	1 (0.6)	1 (0.4)
代謝および栄養障害	1 (1.4)	2 (2.8)	0	2 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity
date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo;
UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg;
UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__2.1.2

Treatment-Emergent Serious Adverse Events per 100 Patient-years (PYS)
by System Organ Class and Preferred Term - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	Total (N=131) (PYS=244) Events (E/100PY)
代謝および栄養障害 (cont.)				
低カリウム血症	0	1 (1.4)	0	1 (0.4)
低ナトリウム血症	1 (1.4)	1 (1.4)	0	1 (0.4)
筋骨格系および結合組織障害	3 (4.2)	1 (1.4)	2 (1.2)	3 (1.2)
椎間板突出	1 (1.4)	0	0	0
腰部脊柱管狭窄症	1 (1.4)	1 (1.4)	0	1 (0.4)
半月板変性	0	0	1 (0.6)	1 (0.4)
変形性関節症	1 (1.4)	0	1 (0.6)	1 (0.4)
良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む)	0	2 (2.8)	3 (1.8)	5 (2.0)
肺腺癌	0	1 (1.4)	0	1 (0.4)
粘液腫	0	0	1 (0.6)	1 (0.4)
甲状腺乳頭癌	0	1 (1.4)	0	1 (0.4)
前立腺癌	0	0	1 (0.6)	1 (0.4)
前立腺腺腫	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo;
UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg;
UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__2.1.2

Treatment-Emergent Serious Adverse Events per 100 Patient-years (PYS)
by System Organ Class and Preferred Term - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	Total (N=131) (PYS=244) Events (E/100PY)
神経系障害	2 (2.8)	1 (1.4)	2 (1.2)	3 (1.2)
脳アミロイド血管障害	1 (1.4)	0	0	0
脳脊髄癆	1 (1.4)	0	0	0
頭痛	0	0	1 (0.6)	1 (0.4)
4分の1盲	0	0	1 (0.6)	1 (0.4)
坐骨神経痛	0	1 (1.4)	0	1 (0.4)
腎および尿路障害	1 (1.4)	0	0	0
血尿	1 (1.4)	0	0	0
呼吸器、胸郭および縦隔障害	0	1 (1.4)	2 (1.2)	3 (1.2)
胸水	0	0	1 (0.6)	1 (0.4)
肺塞栓症	0	0	1 (0.6)	1 (0.4)
肺腫瘤	0	1 (1.4)	0	1 (0.4)
皮膚および皮下組織障害	1 (1.4)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity
date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo;
UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg;
UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__2.1.2

Treatment-Emergent Serious Adverse Events per 100 Patient-years (PYS)
by System Organ Class and Preferred Term - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	Total (N=131) (PYS=244) Events (E/100PY)
皮膚および皮下組織障害 (cont.)				
皮膚潰瘍	1 (1.4)	0	0	0
血管障害	1 (1.4)	0	1 (0.6)	1 (0.4)
動脈硬化症	1 (1.4)	0	0	0
巨細胞性動脈炎	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo;
UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg;
UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

表10

TABLE 14.3__2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
Any adverse event	29 (25.9)	23 (21.5)	36 (17.2)	59 (18.7)
心臓障害	1 (0.9)	1 (0.9)	0	1 (0.3)
大動脈弁狭窄	0	1 (0.9)	0	1 (0.3)
線維性心内膜炎	1 (0.9)	0	0	0
内分泌障害	0	0	1 (0.5)	1 (0.3)
クッシング症候群	0	0	1 (0.5)	1 (0.3)
眼障害	0	1 (0.9)	1 (0.5)	2 (0.6)
黄斑浮腫	0	0	1 (0.5)	1 (0.3)
眼部不快感	0	1 (0.9)	0	1 (0.3)
霧視	0	1 (0.9)	0	1 (0.3)
胃腸障害	2 (1.8)	2 (1.9)	4 (1.9)	6 (1.9)
腹部不快感	1 (0.9)	0	0	0
腹痛	0	0	1 (0.5)	1 (0.3)
潰瘍性大腸炎	0	0	1 (0.5)	1 (0.3)
下痢	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
胃腸障害 (cont.)				
嚥下障害	0	1 (0.9)	0	1 (0.3)
胃食道逆流性疾患	0	0	1 (0.5)	1 (0.3)
急性膵炎	1 (0.9)	0	0	0
口内炎	0	1 (0.9)	0	1 (0.3)
一般・全身障害および投与部位の状態	0	2 (1.9)	3 (1.4)	5 (1.6)
死亡	0	0	1 (0.5)	1 (0.3)
疲労	0	0	1 (0.5)	1 (0.3)
末梢性浮腫	0	0	1 (0.5)	1 (0.3)
発熱	0	1 (0.9)	0	1 (0.3)
治療非遵守	0	1 (0.9)	0	1 (0.3)
肝胆道系障害	3 (2.7)	0	0	0
硬化性胆管炎	1 (0.9)	0	0	0
薬物性肝障害	1 (0.9)	0	0	0
急性肝炎	1 (0.9)	0	0	0
免疫系障害	1 (0.9)	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
免疫系障害 (cont.)				
アナフィラキシー様反応	1 (0.9)	0	0	0
薬物過敏症	0	0	1 (0.5)	1 (0.3)
感染症および寄生虫症	6 (5.4)	3 (2.8)	7 (3.3)	10 (3.2)
COVID-19	0	0	1 (0.5)	1 (0.3)
医療機器関連感染	0	0	1 (0.5)	1 (0.3)
帯状疱疹	0	0	1 (0.5)	1 (0.3)
椎間板炎	0	0	1 (0.5)	1 (0.3)
潜伏結核	0	1 (0.9)	0	1 (0.3)
眼帯状疱疹	0	0	1 (0.5)	1 (0.3)
ニューモシスチス・イロベチイ肺炎	0	0	1 (0.5)	1 (0.3)
肺炎	3 (2.7)	2 (1.9)	0	2 (0.6)
細菌性肺炎	1 (0.9)	0	0	0
シュードモナス性肺炎	0	0	1 (0.5)	1 (0.3)
敗血症	1 (0.9)	0	0	0
ブドウ球菌性敗血症	1 (0.9)	0	0	0

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
傷害、中毒および処置合併症	0	1 (0.9)	0	1 (0.3)
脊椎骨折	0	1 (0.9)	0	1 (0.3)
臨床検査	2 (1.8)	1 (0.9)	0	1 (0.3)
ヘモグロビン減少	1 (0.9)	0	0	0
トランスアミナーゼ上昇	0	1 (0.9)	0	1 (0.3)
体重減少	1 (0.9)	0	0	0
筋骨格系および結合組織障害	3 (2.7)	2 (1.9)	1 (0.5)	3 (0.9)
関節痛	0	0	1 (0.5)	1 (0.3)
背部痛	0	1 (0.9)	0	1 (0.3)
筋骨格硬直	0	0	1 (0.5)	1 (0.3)
リウマチ性多発筋痛	2 (1.8)	1 (0.9)	0	1 (0.3)
関節リウマチ	1 (0.9)	0	0	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2 (1.8)	0	3 (1.4)	3 (0.9)
線維腫	0	0	1 (0.5)	1 (0.3)
ファーター膨大部の悪性新生物	0	0	1 (0.5)	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (cont.)				
前立腺癌	1 (0.9)	0	0	0
肺扁平上皮癌	0	0	1 (0.5)	1 (0.3)
遠隔転移を伴う扁桃癌	1 (0.9)	0	0	0
神経系障害	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
脱髄	1 (0.9)	0	0	0
頭痛	0	1 (0.9)	1 (0.5)	2 (0.6)
ヘルペス後神経痛	0	0	1 (0.5)	1 (0.3)
精神障害	0	0	2 (1.0)	2 (0.6)
物質誘発性精神病性障害	0	0	2 (1.0)	2 (0.6)
生殖系および乳房障害	0	0	1 (0.5)	1 (0.3)
子宮頚部上皮異形成	0	0	1 (0.5)	1 (0.3)
呼吸器、胸郭および縦隔障害	2 (1.8)	4 (3.7)	4 (1.9)	8 (2.5)
労作性呼吸困難	0	1 (0.9)	0	1 (0.3)
血胸	0	1 (0.9)	0	1 (0.3)
肺塞栓症	2 (1.8)	2 (1.9)	4 (1.9)	6 (1.9)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by System Organ Class and Preferred Term in Period 1
(SS1)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=112) n (%)	UPA 7.5 + 26 WK CS-T (N=107) n (%)	UPA 15 + 26 WK CS-T (N=209) n (%)	Total (N=316) n (%)
皮膚および皮下組織障害	0	0	1 (0.5)	1 (0.3)
紅斑	0	0	1 (0.5)	1 (0.3)
血管障害	8 (7.1)	8 (7.5)	9 (4.3)	17 (5.4)
大動脈血栓症	0	0	1 (0.5)	1 (0.3)
深部静脈血栓症	1 (0.9)	1 (0.9)	2 (1.0)	3 (0.9)
巨細胞性動脈炎	7 (6.3)	6 (5.6)	5 (2.4)	11 (3.5)
末梢血管塞栓症	0	0	1 (0.5)	1 (0.3)
表在性静脈血栓症	0	1 (0.9)	0	1 (0.3)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

表11

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ABT-494 (GIANT CELL ARTERITIS)

STUDY M16-852 (CUTOFF 06FEB2024)

R&D/23/2455 - CLINICAL/STATISTICAL

TABLE 14.3__2.2.2

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug per 100 Patient-years (PYS)
by System Organ Class and Preferred Term - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	Total (N=131) (PYS=244) Events (E/100PY)
Any adverse event	4 (5.5)	2 (2.8)	9 (5.3)	11 (4.5)
心臓障害	0	0	1 (0.6)	1 (0.4)
心房細動	0	0	1 (0.6)	1 (0.4)
胃腸障害	0	0	1 (0.6)	1 (0.4)
下痢	0	0	1 (0.6)	1 (0.4)
一般・全身障害および投与部位の状態	0	0	1 (0.6)	1 (0.4)
疲労	0	0	1 (0.6)	1 (0.4)
感染症および寄生虫症	1 (1.4)	1 (1.4)	1 (0.6)	2 (0.8)
アスペルギルス感染	1 (1.4)	0	0	0
潜伏結核	0	1 (1.4)	0	1 (0.4)
肺炎	0	0	1 (0.6)	1 (0.4)
傷害、中毒および処置合併症	0	0	1 (0.6)	1 (0.4)
足骨折	0	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity
date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo;
UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg;
UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__2.2.2

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug per 100 Patient-years (PYS)
by System Organ Class and Preferred Term - Long-Term
(SS_LT)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=43) (PYS=72.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=39) (PYS=72.6) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=92) (PYS=171.4) Events (E/100PY)	Total (N=131) (PYS=244) Events (E/100PY)
臨床検査	1 (1.4)	0	0	0
ヘモグロビン減少	1 (1.4)	0	0	0
筋骨格系および結合組織障害	0	0	1 (0.6)	1 (0.4)
変形性関節症	0	0	1 (0.6)	1 (0.4)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	1 (1.4)	1 (0.6)	2 (0.8)
甲状腺乳頭癌	0	1 (1.4)	0	1 (0.4)
前立腺癌	0	0	1 (0.6)	1 (0.4)
皮膚および皮下組織障害	0	0	1 (0.6)	1 (0.4)
びまん性脱毛症	0	0	1 (0.6)	1 (0.4)
血管障害	2 (2.8)	0	1 (0.6)	1 (0.4)
大動脈炎	1 (1.4)	0	0	0
巨細胞性動脈炎	1 (1.4)	0	1 (0.6)	1 (0.4)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity
date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo;
UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg;
UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1_J

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1, Japanese Population)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=5) n (%)	UPA 7.5 + 26 WK CS-T (N=5) n (%)	UPA 15 + 26 WK CS-T (N=10) n (%)	Total (N=15) n (%)
Any adverse event	4 (80.0)	4 (80.0)	9 (90.0)	13 (86.7)
血液およびリンパ系障害	1 (20.0)	0	0	0
貧血	1 (20.0)	0	0	0
耳および迷路障害	1 (20.0)	0	0	0
回転性めまい	1 (20.0)	0	0	0
眼障害	2 (40.0)	1 (20.0)	4 (40.0)	5 (33.3)
結膜出血	0	1 (20.0)	2 (20.0)	3 (20.0)
ドライアイ	2 (40.0)	1 (20.0)	2 (20.0)	3 (20.0)
緑内障	0	0	1 (10.0)	1 (6.7)
胃腸障害	1 (20.0)	0	4 (40.0)	4 (26.7)
腹痛	0	0	1 (10.0)	1 (6.7)
大腸炎	1 (20.0)	0	0	0
虚血性大腸炎	0	0	1 (10.0)	1 (6.7)
歯肉痛	0	0	1 (10.0)	1 (6.7)
腰ヘルニア	0	0	1 (10.0)	1 (6.7)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1_J

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1, Japanese Population)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=5) n (%)	UPA 7.5 + 26 WK CS-T (N=5) n (%)	UPA 15 + 26 WK CS-T (N=10) n (%)	UPA Total (N=15) n (%)
胃腸障害 (cont.)				
悪心	0	0	1 (10.0)	1 (6.7)
一般・全身障害および投与部位の状態	0	0	2 (20.0)	2 (13.3)
末梢性浮腫	0	0	1 (10.0)	1 (6.7)
発熱	0	0	1 (10.0)	1 (6.7)
肝胆道系障害	0	0	1 (10.0)	1 (6.7)
肝機能異常	0	0	1 (10.0)	1 (6.7)
感染症および寄生虫症	2 (40.0)	3 (60.0)	7 (70.0)	10 (66.7)
気管支炎	0	0	1 (10.0)	1 (6.7)
結膜炎	0	0	1 (10.0)	1 (6.7)
膀胱炎	2 (40.0)	0	1 (10.0)	1 (6.7)
歯肉炎	0	0	1 (10.0)	1 (6.7)
帯状疱疹	0	1 (20.0)	1 (10.0)	2 (13.3)
インフルエンザ	0	0	1 (10.0)	1 (6.7)
上咽頭炎	0	0	2 (20.0)	2 (13.3)
口腔カンジダ症	1 (20.0)	0	1 (10.0)	1 (6.7)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1_J

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1, Japanese Population)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=5) n (%)	UPA 7.5 + 26 WK CS-T (N=5) n (%)	UPA 15 + 26 WK CS-T (N=10) n (%)	UPA Total (N=15) n (%)
感染症および寄生虫症 (cont.)				
肺炎	0	1 (20.0)	0	1 (6.7)
RSウイルス感染	0	1 (20.0)	0	1 (6.7)
傷害、中毒および処置合併症	1 (20.0)	0	0	0
創傷	1 (20.0)	0	0	0
臨床検査	1 (20.0)	1 (20.0)	2 (20.0)	3 (20.0)
B型肝炎ウイルス検査陽性	0	0	1 (10.0)	1 (6.7)
肝機能検査異常	0	0	1 (10.0)	1 (6.7)
リンパ球数減少	0	1 (20.0)	0	1 (6.7)
腎機能検査異常	1 (20.0)	0	0	0
代謝および栄養障害	0	0	1 (10.0)	1 (6.7)
痛風	0	0	1 (10.0)	1 (6.7)
筋骨格系および結合組織障害	1 (20.0)	2 (40.0)	5 (50.0)	7 (46.7)
背部痛	0	1 (20.0)	1 (10.0)	2 (13.3)
腰部脊柱管狭窄症	0	0	1 (10.0)	1 (6.7)
筋痙縮	0	0	1 (10.0)	1 (6.7)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1_J

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1, Japanese Population)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=5) n (%)	UPA 7.5 + 26 WK CS-T (N=5) n (%)	UPA 15 + 26 WK CS-T (N=10) n (%)	UPA Total (N=15) n (%)
筋骨格系および結合組織障害 (cont.)				
筋骨格硬直	0	0	1 (10.0)	1 (6.7)
頚部痛	1 (20.0)	0	1 (10.0)	1 (6.7)
変形性関節症	0	0	1 (10.0)	1 (6.7)
四肢痛	0	0	1 (10.0)	1 (6.7)
足底筋膜炎	0	1 (20.0)	0	1 (6.7)
リウマチ性多発筋痛	0	1 (20.0)	0	1 (6.7)
脊柱管狭窄症	0	0	1 (10.0)	1 (6.7)
神経系障害	2 (40.0)	0	3 (30.0)	3 (20.0)
頭痛	2 (40.0)	0	1 (10.0)	1 (6.7)
ヘルペス後神経痛	0	0	1 (10.0)	1 (6.7)
味覚障害	0	0	1 (10.0)	1 (6.7)
呼吸器、胸郭および縦隔障害	0	0	2 (20.0)	2 (13.3)
喘息	0	0	1 (10.0)	1 (6.7)
無気肺	0	0	1 (10.0)	1 (6.7)
皮膚および皮下組織障害	1 (20.0)	0	3 (30.0)	3 (20.0)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__1.4.1.1_J

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1, Japanese Population)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=5) n (%)	UPA 7.5 + 26 WK CS-T (N=5) n (%)	UPA 15 + 26 WK CS-T (N=10) n (%)	Total (N=15) n (%)
皮膚および皮下組織障害 (cont.)				
接触皮膚炎	1 (20.0)	0	1 (10.0)	1 (6.7)
皮膚乾燥	0	0	1 (10.0)	1 (6.7)
皮膚潰瘍	0	0	1 (10.0)	1 (6.7)
乾皮症	1 (20.0)	0	0	0
血管障害	2 (40.0)	2 (40.0)	2 (20.0)	4 (26.7)
巨細胞性動脈炎	2 (40.0)	2 (40.0)	1 (10.0)	3 (20.0)
高血圧	0	0	1 (10.0)	1 (6.7)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

表2 (J)

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ABT-494 (GIANT CELL ARTERITIS)
STUDY M16-852 (CUTOFF 06FEB2024)
R&D/23/2788 - CLINICAL/STATISTICAL

TABLE 14.3__1.4.3.1_J

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term
(SS_LT, Japanese Population)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=3) (PYS=4.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=3) (PYS=5.7) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=4) (PYS=8.3) Events (E/100PY)	UPA Total (N=7) (PYS=13.9) Events (E/100PY)
Any adverse event	11 (253.0)	13 (229.9)	46 (555.2)	59 (423.3)
心臓障害	0	0	2 (24.1)	2 (14.3)
心不全	0	0	2 (24.1)	2 (14.3)
眼障害	1 (23.0)	2 (35.4)	4 (48.3)	6 (43.0)
結膜出血	0	1 (17.7)	2 (24.1)	3 (21.5)
ドライアイ	1 (23.0)	1 (17.7)	2 (24.1)	3 (21.5)
胃腸障害	1 (23.0)	0	5 (60.4)	5 (35.9)
腹痛	0	0	2 (24.1)	2 (14.3)
虚血性大腸炎	0	0	1 (12.1)	1 (7.2)
悪心	0	0	1 (12.1)	1 (7.2)
口内炎	1 (23.0)	0	1 (12.1)	1 (7.2)
一般・全身障害および投与部位の状態	0	0	3 (36.2)	3 (21.5)
末梢性浮腫	0	0	2 (24.1)	2 (14.3)
発熱	0	0	1 (12.1)	1 (7.2)
肝胆道系障害	1 (23.0)	0	0	0
脂肪肝	1 (23.0)	0	0	0
感染症および寄生虫症	3 (69.0)	7 (123.8)	10 (120.7)	17 (122.0)
気管支炎	0	0	1 (12.1)	1 (7.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1_J

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term
(SS_LT, Japanese Population)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=3) (PYS=4.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=3) (PYS=5.7) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=4) (PYS=8.3) Events (E/100PY)	UPA Total (N=7) (PYS=13.9) Events (E/100PY)
感染症および寄生虫症 (cont.)				
COVID-19	1 (23.0)	0	0	0
膀胱炎	1 (23.0)	0	2 (24.1)	2 (14.3)
歯肉炎	0	0	2 (24.1)	2 (14.3)
帯状疱疹	0	1 (17.7)	1 (12.1)	2 (14.3)
潜伏結核	0	1 (17.7)	0	1 (7.2)
上咽頭炎	0	2 (35.4)	1 (12.1)	3 (21.5)
口腔カンジダ症	0	0	1 (12.1)	1 (7.2)
肺炎	0	0	2 (24.1)	2 (14.3)
RSウイルス感染	0	1 (17.7)	0	1 (7.2)
副鼻腔炎	0	1 (17.7)	0	1 (7.2)
上気道感染	1 (23.0)	0	0	0
尿路感染	0	1 (17.7)	0	1 (7.2)
傷害、中毒および処置合併症	1 (23.0)	1 (17.7)	1 (12.1)	2 (14.3)
挫傷	1 (23.0)	1 (17.7)	0	1 (7.2)
創傷	0	0	1 (12.1)	1 (7.2)
臨床検査	1 (23.0)	0	1 (12.1)	1 (7.2)
B型肝炎ウイルス検査陽性	0	0	1 (12.1)	1 (7.2)
腎機能検査異常	1 (23.0)	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1_J

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term
(SS_LT, Japanese Population)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=3) (PYS=4.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=3) (PYS=5.7) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=4) (PYS=8.3) Events (E/100PY)	UPA Total (N=7) (PYS=13.9) Events (E/100PY)
代謝および栄養障害	0	0	1 (12.1)	1 (7.2)
低カリウム血症	0	0	1 (12.1)	1 (7.2)
筋骨格系および結合組織障害	1 (23.0)	0	11 (132.8)	11 (78.9)
背部痛	0	0	2 (24.1)	2 (14.3)
筋痙縮	0	0	1 (12.1)	1 (7.2)
筋骨格痛	0	0	1 (12.1)	1 (7.2)
筋肉痛	0	0	1 (12.1)	1 (7.2)
頚部痛	0	0	1 (12.1)	1 (7.2)
骨粗鬆症	1 (23.0)	0	1 (12.1)	1 (7.2)
四肢痛	0	0	3 (36.2)	3 (21.5)
脊柱管狭窄症	0	0	1 (12.1)	1 (7.2)
神経系障害	1 (23.0)	1 (17.7)	3 (36.2)	4 (28.7)
頭痛	1 (23.0)	1 (17.7)	2 (24.1)	3 (21.5)
ヘルペス後神経痛	0	0	1 (12.1)	1 (7.2)
精神障害	0	1 (17.7)	0	1 (7.2)
不安	0	1 (17.7)	0	1 (7.2)
呼吸器、胸郭および縦隔障害	0	0	2 (24.1)	2 (14.3)
喘息	0	0	1 (12.1)	1 (7.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

TABLE 14.3__1.4.3.1_J

Treatment-Emergent Adverse Events per 100 Patient-years (PYS) by System Organ Class and Preferred Term - Long-Term
(SS_LT, Japanese Population)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=3) (PYS=4.3) Events (E/100PY)	UPA 7.5 + 26 WK CS-T (N=3) (PYS=5.7) Events (E/100PY)	UPA 15 + 26 WK CS-T (N=4) (PYS=8.3) Events (E/100PY)	UPA Total (N=7) (PYS=13.9) Events (E/100PY)
呼吸器、胸郭および縦隔障害 (cont.)				
肺塞栓症	0	0	1 (12.1)	1 (7.2)
皮膚および皮下組織障害	0	0	3 (36.2)	3 (21.5)
皮膚嚢腫	0	0	1 (12.1)	1 (7.2)
皮膚炎	0	0	1 (12.1)	1 (7.2)
皮膚潰瘍	0	0	1 (12.1)	1 (7.2)
血管障害	1 (23.0)	1 (17.7)	0	1 (7.2)
巨細胞性動脈炎	1 (23.0)	1 (17.7)	0	1 (7.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening in severity date after initiation of study drug and no more than 30 days after the last dose of study drug in the study.
E/100PY = Events per 100 patient-years.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper / Placebo; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 7.5 mg; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper / Upadacitinib 15 mg.

Program Source Code: [redacted]

表3 (J)

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ABT-494 (GIANT CELL ARTERITIS)
STUDY M16-852 (CUTOFF 06FEB2024)
R&D/23/2788 - CLINICAL/STATISTICAL

TABLE 14.3__2.1.1_J

Subjects with Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term in Period 1
(SS1, Japanese Population)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=5) n (%)	UPA 7.5 + 26 WK CS-T (N=5) n (%)	UPA 15 + 26 WK CS-T (N=10) n (%)	Total (N=15) n (%)
Any adverse event	0	0	3 (30.0)	3 (20.0)
眼障害	0	0	1 (10.0)	1 (6.7)
緑内障	0	0	1 (10.0)	1 (6.7)
胃腸障害	0	0	1 (10.0)	1 (6.7)
虚血性大腸炎	0	0	1 (10.0)	1 (6.7)
感染症および寄生虫症	0	0	1 (10.0)	1 (6.7)
膀胱炎	0	0	1 (10.0)	1 (6.7)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]

TABLE 14.3__2.2.1_J

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by System Organ Class and Preferred Term in Period 1
(SS1, Japanese Population)

MedDRA 26.1 System Organ Class Preferred Term	PBO + 52 WK CS-T (N=5) n (%)	UPA 7.5 + 26 WK CS-T (N=5) n (%)	UPA 15 + 26 WK CS-T (N=10) n (%)	Total (N=15) n (%)
Any adverse event	0	1 (20.0)	0	1 (6.7)
筋骨格系および結合組織障害	0	1 (20.0)	0	1 (6.7)
リウマチ性多発筋痛	0	1 (20.0)	0	1 (6.7)

Note: Treatment-emergent adverse events in Period 1 are defined as any adverse events with an onset or worsening in severity date on or after the first dose date of study drug and prior to the first dose of study drug in Period 2 or no more than 30 days after the last dose of study drug in Period 1, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.
PBO + 52 WK CS-T = Placebo + 52 Weeks Corticosteroid Taper; UPA 7.5 + 26 WK CS-T = Upadacitinib 7.5 mg + 26 Weeks Corticosteroid Taper; UPA 15 + 26 WK CS-T = Upadacitinib 15 mg + 26 Weeks Corticosteroid Taper.

Program Source Code: [redacted]