2.7.2 臨床薬理試験

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略語又は用語	省略していない表現又は説明（英語）	省略していない表現又は説明（日本語）
AD	atopic dermatitis	アトピー性皮膚炎
AUC_{24}	steady state area under the plasma concentration time curve from time zero to 24 hours after dosing	投与後 0 時間から 24 時間までの定常状態における血漿中濃度 時間曲線下面積
C_{avg}	average plasma concentration over a dosing interval	投与間隔中の平均血漿中濃度
CD	Crohn's disease	クローン病
CI	confidence interval	信頼区間
C_{max}	maximum plasma concentration	最高血漿中濃度
C_{min}	concentration at the end of the dosing interval	投与間隔の終点における濃度
CS	corticosteroid	コルチコステロイド
CYP	cytochrome P450	チトクロム P450
GCA	giant cell arteritis	巨細胞性動脈炎
IFNγ	interferon gamma	インターフェロンγ
IL	interleukin	インターロイキン
JAK	Janus kinase	ヤヌスキナーゼ
OATP	organic anion transporting polypeptide	有機アニオン輸送ポリペプチド
PsA	psoriatic arthritis	乾癬性関節炎
QD	quaque die	1 日 1 回投与
RA	rheumatoid arthritis	関節リウマチ
UC	ulcerative colitis	潰瘍性大腸炎

2.7.2.1 背景及び概観

ウパダシチニブは選択的かつ可逆的なヤヌスキナーゼ（以下「JAK」）阻害剤である。ウパダシチニブは JAK2 及び JAK3 と比較して JAK1 を強力に阻害する。JAK1 の阻害により，インターロイキン（以下「IL」）-2，IL-6，IL-7，IL-15，インターフェロン γ（以下「IFNγ」）などの多くの重要な炎症性サイトカインのシグナル伝達が阻害される。ウパダシチニブは，これらの炎症性サイトカイン経路の調節を介して，免疫介在性炎症状態を効果的に治療する可能性があり，巨細胞性動脈炎（以下「GCA」）の病因に関与する複数の経路（IL-6，IFNγ）を標的とする可能性を有している。

ウパダシチニブは，関節リウマチ（以下「RA」），乾癬性関節炎（以下「PsA」），強直性脊椎炎，X 線基準を満たさない体軸性脊椎関節炎，潰瘍性大腸炎（以下「UC」）及びクローン病（以下「CD」），並びに成人及び青少年のアトピー性皮膚炎（以下「AD」）を適応症として承認されている。更に，高安動脈炎，化膿性汗腺炎，非分節型尋常性白斑，円形脱毛症，全身性エリテマトーデス，多関節型若年性特発性関節炎，全身型若年性特発性関節炎，小児 AD，小児 CD 及び小児 UC に対しても開発中である。

本承認申請におけるウパダシチニブの用法・用量（案）は，ウパダシチニブとして 15 mg を 1 日 1 回（以下「QD」）経口投与である。

ウパダシチニブを単回及び反復投与したときの薬物動態，吸収，分布，代謝及び排泄，薬物相互作用及び特別な患者集団における薬物動態の評価を目的とした第 I 相試験の結果は，RA の承認申請時に提出している。第 III 相試験で用いた製剤と市販製剤は，PsA 及び AD の承認申請時に提出した M20-017 試験の成績より，生物学的に同等な製剤であることが確認されている。

GCA に対するウパダシチニブの臨床開発では，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る M16-852 試験を実施した。M16-852 試験では，52 週間のランダム化，二重盲検，並行群間投与期間（第 1 ピリオド）において 50 歳以上の GCA 成人患者を対象に 7.5 mg 及び 15 mg の 2 用量でウパダシチニブの有効性及び安全性を評価した。更に M16-852 試験は，被験者が再ランダム化された又は当初割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ている。

本試験の用量である 15 mg QD は，RA 患者を対象とした第 II 相試験の曝露-反応関係の結果，RA 患者を対象とした第 III 相試験の試験成績，並びに IL-6 阻害剤トシリズマブの GCA 患者を対象とした第 II 相試験及び第 III 相試験の公表結果に基づき選択した。また 7.5 mg QD レジメンを選択して，GCA におけるウパダシチニブの最小有効用量の特徴を検討した。

2.7.2.2 個々の試験結果の要約

本申請において，新たな第 I 相臨床薬理試験は実施しなかった。

2.7.2.3 全試験を通しての結果の比較と解析

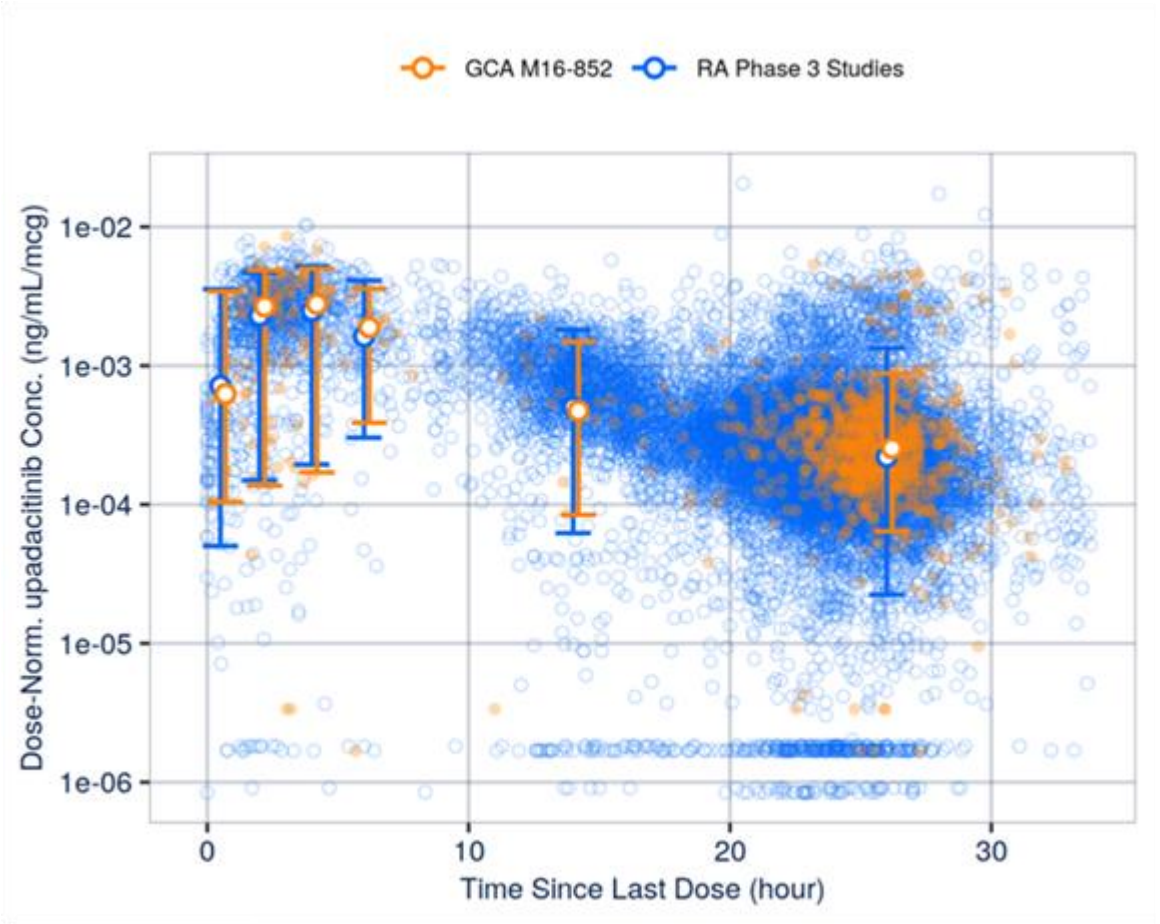
第 III 相試験（M16-852 試験）のデータを用いた母集団薬物動態解析（R&D/24/0051）により，GCA 患者におけるウパダシチニブの薬物動態を評価した。GCA 患者におけるウパダシチニブの薬物動態の要約及び GCA 患者と RA 患者におけるウパダシチニブの薬物動態の比較は 2.7.2.3.1 項に示す。また，第 III 相試験（M16-852 試験）のデータを用いて，GCA 患者におけるウパダシチニブ血漿中曝露量と有効性及び安全性との関係を評価した（R&D/24/0051）。GCA 患者における有効性及び安全性に関するウパダシチニブの曝露-反応関係の要約は 2.7.2.5 項に示す。

2.7.2.3.1 GCA 患者におけるウパダシチニブの母集団薬物動態

健康被験者及び RA 患者のデータを用いて先に構築したウパダシチニブの母集団薬物動態モデル（R&D/18/0165：RA の承認申請時に提出）に基づき，GCA 患者を対象とした第 III 相試験のデータセットを用いて，ウパダシチニブの薬物動態及び共変量の影響を評価した（R&D/24/0051）。

ウパダシチニブの濃度-時間プロファイルは RA 患者集団と GCA 患者集団で顕著な重複が認められており，GCA 患者におけるウパダシチニブの薬物動態を記述するために先に構築した薬物動態モデルを使用することの妥当性が支持された。

図 2.7.2-1. GCA 患者（M16-852 試験）及び RA 患者（第 III 相試験）におけるウパダシチニブ濃度（用量標準化）



Orange circles represent observed dose normalized upadacitinib concentrations from GCA subjects. Blue circles represent observed dose normalized upadacitinib concentrations from RA subjects from Phase 3 studies included in the previous model (R&D/18/0165). Framed circles with error bars represent the median and 5th to 95th percentiles for the binned (0.5, 2, 4, 6, 14, and 26 hours since last dose) observed data in RA, or GCA subjects.

Cross reference: R&D/24/0051 Figure 1

M16-852 試験の被験者におけるウパダシチニブの薬物動態は，徐放製剤としてのラグ時間を有する 0 次及び 1 次混合吸収を伴う 2-コンパートメントモデルにより適切に記述された（R&D/24/0051）。最終モデルのパラメータ推定値を表 2.7.2-1 に示す。

表 2.7.2-1. GCA 患者におけるウパダシチニブ薬物動態のパラメータ推定値

Parameter	Population Estimate	%RSE	95% Confidence Interval
CL/F (L/h)	40.9		
Vc/F (L/h)	156		
Extended Release KA (1/h)	0.0523		
Extended Release Absorption Lag Time (h)	0.154		
Fraction of Extended Release Dose Absorbed through Zero Order Process	0.745		
Zero Order Absorption Duration (h)	3.29		
Immediate Release KA (1/h)	2.77		
Immediate Release Absorption Lag Time (h)	0.200		
Bioavailability of the Extended Release Formulation Relative to the Immediate Release Formulation	0.762		
Q/F (L/h)	3.22		
Vp/F (L)	68.0		
CL/F Ratio of GCA Subjects Compared to Healthy Subjects	0.754		
Covariate Exponent of Creatinine Clearance on CL/F	0.256		
Covariate Exponent of Weight on Vc/F	0.804		
Covariate Exponent of Weight on CL/F	0.132		
Additive Error	0.00736		
Proportional Error in Phase 2/3	0.295		

Parameter	Population Estimate	%CV	%Shrinkage
IIV on Extended Release KA	0.446	75.0	62.6
IIV on CL/F in Phase 2/3	0.133	37.7	33.6
IIV on Vc/F in Phase 2/3	0.281	57.0	60.2

% RSE % relative standard error; % IIV % inter individual variability; Q/F apparent inter compartmental clearance; V_p/F apparent peripheral volume; CL/F apparent oral clearance; Vc/F apparent volume of distribution of central compartment; KA absorption rate constant; Q/F apparent intercompartmental clearances; Vp/F apparent peripheral volume of distribution; %CV coefficient of variation

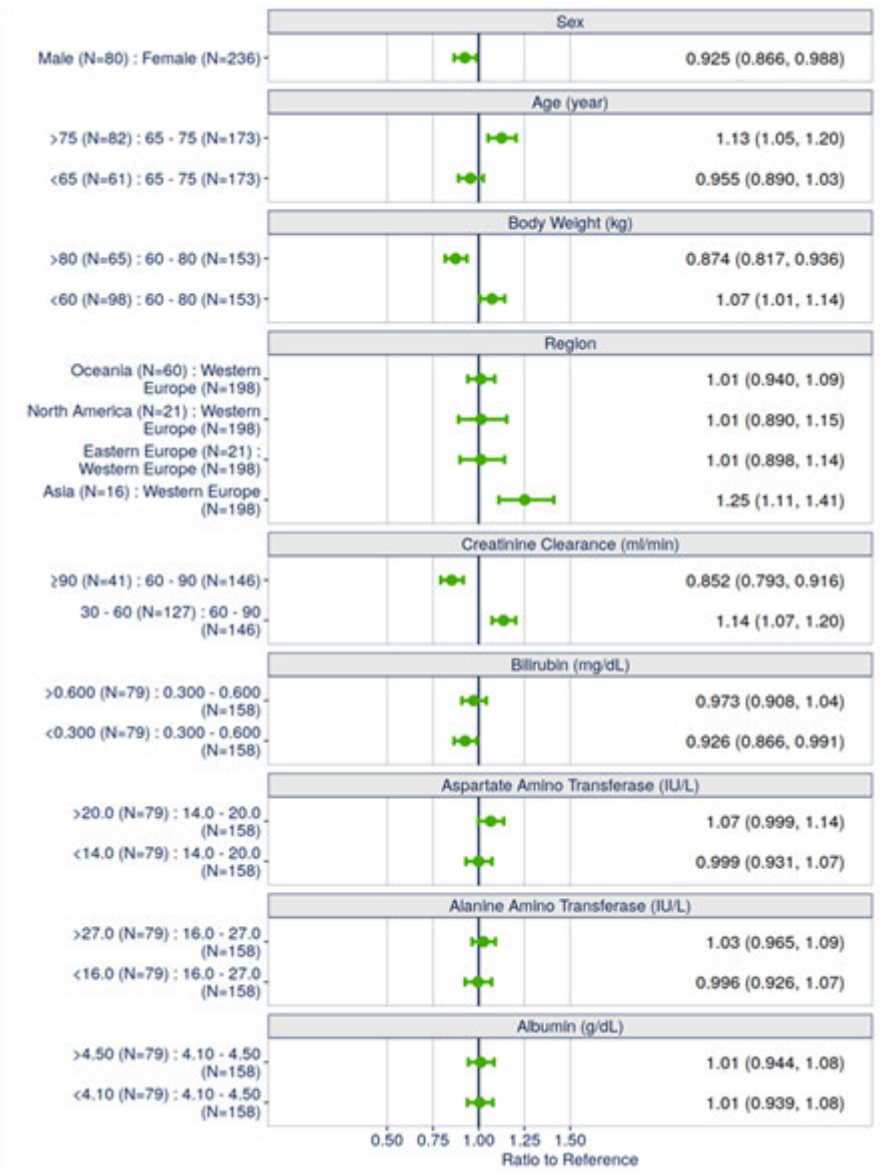
%RSE was calculated as the standard error of the estimate divided by the absolute value of the mean of the estimate multiplied by 100. %CV was calculated as SQRT(exp(ω^2) 1)*100). %Shrinkage was calculated as 100*(1SD(ETA)/SQRT(ω)), with non influential ETAs removed.

Cross reference: R&D/24/0051 Table 4

注目すべき共変量に関して，用量で標準化した定常状態時のウパダシチニブ C_{avg} のモデル推定値に対する共変量の影響を，人口統計学及び疾患に関連した共変量に分けてそれぞれ図 2.7.2-

2 及び図 2.7.2-3 に示す。用量で標準化したウパダシチニブ C_{avg} に対するこれらの共変量の影響は，参照群と比較して，いずれも 25%以下であった。

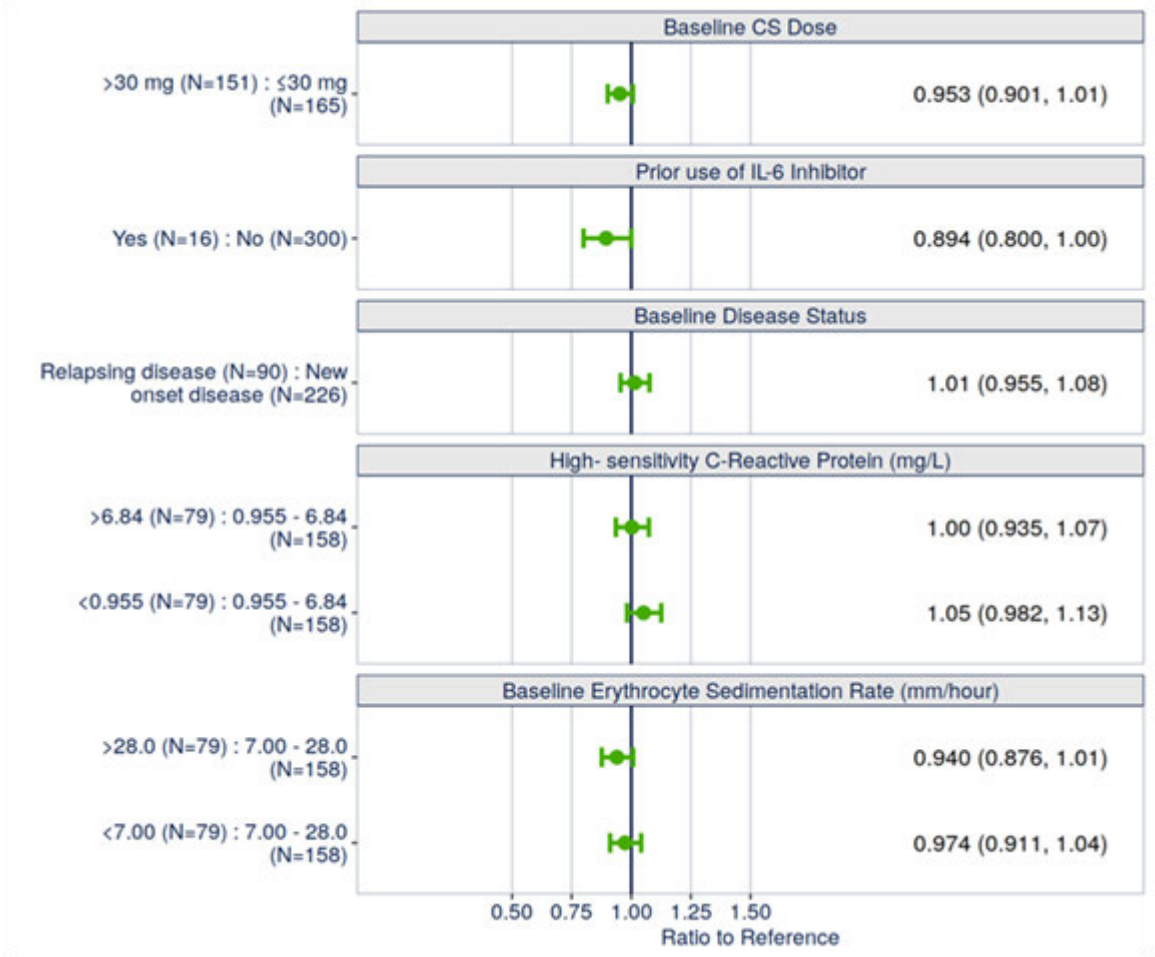
図 2.7.2-2. モデルから推定された GCA 患者におけるウパダシチニブ C_{avg} に対する共変量の影響（人口統計学関連）



Dots and error bars represent geometric mean ratio and its 95% CI of model predicted dose normalized C_{avg} relative to reference groups. The vertical black line shows the exposure ratio of 1 relative to the reference group. Female subjects, age 65 75 years, body weight 60 80 kg, Western Europe, creatinine clearance 60 90 mL/min, subjects within the 25th to 75th range of bilirubin, AST, ALT and albumin were chosen as reference covariate categories.

Cross reference: R&D/24/0051 Figure 4

図 2.7.2-3. モデルから推定された GCA 患者におけるウパダシチニブ C_{avg} に対する共変量の影響（疾患関連）



Dots and error bars represent geometric mean ration and its 95% CI of model predicted dose normalized C_{avg} relative to reference groups. The vertical black line shows the exposure ratio of 1 relative to the reference group. Corticosteroid dose ≤ 30 mg, subjects with no IL 6 inhibitor, new onset disease, subjects within the 25th to 75th range of hsCRP and ESR were chosen as reference covariate categories.

Cross reference: R&D/24/0051 Figure 5

第 III 相試験におけるモデルから推定されたウパダシチニブ血漿中曝露量は，GCA 患者及び RA 患者の両集団で類似していた（表 2.7.2-2）。

表 2.7.2-2. モデルから推定された GCA 患者又は RA 患者における定常状態でのウパダシチニブ血漿中曝露量（C_{avg}，C_{max} 及び C_{min}）

Population	Dose (mg)	Median (5th, 95th Percentile)		
		C_{avg} (ng/mL)	C_{max} (ng/mL)	C_{min} (ng/mL)
GCA	7.5	7.85 (5.54, 11.7)	22.8 (16.5, 30.3)	1.88 (0.909, 4.85)
GCA	15	15.7 (10.9, 25.5)	45.3 (36.2, 56.8)	3.87 (1.56, 10.6)
RA	15	15.1 (9.0, 32.7)	41.1 (28.2, 56.0)	3.82 (1.28, 21.3)

C_{min} concentration at the end of the dosing interval; C_{max} maximum plasma concentration
Cross reference: R&D/24/0051 Table 5; RA data from R&D/18/0165 Table 10 (previously submitted with RA dossier).
Note: C_{min} is referred to as C_{trough} in R&D/18/0165

2.7.2.4 ウパダシチニブの薬物動態に対する内因性要因及び外因性要因の影響

2.7.2.4.1 被験者集団の影響

2.7.2.3.1 項で述べたように，GCA 患者及び RA 患者で用量補正したウパダシチニブ濃度の実測値には顕著な重複が認められた（図 2.7.2-1）。RA 患者の最終母集団薬物動態モデルは，GCA 患者の薬物動態を十分特徴づけており，2 つの集団における薬物動態が類似していることが確認された（表 2.7.2-2）。

2.7.2.4.2 患者背景及び臓器障害の影響

体重，年齢，人種，性別，肝機能障害及び腎機能障害の影響に関する評価は RA 申請時に提出済みである。GCA 患者を対象とした母集団薬物動態解析のモデル推定より（2.7.2.3.1 項），これらの因子を有する被験者における用量で標準化したウパダシチニブ C_{avg} の変化量は 25%以下であった。

また，母集団薬物動態解析から推定された定常状態におけるウパダシチニブ曝露量（C_{avg}，AUC_{24}，C_{min} 及び C_{max}）は，日本人被験者と非日本人被験者で同程度であった（表 2.7.2-3）。

表 2.7.2-3. モデルから推定された GCA 患者における定常状態でのウパダシチニブ血漿中曝露量（日本人と非日本人で層別：M16-852 試験）

Treatment	Country	Number of Subjects	C_{avg} (ng/mL) Median (5th to 95th Percentile)	AUC_{24} (ng/mL*h) Median (5th to 95th Percentile)	C_{min} (ng/mL) Median (5th to 95th Percentile)	C_{max} (ng/mL) Median (5th to 95th Percentile)
7.5 mg QD	Japanese	5	10.9 (7.81, 13.5)	262 (187, 324)	2.57 (1.74, 5.07)	29.8 (23.4, 34.9)
7.5 mg QD	Non Japanese	94	7.71 (5.51, 11.2)	185 (132, 269)	1.87 (0.897, 4.45)	22.6 (16.5, 29.5)
15 mg QD	Japanese	10	20.1 (14.8, 25.7)	481 (354, 617)	5.49 (2.97, 9.50)	55.8 (44.6, 60.4)
15 mg QD	Non Japanese	183	15.6 (10.9, 24.1)	374 (262, 578)	3.80 (1.56, 11.2)	44.6 (36.2, 54.1)

Cross reference: R&D/24/0051 Table 6

2.7.2.4.3 ウパダシチニブの薬物動態に対する併用薬の影響

併用薬の影響に関する評価は RA 申請時に提出済みである。ウパダシチニブは，CYP3A に対しての感受性は高くない基質（non-sensitive substrate）である。ウパダシチニブの C_{max} 及び AUC は，強い CYP3A 阻害薬との併用によってそれぞれ約 70%及び 75%上昇し，強い CYP3A 誘導薬との併用によっていずれも約 50%低下することが示されている。また，強い CYP2D6 阻害薬，OATP1B 阻害薬，メトトレキサート，pH 調整剤，スタチン系薬剤については，これらの薬剤との併用はウパダシチニブ曝露量に影響を及ぼさないことが示されている。

今回，GCA 患者を対象とした母集団薬物動態解析より，ベースラインにおける副腎皮質ステロイドの用量はウパダシチニブの薬物動態に影響を及ぼさないことが示された（図 2.7.2-3）。

2.7.2.4.4 食事の影響

食事の影響に関する評価は RA 申請時に提出済みである。GCA 患者を対象とした M16-852 試験では，食事の有無にかかわらずウパダシチニブを投与した。ウパダシチニブ市販用製剤は，高脂肪食摂取時にウパダシチニブ AUC が 29%，C_{max} が 39%増加したが，GCA 患者における安全性曝露-反応解析より（2.7.2.5.2 項），これらの増加に臨床的な意味はないと考えられた。

2.7.2.4.5 ウパダシチニブが併用薬の薬物動態に及ぼす影響

併用薬に及ぼすウパダシチニブの影響に関する評価は RA 申請時に提出済みである。臨床薬物相互作用試験及び生理学的薬物速度論モデルによる評価より，ウパダシチニブは，メトトレキサート，経口避妊薬（エチニルエストラジオール，レボノルゲストレル），スタチン系薬剤

（ロスバスタチン，アトルバスタチン）並びに CYP1A2，CYP2B6，CYP2C9，CYP2C19，CYP2D6，CYP3A で代謝される薬物の曝露量に臨床的に意味のある影響を及ぼさないことが示されている。したがって，ウパダシチニブとの併用において，これらの薬剤に対する用量調節は必要ないと考えられた。

2.7.2.5 GCA 患者における曝露-反応解析及び 15 mg QD の申請用量の妥当性

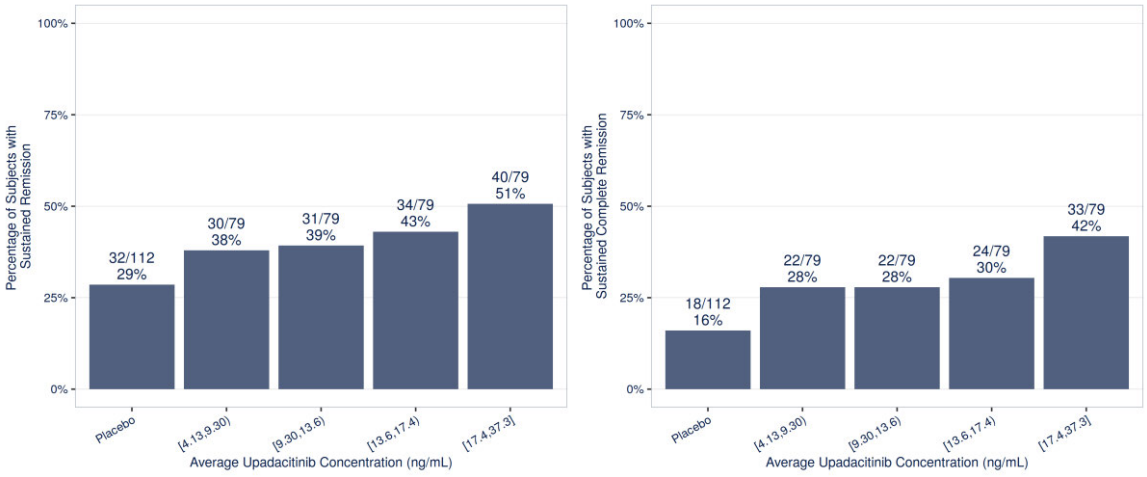
2.7.2.5.1 GCA 患者における有効性の曝露-反応解析（M16-852 試験）

曝露-反応解析により，GCA 患者におけるウパダシチニブ血漿中曝露量と有効性との関係を検討した（R&D/24/0051）。評価項目は，投与 52 週時の寛解維持，投与 52 週時の完全寛解維持，及び投与 52 週時までのコルチコステロイド（以下「CS」）累積曝露量とした。

<u>投与 52 週時の寛解維持及び完全寛解維持</u>

四分位プロットを用いてウパダシチニブ曝露量（C_{avg}）と有効性評価項目である寛解維持又は完全寛解維持を達成した被験者の割合との関係を検討した（図 2.7.2-4）。寛解維持及び完全寛解維持を達成した被験者の割合はウパダシチニブ血漿中曝露量の上昇に伴い増加し，ウパダシチニブ曝露量の最も高い四分位で最も高い割合が達成された。

図 2.7.2-4. ウパダシチニブ C_{avg} に対する寛解維持（左図）及び完全寛解維持（右図）の四分位プロット

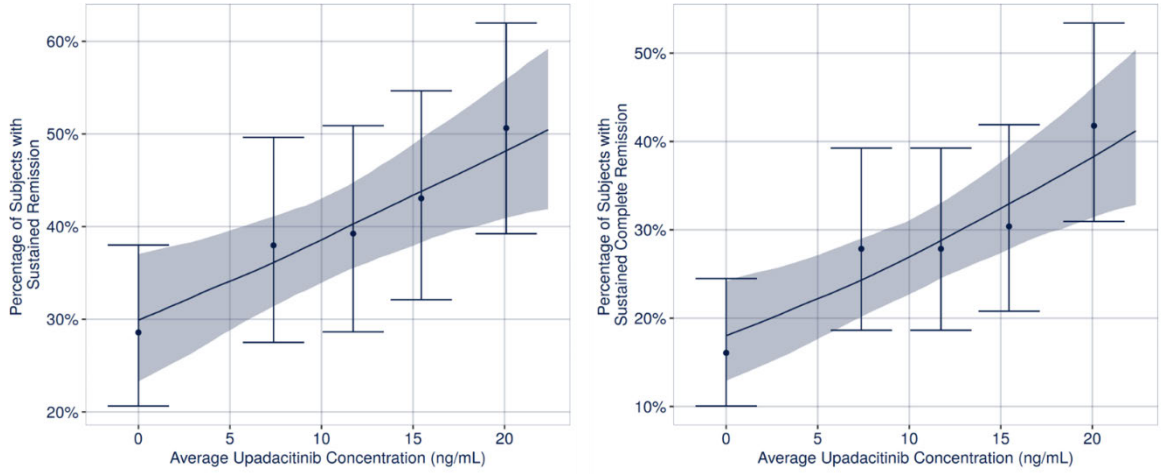


Cross reference: R&D/24/0051 Figure 6; Figure 9

寛解維持及び完全寛解維持の両評価項目の曝露-反応関係は線形モデルで最も良好に記述され，ウパダシチニブ C_{avg} と両有効性評価項目との間に有意な関連が認められた。評価した層別因子又は共変量はいずれも有意ではなかった。

曝露-反応モデルに基づくシミュレーションから，ウパダシチニブ 15 mg QD 投与時の投与 52 週時に寛解維持及び完全寛解維持を達成する被験者の割合は，7.5 mg QD 投与時と比較してそれぞれ 9%及び 10%高いと予測された。

図 2.7.2-5. GCA 患者における寛解維持（左図）及び完全寛解維持（右図）を達成した被験者の割合の実測値及びモデル予測値



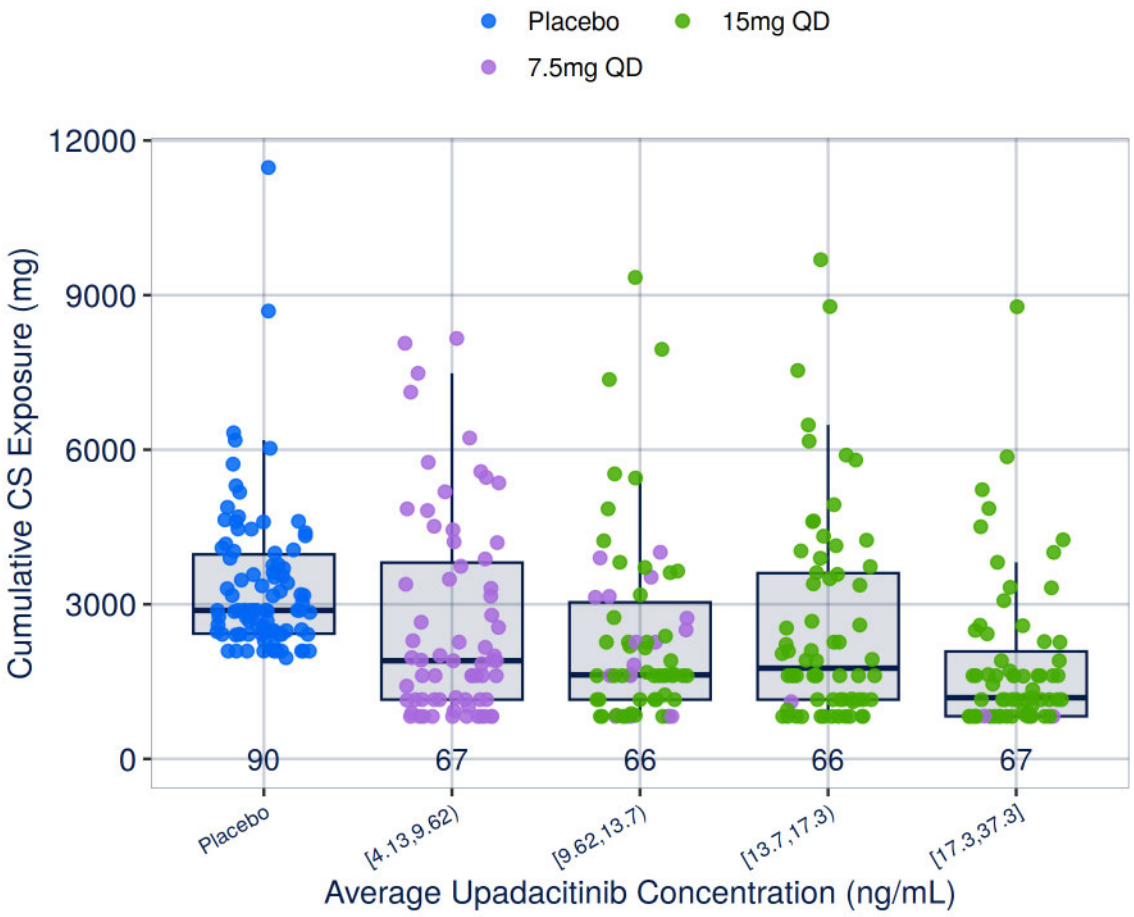
The solid lines represent median predicted response and the shaded areas represent 95% CIs of the response. The dots and error bars represent median and 95% binomial CIs of binned observed responses.

Cross reference: R&D/24/0051 Figure 7; Figure 10

投与 52 週時までの CS 累積曝露量

四分位プロットを用いてウパダシチニブ血漿中曝露量と CS 累積曝露量との関係を検討した（図 2.7.2-6）。また，ウパダシチニブ C_{avg} と CS 累積曝露量との間でガウス回帰モデル構築を検討した。曝露-反応関係を最もよく表しているのは，曝露-反応関係がないことを仮定した治療効果モデルであった（図 2.7.2-7）。CS 累積曝露量は，プラセボ被験者と比較してウパダシチニブ被験者で明らかな差が認められたが，ウパダシチニブ C_{avg} の上昇に伴う明らかな傾向は認められなかった。

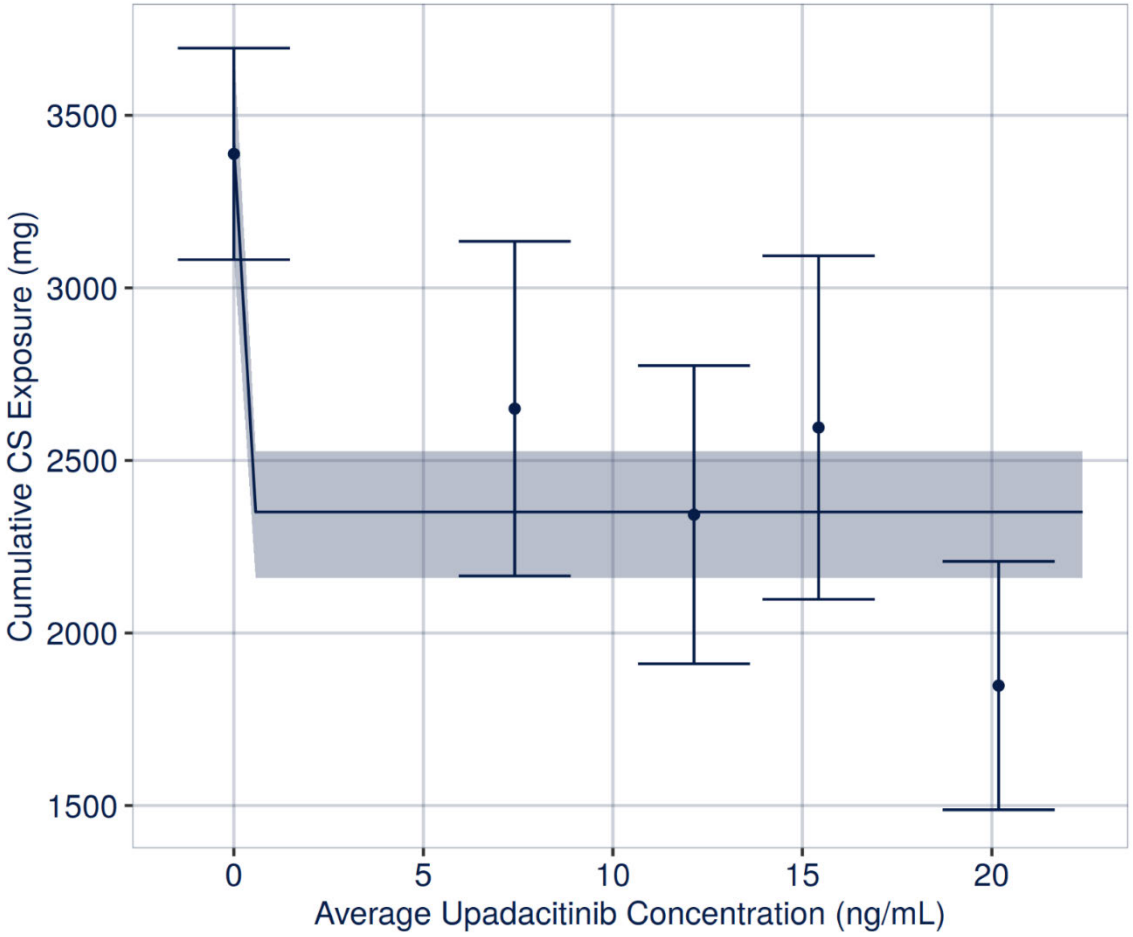
図 2.7.2-6. CS 累積曝露量とウパダシチニブ C_{avg} の四分位プロット



Boxes show median, 25th to 75th percentiles Inter Quartile Range (IQR) and whiskers represent 1.5fold IQR of cumulative CS exposure per C_{avg} quartile. The number of subjects per C_{avg} quartile is additionally printed on the bottom of the figure.

Cross reference: R&D/24/0051 Figure 12

図 2.7.2-7. 曝露-反応解析：CS 累積曝露量の実測値及びモデル予測値



The solid lines represent median predicted response and the shaded areas represent 95% Cis of the response. The circles and error bars represent median and 95% CIs of binned observed responses.

Cross reference: R&D/24/0051 Figure 13

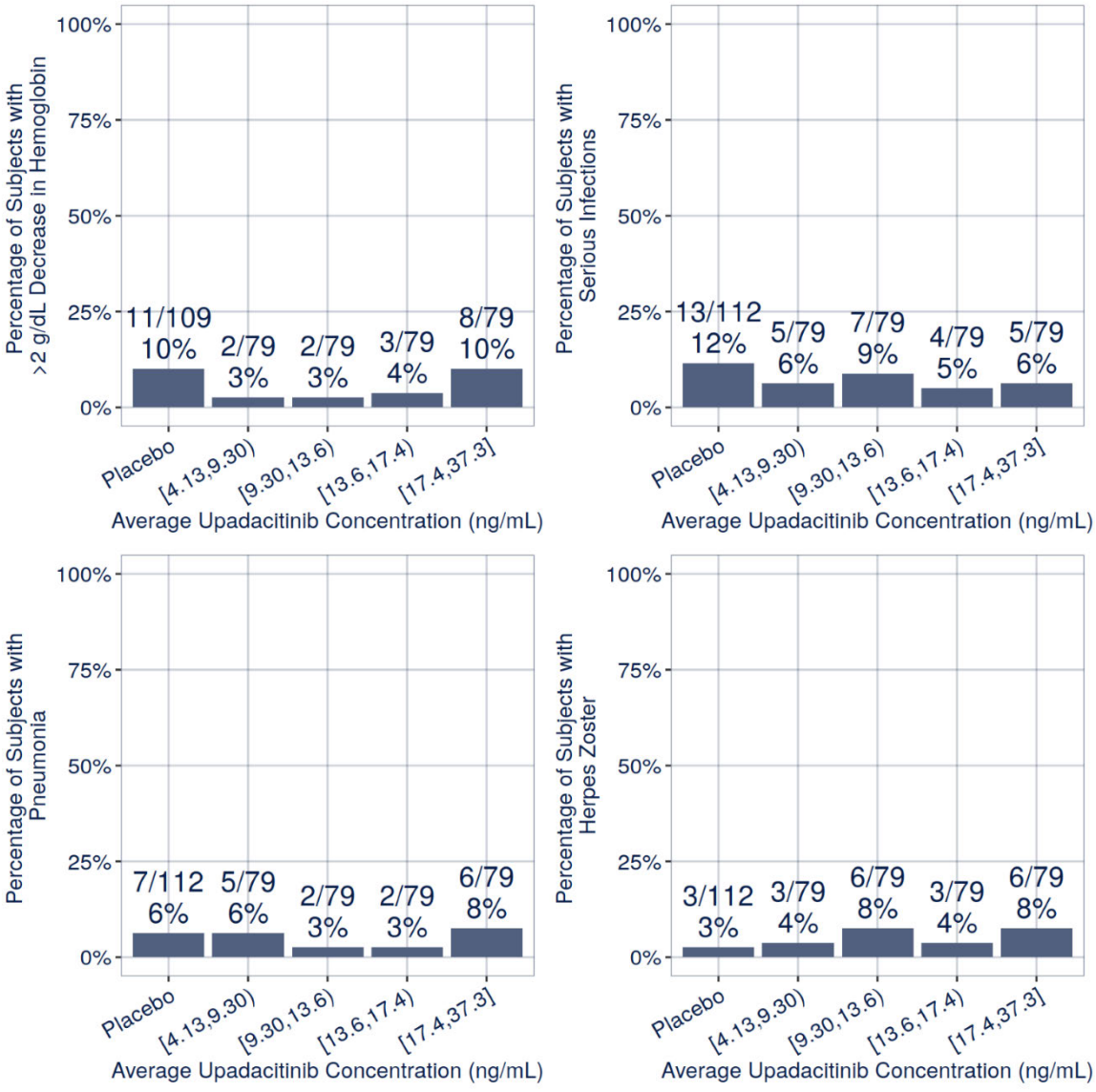
2.7.2.5.2 GCA 患者における安全性の曝露-反応解析（M16-852 試験）

曝露-反応解析により，GCA 患者におけるウパダシチニブ血漿中曝露量と安全性との関係を検討した（R&D/24/0051）。安全性に関する曝露-反応解析では，投与 52 週時の貧血（Grade 3 以上），好中球減少症（Grade 3 以上），リンパ球減少症（Grade 3 以上），ヘモグロビンのベースラインから 2 g/dL を超える減少，投与 52 週時までの重篤な感染症，肺炎及び帯状疱疹を評価した。

M16-852 試験の第 1 ピリオドでは，貧血（Grade 3 以上），好中球減少症（Grade 3 以上）及びリンパ球減少症（Grade 3 以上）の発現件数が少なく（10 件以下），曝露-反応傾向は認められ

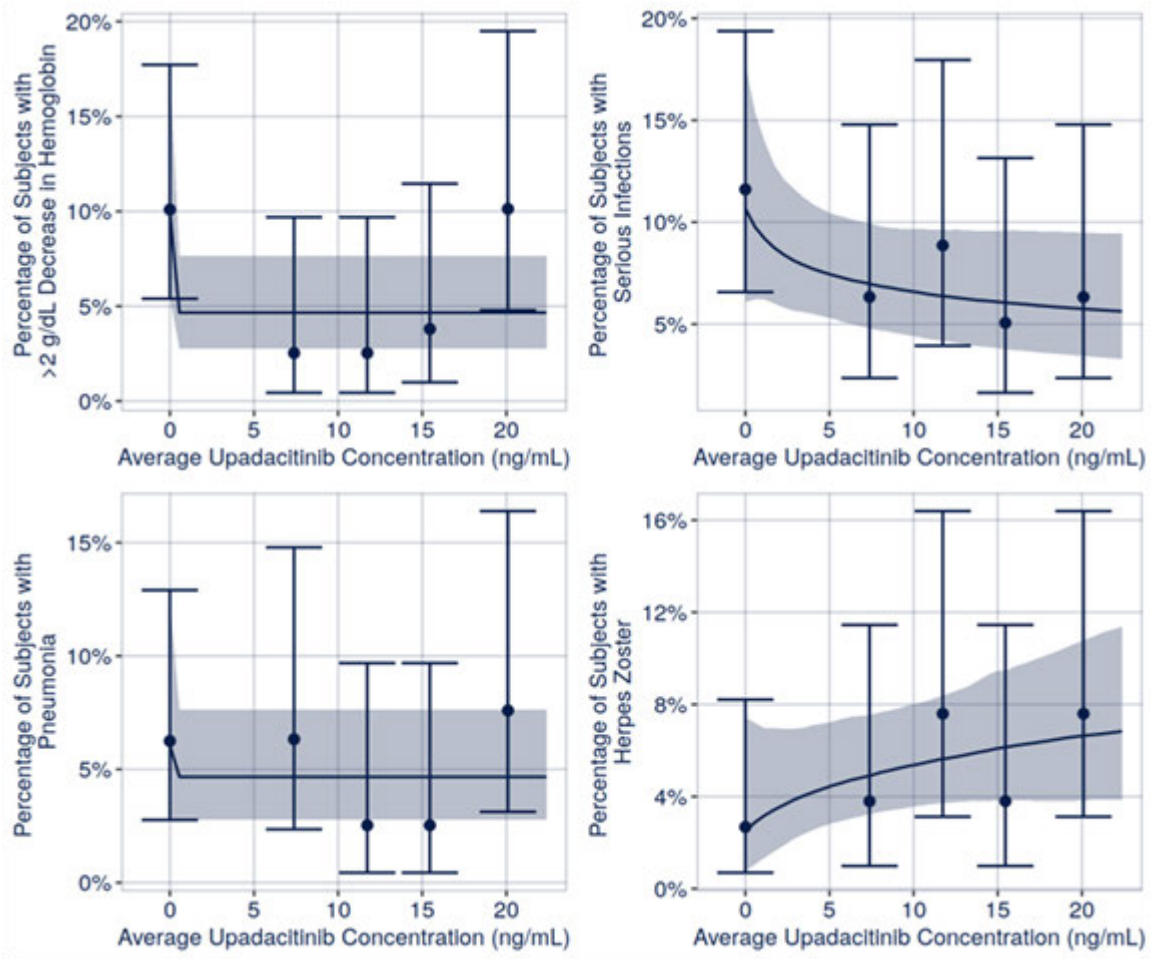
なかった。また，ヘモグロビンのベースラインからの 2 g/dL を超える減少，重篤な感染症及び肺炎についても，明らかな曝露-反応傾向は認められなかった。帯状疱疹を発現した被験者は，ウパダシチニブ C_{avg} 上昇に伴う緩やかな増加傾向が認められたが，統計学的に有意ではなかった。曝露-反応モデルによるシミュレーションに基づくと，曝露量が 75%上昇すると，15 mg QD レジメンで帯状疱疹を発現する被験者の割合は 1.25%増加すると予測された。

図 2.7.2-8. GCA 患者におけるウパダシチニブ C_{avg} と 10 件を超えるイベントが発現した安全性評価項目との関係の四分位プロット



Cross reference: R&D/24/0051 Figure 15

図 2.7.2-9. 曝露-反応解析：安全性評価項目に関する実測値とモデル予測値



The solid lines represent median predicted response and the shaded areas represent 95% CIs of the response. The dots and error bars represent median and 95% binomial CIs of binned observed responses.

Cross reference: R&D/24/0051 Figure 16

2.7.2.5.3 GCA 患者を対象とした第 III 相試験の曝露-反応解析の要約及び申請用量の妥当性

有効性に関する曝露-反応解析より，投与 52 週時の寛解維持及び完全寛解維持を達成した被験者の割合はウパダシチニブ血漿中曝露量の上昇に伴い増加した。曝露-反応モデル（線形モデル）に基づくシミュレーションから，ウパダシチニブ 15 mg QD 投与時の投与 52 週時に寛解維持及び完全寛解維持を達成する被験者の割合は，7.5 mg QD 投与時と比較してそれぞれ 9%及び 10%高いと予測された。CS 累積曝露量は，プラセボ被験者と比較してウパダシチニブ被験者で明らかな差が認められたが，ウパダシチニブ C_{avg} の上昇に伴う明らかな傾向は認められなかった。

ヘモグロビンのベースラインからの 2 g/dL を超える減少，重篤な感染症及び肺炎に関しては，明らかな曝露-反応傾向は認められなかった。帯状疱疹を発現した被験者は，ウパダシチニブ C_{avg}増加に伴う緩やかな上昇傾向が認められたが，統計学的に有意ではなかった。

以上の解析結果は，GCA 患者に対してウパダシチニブ 15 mg QD を用法・用量とすることを支持していると考えられた。

2.7.2.5.4 特別な患者集団及び併用投与における用法・用量の妥当性

GCA 患者における薬物動態は，先に評価済みの RA 患者における薬物動態と類似していた。GCA 患者における安全性の曝露-反応解析では，評価した安全性事象を発現した被験者の割合に明らかな増加傾向は認められず，ウパダシチニブ曝露量と帯状疱疹との間に緩やかな傾向が認められたのみであった。したがって，既承認の RA 患者での特別な患者集団及び併用投与における用法・用量は GCA 患者に対しても適用されると考えられた。

ウパダシチニブは食事の有無にかかわらず投与することが可能である。腎機能障害，軽度又は中等度の肝機能障害，併用薬，年齢，体重，性別，人種に基づく用量調節は，GCA の治療においても必要ないと考えられる。重度肝機能障害を有する被験者を対象としたウパダシチニブの試験は実施していない。強い CYP3A 誘導薬（リファンピシン等）との併用については，ウパダシチニブ曝露量が減少することが報告されており（M13-540 試験：RA 申請時に提出済み），治療効果を減弱させる可能性がある。また，長期にわたって強い CYP3A 阻害薬（ケトコナゾール等）を併用する場合には，注意が必要である（M13-401 試験：RA 申請時に提出済み）。

2.7.2.6 特別な試験

該当なし

2.7.2.7 付録

該当なし

2.7.3 臨床的有効性

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略語及び定義一覧

略語又は用語	省略していない表現又は説明（英語）	省略していない表現又は説明（日本語）
BMI	body mass index	体容量指数
CI	confidence interval	信頼区間
CRP	C reactive protein	C 反応性タンパク
CS	corticosteroid	副腎皮質ステロイド
CSR	clinical study report	治験総括報告書
ePRO	electronic patient reported outcome	電子的患者報告アウトカム
ESR	erythrocyte sedimentation rate	赤血球沈降速度
FACIT Fatigue	functional assessment of chronic illness therapy fatigue	
FAS	Full Analysis Set	最大の解析対象集団
FAS1	FAS in Period 1	第 1 ピリオドの最大の解析対象集団
FDA	Food and Drug Administration	米国食品医薬品局
GCA	giant cell arteritis	巨細胞性動脈炎
hsCRP	high sensitivity C reactive protein	高感度 C 反応性タンパク
IL (x)	interleukin (x)	インターロイキン（ x）
IRT	Interactive Response Technology	自動応答技術
JA	Japan Analysis	
MCS	Mental Component Summary score	精神的側面のサマリースコア
MMRM	mixed effect model repeat measurement	反復測定混合効果モデル
PCS	Physical Component Summary score	身体的側面のサマリースコア
PMDA	Pharmaceuticals and Medical Devices Agency	独立行政法人医薬品医療機器総合機構
PMR	polymyalgia rheumatica	リウマチ性多発筋痛症
PRO	patient reported outcome	患者報告アウトカム
QD	once a day	1 日 1 回
SD	standard deviation	標準偏差
SF 36	36 item short form health survey	
SS1	Safety Analysis Set in Period 1	第 1 ピリオドの安全性解析対象集団
TSQM	Treatment Satisfaction Questionnaire for Medication	薬物治療の満足度に関する質問票

2.7.3.1 背景及び概観

2.7.3.1.1 有効性の評価に用いた臨床試験

ウパダシチニブの有効性は，巨細胞性動脈炎（以下「GCA」）を対象とした第 III 相試験である M16-852 試験（評価資料，M16-852 試験 52 週治験総括報告書［以下「M16-852 52w CSR」］，5.3.5.1-1 項）から評価した。有効性評価に用いた臨床試験の一覧を表 2.7.3.6-1 に示す。

M16-852 試験は，日本人被験者を含む第 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，成人 GCA 患者を対象にウパダシチニブの安全性及び有効性を評価した。データカットオフ時点（2024 年 2 月 6 日）で継続中である。本概要では，投与 52 週時まで（第 1 ピリオド）の有効性の結果を示す。

2.7.3.1.2 試験デザイン

M16-852 試験は第 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った。

試験対象集団は，ベースライン前 8 週間以内に活動性 GCA（新規発症又は再発性）と診断された 50 歳以上の成人被験者で構成した。活動性 GCA は，GCA の明確な頭蓋症状，リウマチ性多発筋痛症（以下「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ひとつ以上を有し，かつ赤血球沈降速度（以下「ESR」）が 30 mm/hr 以上又は C-反応性タンパク（以下「CRP」）が 1 mg/dL 以上であると定義した。

新規発症 GCA は，ベースライン前 8 週間以内に診断された GCA と定義した。再発性 GCA は，副腎皮質ステロイド（以下「CS」）漸減投与を 1 回以上試みたが失敗した活動性 GCA と定義した。

本試験では，新規発症被験者の割合を 30%以上，再発性被験者の割合を 70%以下として組入れ可能とした。また，本試験では，インターロイキン（以下「IL」）-6 阻害薬を過去に使用していたが，再燃以外の理由で使用を中止した被験者も最大 20%組入れ可能とした。

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した。

第 1 ピリオドでは，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 1 日 1 回（以下「QD」） + 26 週間 CS 漸減併用投与（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（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（プラセボ群）

被験者はベースライン前のいずれかの時点で活動性 GCA に対して 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なければならないこととした。被験者は，M16-852 試験治験実施計画書（M16-852 52w CSR Appendix 16.1　1）に規定された CS 漸減投与を安全に開始することができる臨床的に安定した GCA を有していると治験責任医師により判断されていなければならないこととした。

すべての被験者は，本試験外で投与された CS から治験依頼者が提供する CS に切り替えてベースラインから 20，30，40，50 又は 60 mg QD の prednisone 又はプレドニゾロン経口投与を受けた。prednisone 又はプレドニゾロンの初回用量は，治験責任医師が疾患重症度や併存症に基づいて判断したが，ベースライン時に 20 mg QD 以上とした。ベースライン時に被験者が 20，30，40，50 又は 60 mg QD 以外の用量を投与されていた場合は，治験責任医師の判断により，臨床的必要性に応じてこれらのいずれかの用量のうち最も近い用量となるよう切り上げるか，又は切り捨てた。被験者がベースライン来院時に既に自宅で CS を服用していた場合には，治験依頼者が提供する CS を重複して服用してはならないこととした。prednisone 又はプレドニゾロンは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。本試験中の CS 療法に関するその他の詳細については M16-852 試験治験実施計画書（M16-852 52w CSR Appendix 16.1　1 Section 5.8）を参照のこと。

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することとした。

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 ピリオドで引続きプラセボ投与を受けることとした。

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 週間以上の寛解維持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。

第 1 ピリオドで治験薬の投与を中止した被験者は，治験責任医師の判断で各国の標準治療に従って治療（トシリズマブが含まれていても良い）を受け，第 1 ピリオドの残りの試験スケジュールを継続し，M16-852 試験治験実施計画書（M16-852 52w CSR Appendix 16.1　1 Appendix D）に記載した第 1 ピリオドの試験の手順を実施した。

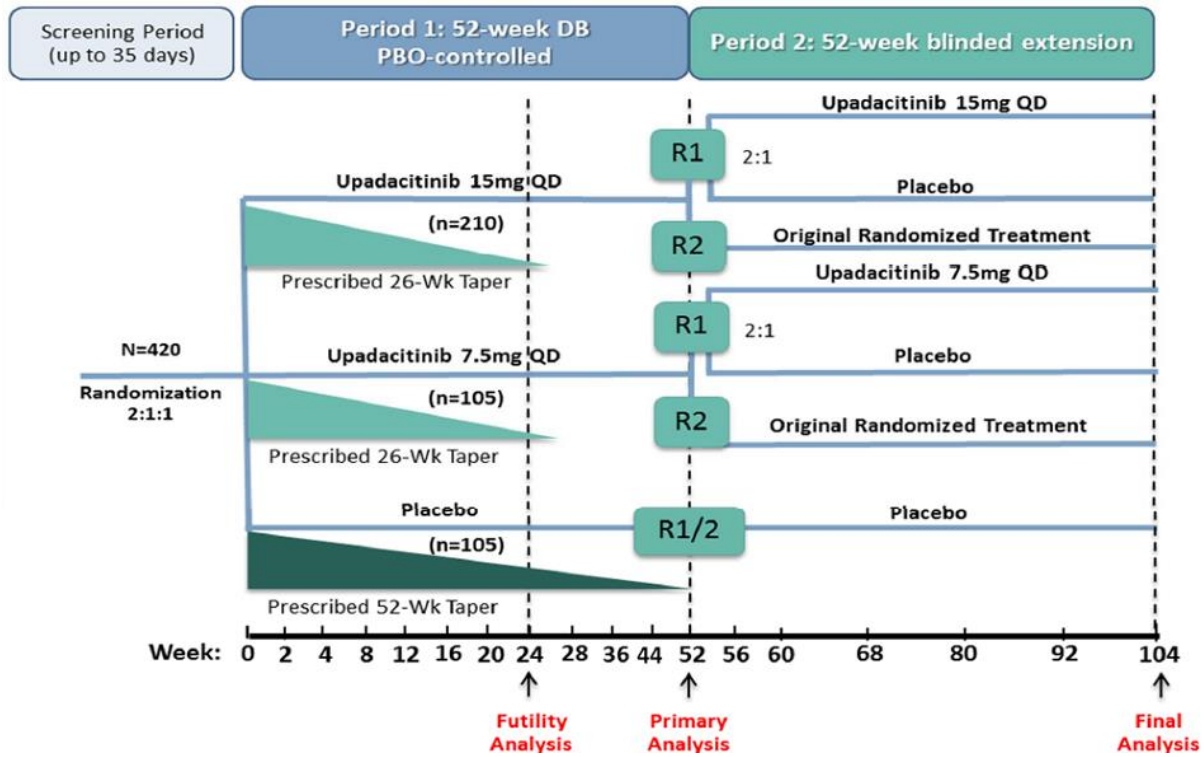
第 2 ピリオドでは，再燃（治験責任医師により GCA の徴候若しくは症状の再発と判断される事象が発現する，又は ESR が［GCA により］30 mm/hr を超え，かつ CS の開始を要する場合と定義した）が認められた被験者は，治験責任医師の判断により，非盲検下で prednisone 又はプレドニゾロンによる治療を開始することとした。再燃を記録するのは規定来院時でも規定外来院時でも良いこととした。再燃基準に該当した被験者は，再評価が必要な再燃が認められてから約 4 週間以内に再来院することとした。再評価の実施は，規定来院時及び規定外来院時のいずれでも行うことができることとした。再燃が確認されてから約 4 週間以内に GCA の徴候及び症状が認められないことが確認されなかった場合，治験薬の投与を中止することとした。治験薬

の投与を中止した被験者は，治験責任医師の判断で各国の標準治療に従って治療（トシリズマブが含まれていても良い）を受け，第 2 ピリオドの試験スケジュールを継続して M16-852 試験治験実施計画書（M16-852 52w CSR Appendix 16.1　1 Appendix D）に記載した試験の手順を実施することとした。

最初に組み入れられた 140 例の被験者が 24 週間の投与を完了した時点で，データモニタリング委員会が無益性の解析を行い，有効性の欠如について評価した。治験実施医療機関及び被験者は，試験期間を通して盲検下に置いた。最後の被験者が投与 52 週時の来院を完了した後，円滑に薬事申請するため，治験依頼者は第 1 ピリオドの治験薬割付けに関して開鍵した。無益性を評価するための中間解析計画に関するその他の詳細は M16-852 試験治験実施計画書（M16-852 52w CSR Appendix 16.1　1 Section 6.3，Section 7.5）を参照のこと。

試験デザインの概略を図 2.7.3-1 に示す。

図 2.7.3-1.　　試験デザインの概略（M16-852 試験［第 III 相試験］）



DB　double blind，PBO　placebo，R1　sustained remission for 24 consecutive weeks prior to Week 52，R2　remission at Week 52 but not achieving sustained remission for at least 24 consecutive weeks prior to the Week 52 visit，Wk　week

Cross reference: M16 852 52w CSR Figure 1

試験デザインの主な特徴を表 2.7.3-1 に示す。

表 2.7.3-1. 試験デザインの主な特徴（M16-852 試験［第 III 相試験］）

Design Feature	Description
Appropriate study population	Subjects who meet the following criteria:
	Diagnosis of GCA according to the following criteria: • Adult male or female, at least 50 years of age • History of ESR ≥ 50 mm/hour or hsCRP/CRP ≥ 1.0 mg/dL • Presence of at least one of the following: ・ Unequivocal cranial symptoms of GCA (new-onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia-related vision loss, or otherwise unexplained mouth or jaw pain upon mastication), or ・ Unequivocal symptoms of PMR (shoulder and/or hip girdle pain associated with inflammatory morning stiffness). • Presence of at least one of the following: ・ Temporal artery biopsy revealing features of GCA, or ・ Evidence of large vessel vasculitis by angiography or cross-sectional imaging such as MRI, CT or PET, assessed by a qualified radiologist experienced in evaluating large vessel vasculitis, or ultrasound of temporal arteries assessed by a qualified physician experienced in evaluating large vessel vasculitis.
	Active new onset or relapsing GCA with active disease within 8 weeks of Baseline. Active disease is defined by the presence of at least one of the following: unequivocal cranial symptoms of GCA, unequivocal symptoms of PMR, or other features judged by the investigator to be consistent with GCA or PMR flares, AND an ESR ≥ 30 mm/hr or hsCRP/CRP ≥ 1 mg/dL.
	Subjects must have received treatment with ≥ 40 mg prednisone (or equivalent) at any time prior to Baseline and must have been receiving prednisone (or prednisolone) 20 mg, 30 mg, 40 mg, 50 mg, or 60 mg QD at Baseline.
	Subjects must have had GCA that, in the opinion of the investigator, was clinically stable to allow the subject to safely initiate the protocol-defined CS taper regimen.
Randomization	Randomization at Baseline of all subjects, except for those in Japan, was stratified by Baseline CS dose (prednisone or prednisolone > 30 mg or ≤ 30 mg), prior use of an IL-6 inhibitor, and whether entering the study with new onset or relapsing disease. In Japan, the study attempted to include a minimum of 8 subjects; no stratification was utilized for randomization, however, data on all 3 stratification factors was collected. In Period 1, subjects were randomized in a 2:1:1 ratio to 1 of 3 treatment groups: upadacitinib15 mg + 26-week CS taper regimen, upadacitinib 7.5 mg + 26-week CS taper regimen, or placebo +

Design Feature	Description
	52-week CS taper regimen. In Period 2, subjects from the Period 1 upadacitinib group who achieved sustained remission for at least 24 weeks prior to the Week 52 visit (at the end of Period 1) were re-randomized to either continue on upadacitinib or switch to placebo (M16-852 52w CSR Section 9.1); re-randomization was stratified by Baseline disease status (new onset or relapsing disease). These subjects were re-randomized in a 2:1 ratio to either continue on the same upadacitinib dose or switch to placebo. Subjects from the Period 1 Placebo group who achieved sustained remission for at least 24 weeks prior to the Week 52 visit (at the end of Period 1) continued to receive placebo. Remission is defined as absence of GCA signs and symptoms AND adherence to the protocol-defined CS taper regimen or CS-free. At Week 52, subjects who had absence of GCA signs and symptoms AND were CS-free, but did not meet the above remission criteria continued in Period 2 on their originally randomized treatment assignment. All other subjects were discontinued from study drug at the end of Period 1.
Double-blind dosing	The 52-week randomized, parallel-group treatment period (Period 1) was double-blind, and investigators and subjects were blinded to treatment arm.
Choice of primary endpoint	The proportion of subjects achieving sustained remission at Week 52 was chosen as the primary endpoint.

事前に規定した主要評価項目及び副次評価項目は，規制当局からのフィードバックに基づき選択した。評価項目は，GCA を対象としたその他の臨床開発プログラム（トシリズマブなど）と一致するものでもある。

2.7.3.1.3 各評価項目の定義

2.7.3.1.3.1 GCA の徴候及び症状

GCA の徴候及び症状は，評価スケジュールに従い，各来院時に評価して電子症例報告書に入力した。GCA の徴候及び症状には下記が含まれる。

- 発熱（38°C 又は 100.4°F 超）
- PMR の症状（肩甲帯及び / 又は腰帯部の朝のこわばり及び / 又は痛み）
- 限局性の頭痛，側頭動脈又は頭皮の圧痛
- 動脈炎性前部虚血性視神経症による急性又は亜急性の視力喪失，一過性の視界不良（概して単眼性である又は発現時点では少なくとも片眼に発現するが，両眼に生じる可能性もある）などの視覚の徴候又は症状
- 顎又は口の痛み
- 四肢の跛行の新規発症又は悪化
- 臨床評価者により GCA 又は PMR の再燃に合致すると判断されるその他の特徴的所見

2.7.3.1.3.2 臨床反応

2.7.3.1.3.2.1 寛解に基づく評価

寛解に基づく評価は，特定の評価時点又はピリオドで以下のように評価した。

寛解

寛解は以下のように定義した。

- 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

寛解維持

投与 52 週時の寛解維持は，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

完全寛解

完全寛解は，下記のすべての条件を満たしていることと定義した。

- GCA の徴候及び症状が認められない
- ESR が（30 mm/hr 以下まで）正常化している（ESR が 30 mm/hr を超え，上昇が GCA によるものでない場合，この基準に該当する可能性がある）
- 高感度 CRP（以下「hsCRP」）が（1 mg/dL 未満に）正常化している
- 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

投与 12 週時から投与 52 週時までの期間の完全寛解維持

投与 12 週時から投与 52 週時までの期間の完全寛解維持は，下記のすべての条件を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
- 投与 12 週時から投与 52 週時までの期間に ESR が（30 mm/hr 以下まで）正常化している（ESR が 30 mm/hr を超え，上昇が GCA によるものでない場合，この基準に該当する可能性がある）
- 投与 12 週時から投与 52 週時までの期間に hsCRP が（［連続する 2 回の来院時に］1 mg/dL 以上に上昇することなく，1 mg/dL 未満に）正常化している
- 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

寛解を評価する事前に規定した主要評価項目及び副次評価項目を以下に要約する。

- 投与 52 週時に寛解維持を達成した被験者の割合
- 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

また，追加解析を実施し，投与 52 週時の寛解維持及び投与 12 週時から投与 52 週時までの期間の完全寛解維持の評価項目の各要素の結果を要約した。

2.7.3.1.3.2.2 再燃に基づく評価

再燃は，複合評価項目であり，治験責任医師により GCA の徴候若しくは症状の再発と判断される事象が発現する，又は ESR が（GCA により）30 mm/hr を超え，かつ CS の増量を要する場合と定義した。再燃は，投与 52 週時までに再燃がない状態（GCA の徴候及び症状の再発が認められない，ESR が正常化している，及び CS の増量がない場合と定義した）が確認された被験者を対象に検討した。投与 52 週時までに再燃がない状態が認められなかった被験者は，ベースライン時に再燃が認められたものと見なした。また，再燃がない状態が認められたがその後に再燃を認めなかった被験者は，第 1 ピリオドの最終評価時に再燃が認められなかったものと見なした。

再燃に基づく以下の副次評価項目を評価した。

- 投与 52 週時までの最初の再燃までの期間（ハザード比により評価した）
- 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 週時までの被験者あたりの再燃回数

2.7.3.1.3.2.3 CS の曝露量に関連した評価

以下の CS の曝露量に関連した評価を実施した。

第 1 の評価は，事前に規定した副次評価項目であった。

- 投与 52 週時までの CS の累積曝露量

第 2 の評価は，追加の CS の曝露量（CS エスケープ療法［非盲検下での CS の増量］及び治験実施計画書に規定された CS 漸減投与以外の併用薬として記録された CS の両者）をよりよく評価するために，追加解析として実施した。

- 投与 52 週時までの追加の CS の累積曝露量（治験実施計画書に規定された CS 漸減投与を除く）

追加の CS の曝露量は，「治験実施計画書に規定された CS 漸減投与以外の追加の CS の累積曝露量」と定義した。

2.7.3.1.3.3 Quality of Life 及び患者報告アウトカム

SF-36

36-item short-form health survey（以下「SF-36」）は，年齢，疾患及び投与群にかかわらず使用できる全般的な健康関連の生活の質評価票であり，8 つの領域（身体機能，日常役割機能の制限［身体］，日常役割機能の制限［精神］，社会生活機能，疼痛，活力 / 疲労，心の健康，全体的健康問題）を含む。8 つの領域は，身体的側面のサマリースコア（以下「PCS」）及び精神的側面のサマリースコア（以下「MCS」）の 2 つのサマリースコアに要約できる。すべての項目，尺度及びサマリースコアの各スコアは 0–100 の範囲であり，スコアが高値であるほど，転帰が良好であることを示す。

申請者は定性調査を実施し，SF-36 の内容の妥当性，具体的には，この患者報告アウトカム（以下「PRO」）尺度が GCA 患者に関連した概念を測定するものであり，GCA 患者がこの質問票の項目を解釈し，回答できることに対する患者報告のエビデンスを得た。更に，申請者は，M16-852 試験のデータを用いて一連の定量解析を実施し，SF-36 PCS スコアの心理測定の性能とスコア解釈を評価した。GCA を対象とした試験で副次評価項目を裏付けるために SF-36 を用いることのエビデンスの全体は，Clinical Outcome Assessment Evidence Package（5.3.5.4-6 項，5.3.5.4-7 項）に示した。

FACIT-Fatigue

functional assessment of chronic illness therapy - fatigue（以下「FACIT-Fatigue」）は，13 項目の電子的 PRO（以下「ePRO」）による疲労 / 倦怠感とその日常の活動及び機能への影響の評価法であり，一般集団及び慢性疾患患者で検証されてきた。FACIT-Fatigue は，倦怠感，弱っていると感じる，（疲れ切って）関心がわかない，活力がない，及び疲れによる日常機能への影響（睡眠及び社会的活動など）などの項目で構成される。

申請者は定性調査を実施し，FACIT-Fatigue の内容の妥当性，具体的には，この PRO 尺度が GCA 患者に関連した概念を測定するものであり，GCA 患者がこの質問票の項目を解釈し，回答できることに対する患者報告のエビデンスを得た。更に，申請者は，M16-852 試験のデータを用いて一連の定量解析を実施し，FACIT-Fatigue の心理測定の性能とスコア解釈を評価した。GCA を対象とした試験で副次評価項目を裏付けるために FACIT-Fatigue を用いることのエビデンスの全体は，Clinical Outcome Assessment Evidence Package（5.3.5.4-7 項）に示した。

TSQM

薬物治療の満足度に関する質問票（以下「TSQM」）は，薬物治療の満足度に関する汎用されている ePRO 評価手法であり，薬剤の種類と症状間での治療満足度を比較するために開発されたものである [1]。

TSQM 1.4 は，4 領域（有効性，副作用，利便性，及びひとつの総合的尺度である総合的な満足度）を評価する 14 項目から構成される。4 領域の各スコアは 0–100 の範囲であり，スコアが高いほど満足度が高い。

2.7.3.1.3.4 CS に関連した有害事象

CS は依然として GCA 治療の要であることから，CS に関連した有害事象の発現（又は発現がないこと）によっても有効性を間接的に評価することが可能である。CS に関連した有害事象は，prednisone / プレドニゾロン（又はプラセボ）と関連ありの有害事象（治験責任医師による判断）と定義した。この有効性の評価の目的は，投与コースを通して，CS のより長期（52 週間）の漸減併用投与と比較してより短期（26 週間）の漸減併用投与の方が CS に関連した有害事象の発現を減らすベネフィットがあり得ることを示すことである。

2.7.3.1.4 主要評価項目

主要評価項目は，投与 52 週時に寛解維持を達成した被験者の割合とした。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

以下のいずれかのカテゴリーに含まれる被験者は，治験実施計画書に規定された CS 漸減投与を遵守していないと見なした。

- 第 1 ピリオドのいずれかの時点で，治験責任医師により CS エスケープ療法を開始した
- 第 1 ピリオドの間に，CS エスケープ療法と認められることなく，GCA に対して 100 mg 超の prednisone（又は同等の CS）の追加の全身性 CS による治療を受けた。追加の全身性 CS は，自動応答技術（以下「IRT」）で処方された CS 漸減投与以外の併用薬として記録されたすべての全身性 CS と定義した

2.7.3.1.5 多重性を制御した副次評価項目

多重性を制御した副次評価項目には下記を含めた。

1. 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。完全寛解維持は，下記のすべての条件を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 • 投与 12 週時から投与 52 週時までの期間に ESR が（30 mm/hr 以下まで）正常化している（ESR が 30 mm/hr を超え，上昇が GCA によるものでない場合，この基準に該当する可能性がある） • 投与 12 週時から投与 52 週時までの期間に hsCRP が（［連続する 2 回の来院時に］1 mg/dL 以上に上昇することなく，1 mg/dL 未満に）正常化している • 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
2. 投与 52 週時までの CS の累積曝露量
3. 投与 52 週時までの最初の再燃までの期間。再燃は，治験責任医師により GCA の徴候若しくは症状の再発と判断される事象が発現する，又は ESR が（GCA により）30 mm/hr を超え，かつ CS の増量を要する場合と定義した。
4. 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
5. 投与 52 週時に完全寛解を達成した被験者の割合。完全寛解は，下記のすべての条件を満たしていることと定義した。 • GCA の徴候及び症状が認められない • ESR が（30 mm/hr 以下まで）正常化している（ESR が 30 mm/hr を超え，上昇が GCA によるものでない場合，この基準に該当する可能性がある） • hsCRP が（1 mg/dL 未満に）正常化している • 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
6. 投与 24 週時に完全寛解を達成した被験者の割合
7. 投与 52 週時の SF-36 PCS のベースラインからの変化量
8. グループとして扱う 4 つの評価項目 [a] • 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 FACIT-Fatigue のベースラインからの変化量 • 投与 52 週時の 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 [b] の発現率

a. 独立した 4 つの評価項目を，ひとつのグループにまとめ，Hochberg 法を用いて多重性を調整した。

b. CS に関連した有害事象は，prednisone / プレドニゾロン（又はプラセボ）と関連ありの有害事象と定義した。

寛解に関連した副次評価項目（投与 24 週時の完全寛解の評価項目を除く）では，以下のいずれかのカテゴリーに含まれる被験者は，治験実施計画書に規定された CS 漸減投与を遵守していないと見なした。

- 第 1 ピリオドのいずれかの時点で，治験責任医師により CS エスケープ療法を開始した
- 第 1 ピリオドの間に，CS エスケープ療法と認められることなく，GCA に対して 100 mg 超の prednisone（又は同等の CS）の追加の全身性 CS による治療を受けた。追加の全身性 CS は，IRT で処方された CS 漸減投与以外の併用薬として記録されたすべての全身性 CS と定義した

投与 24 週時の完全寛解の評価項目では，以下のいずれかのカテゴリーに含まれる被験者は，治験実施計画書に規定された CS 漸減投与を遵守していないと見なした。

- 投与 24 週時までに，治験責任医師により CS エスケープ療法を開始した
- 投与 24 週時までに，GCA に対して 100 mg 超の prednisone（又は同等の CS）の追加の全身性 CS による治療を受けた

再燃は，投与 52 週時までに以下の 3 条件のすべてが満たされた被験者を対象に検討した。

- GCA の徴候及び症状の再発が認められない
- ESR が正常化している
- CS の増量がない

再燃の評価項目では，CS の増量は以下のとおり定義した。

- 第 1 ピリオドで，治験責任医師により CS エスケープ療法を開始した
- 第 1 ピリオドで，GCA に対して追加の全身性 CS による治療を受けた

投与 52 週時までの被験者あたりの再燃回数の評価項目では，投与 52 週時までに認められたすべての再燃をカウントした。

2.7.3.1.6 追加評価項目

第 1 ピリオドのその他の評価項目：

• 投与 12 週時に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 [a]
• 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 EQ-5D-5L のベースラインからの変化量
• 各来院での PGIC の評価 [b]
• 各来院での PGA 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。定義は以下のとおりとした。 ・ 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

EQ 5D 5L European Quality of Life 5 Dimensions 5 Levels，PGA patient global assessment，PGIC Patient Global Impression of Change

a. SF 36 は，PCS，MCS 及び 8 つの下位領域を含む。

b. PGIC の評価は，PGIC の「非常に改善した」又は「かなり改善した」の達成と定義した。

2.7.3.1.7 解析対象集団

以下の解析対象集団を対象に解析した。

- 最大の解析対象集団（以下「FAS」）は，第 1 ピリオド及び第 2 ピリオドで定義した
  - 第 1 ピリオドの FAS（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
  - 第 2 ピリオドの FAS は，投与 52 週来院の前（第 1 ピリオド終了時）に 24 週間以上連続で寛解を達成し，第 2 ピリオドで治験薬を 1 回以上投与した全被験者
- 第 1 ピリオドの安全性解析対象集団（以下「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。CS に関連した有害事象の発現率の評価項目の解析では SS1 を用いた

評価資料とした M16-852 試験は，日本人を含む国際共同試験であり，日本人部分集団を解析対象とした部分集団解析を実施した（M16-852 試験 52 週 Japan Analysis［以下「M16-852 52w JA」］：5.3.5.4-1 項）。

2.7.3.1.8 統計解析

M16-852 試験の解析方法の詳細は，M16-852 試験の統計解析計画書（M16-852 52w CSR Appendix 16.1　9.1）及び M16-852 52w CSR Section 9.6.2 に示した。

主要解析はすべての被験者が投与 52 週時の来院を完了した後，又は投与 52 週時前に試験を中止した後に実施した。主要評価項目を含むカテゴリー変数には，層別因子で調整した Cochran-Mantel-Haenszel 法を用いて，ウパダシチニブ群をプラセボ群と比較した。欠測データの主な取扱い方法には，新型コロナウイルス感染症による行動制限又は政治的対立によって生じた欠測データを多重代入法で補完する規定を組み込んだノンレスポンダー補完法を用いた。

SF-36，patient global assessment，European Quality of Life-5 Dimensions 5 Levels 及び FACIT-Fatigue のベースラインからの変化量のような連続データである評価項目は，投与群，来院，投与群と来院の交互作用及び層別因子を固定効果，対応するベースライン値を共変量とする反復測定混合効果モデル（以下「MMRM」）を用いて，ウパダシチニブ群とプラセボ群を比較した。TSQM 値は投与群，来院，投与群と来院の交互作用及び層別因子を固定効果とする MMRM を用いて解析した。CS の累積曝露量のウパダシチニブ群とプラセボ群の比較は，層別因子により層別した van Elteren 検定により解析した。各投与群の投与 52 週時の prednisone の合計累積曝露量の中央値及び対応する 95%信頼区間（以下「CI」）を求めた。

事象発現までの期間の評価項目は，各投与群の事象発現までの期間の中央値を記録した。層別ログランク検定と，ベースライン値及び層別因子を共変量とする Cox 回帰を用いてウパダシチニブ群とプラセボ群を比較した。

カウントデータの評価項目のウパダシチニブ群とプラセボ群の比較は，層別因子及び投与群を共変量として，曝露期間で調整したポアソン回帰モデルを用いて行った。

2.7.3.1.4 項及び 2.7.3.1.5 項に示した主要評価項目及び副次評価項目に加え，以下の追加解析を実施した：過去の PMR の明確な症状の有無別の投与 52 週時の寛解維持の部分集団解析，投与 52 週時の寛解維持及び投与 12 週時から投与 52 週時までの期間の完全寛解維持の評価項目の各要素の解析，並びに追加の CS の累積曝露量（治験実施計画書に規定された CS の累積曝露量を除く）の解析。寛解の評価項目の各要素の解析では，2 値データの評価項目と同様の解析を行い，追加の CS の累積曝露量の解析では，事前に規定した CS の累積曝露量と同様の解析を行った。

第 I 種の過誤率の制御

主要評価項目及び多重性を制御した副次評価項目の試験全体での第 1 種の過誤率は，graphical multiplicity adjustment method により厳密に制御した。

特に，2.7.3.1.4 項及び 2.7.3.1.5 項に示す主要評価項目及び多重性を制御した副次評価項目は，以下に示す順序で検定し，ウパダシチニブ 15 mg QD 群の主要評価項目に対する有意水準 $\alpha = 0.05$ での検定から開始した。その後の検定は，事前に規定した有意水準の移行順序に従って行い，これには各用量群の評価項目間だけでなく，異なる用量群の評価項目間の移行を含めた。

米国 / FDA の多重性を制御した検定手順は M16-852 52w CSR Appendix 16.1　9.1 Figure 2 に示した。独立行政法人医薬品医療機器総合機構（以下「PMDA」）の多重性を制御した検定手順を図 2.7.3-2 に示す。図の矢印は，有意水準の移行順序を示す。割り当てられた有意水準で評価項目の帰無仮説が棄却された（検定結果が有意となった）場合，有意水準は矢印に従って次の評価項目へ移動する。矢印にある数字は，配分される有意水準の重みを示し，重み 1 及び 1/2 はそれぞれ全体の有意水準の 100%及び 50%が移動することを示している。主要評価項目及び多重性を制御した副次評価項目（表 2.7.3-2 の V0–V7）は順番に検定した。残りの多重性を制御した副次評価項目はグループとして扱い（表 2.7.3-2 の V8-H），Hochberg 法を用いて検定した。

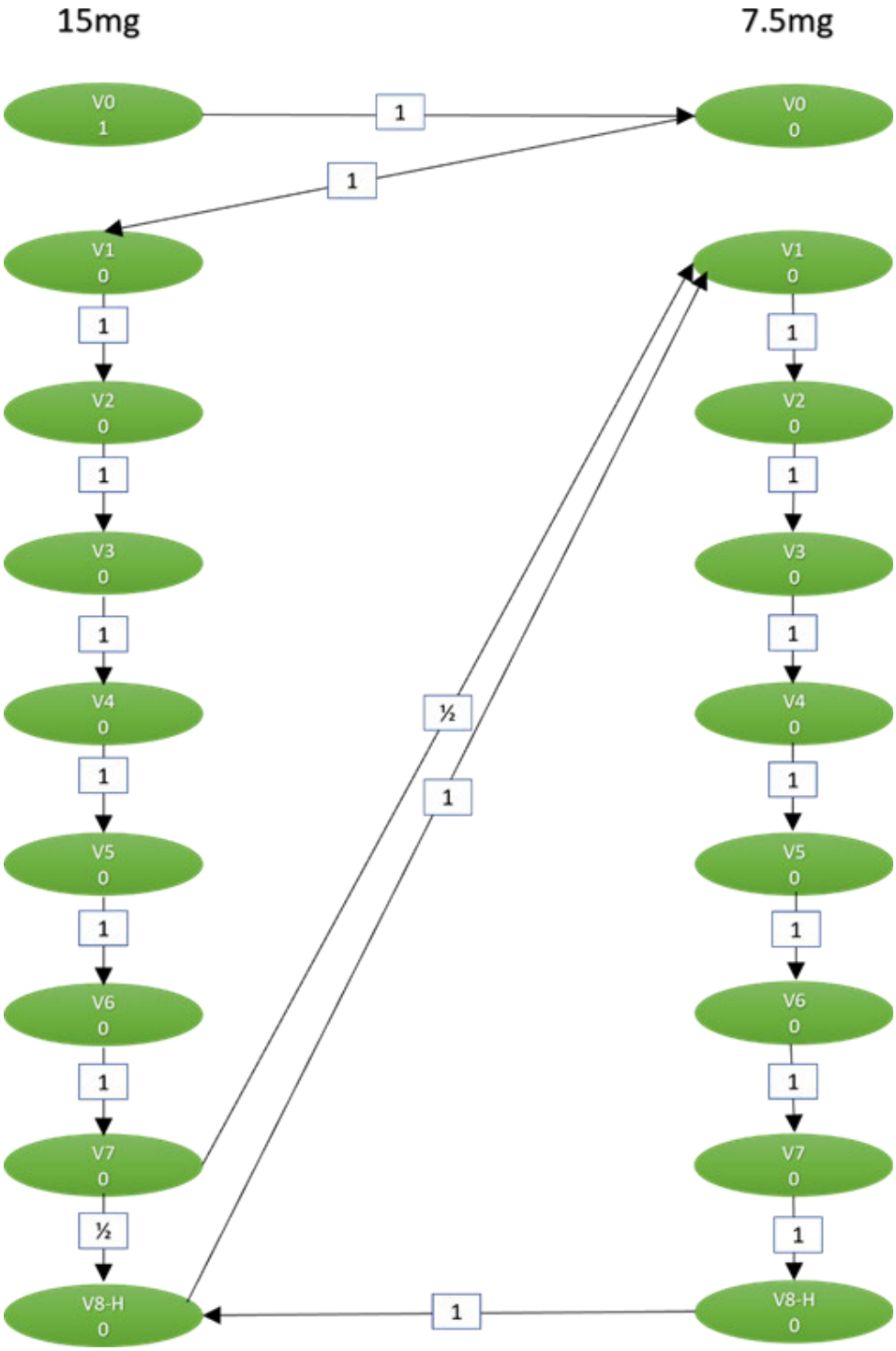
本概要では，PMDA の多重性を制御した検定手順（図 2.7.3-2）に基づく結果を示す。

表 2.7.3-2. 薬事要件に準じた主要評価項目及び副次評価項目（M16-852 試験，FAS1）

記号	評価項目
V0	投与 52 週時に寛解維持を達成した被験者の割合
V1	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
V2	投与 52 週時までの CS の累積曝露量
V3	投与 52 週時までの最初の再燃までの期間
V4	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
V5	投与 52 週時に完全寛解を達成した被験者の割合
V6	投与 24 週時に完全寛解を達成した被験者の割合
V7	投与 52 週時の SF 36 PCS のベースラインからの変化量
V8 H	• 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 FACIT Fatigue のベースラインからの変化量 • 投与 52 週時の 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

Cross reference: M16 852 52w CSR Appendix 16.1 9.1 Table 3

図 2.7.3-2. PMDA の多重性を制御した検定手順（M16-852 試験，FAS1）



Cross reference: M16 852 52w CSR Appendix 16.1 9.1 Figure 3

2.7.3.2 個々の試験結果の要約

2.7.3.2.1 人口統計学的特性及びベースラインの疾患特性

M16-852 試験の第 1 ピリオドの人口統計学的特性を表 2.7.3.6-2 に示す。人口統計学的特性は，ウパダシチニブ群とプラセボ群でおおむね均衡していた。全体で，多くの被験者が女性（73.1%［313/428 例］），白人（93.7%［401/428 例］），非ヒスパニック若しくはラテン系（97.0%［415/428 例］），たばこ製品の使用歴なし（57.2%［245/428 例］），及び 65 歳以上（81.8%［350/428 例］。65 歳以上 75 歳未満が 49.1%［210/428 例］，75 歳以上が 32.7%［140/428 例］）であった。体容量指数（以下「BMI」）の平均値（標準偏差［以下「SD」］）は 25.3946 kg/m^2（4.6832）であった。

M16-852 試験の第 1 ピリオドでは，ベースラインの疾患特性は，ウパダシチニブ群とプラセボ群でおおむね均衡していた。多くの被験者がベースライン時に新規発症 GCA（ウパダシチニブ群合計 70.6%［223/316 例］，プラセボ群 67.9%［76/112 例］），IL-6 阻害薬の前治療歴なし（ウパダシチニブ群合計 94.9%［300/316 例］，プラセボ群 93.8%［105/112 例］）であった。ベースライン時の CS 用量の平均値は，いずれの投与群でも約 35 mg であった。ベースライン時の CS 用量が 30 mg 以下であった被験者の割合は，ウパダシチニブ群とプラセボ群で同様であった（ウパダシチニブ群合計 52.2%［165/316 例］，プラセボ群 52.7%［59/112 例］）。診断後の罹病期間の中央値（範囲）は，ウパダシチニブ群合計が 41.0 日（14–4903），プラセボ群が 42.0 日（15–2993）であった（M16-852 52w CSR Table 14.1　5.1）。

ベースラインでは，CRP の平均値は，ウパダシチニブ群合計が 6.479 mg/L，プラセボ群が 5.701 mg/L であった。ESR の平均値は，ウパダシチニブ群合計が 19.7 mm/hr，プラセボ群が 21.7 mm/hr であった。FACIT-Fatigue の平均値は，ウパダシチニブ群合計が 35.9，プラセボ群が 37.5 であった（M16-852 52w CSR Table 14.1　5.1）。

2.7.3.2.2 被験者の内訳

M16-852 試験の第 1 ピリオドの被験者の内訳を表 2.7.3-3 に示す。第 1 ピリオドでは，23 ヵ国の 100 施設でランダム化した被験者は 428 例であり，全被験者に治験薬を 1 回以上投与した。全体で，第 1 ピリオドを完了した被験者の割合は 81.3%（348/428 例）であった。第 1 ピリオドでは，各投与群で割合が高かった試験中止の主な理由（いずれかの投与群で 5%以上）は，有害事象及び同意撤回であり，有害事象又は同意撤回により試験を中止した被験者の割合は，ウパダシチニブ群とプラセボ群で同様であった。

表 2.7.3-3. 被験者の内訳（M16-852 試験の第 1 ピリオド，FAS1）

	PBO + 52 WK CS T (N 112) n (%)	7.5 + 26 WK CS T (N 107) n (%)	UPA 15 + 26 WK CS T (N 209) n (%)	Total (N 316) n (%)	Overall Total (N 428) n (%)
Received randomized study drug	112 (100)	107 (100)	209 (100)	316 (100)	428 (100)
Completed Period 1	86 (76.8)	85 (79.4)	177 (84.7)	262 (82.9)	348 (81.3)
Ongoing in Period 1	0	0	0	0	0
Discontinued study in Period 1	26 (23.2)	22 (20.6)	32 (15.3)	54 (17.1)	80 (18.7)
All reasons for discontinuation$					
Adverse event	15 (13.4)	12 (11.2)	17 (8.1)	29 (9.2)	44 (10.3)
Withdrew consent	5 (4.5)	7 (6.5)	11 (5.3)	18 (5.7)	23 (5.4)
Lost to follow up	0	0	0	0	0
COVID 19 infection	0	0	1 (0.5)	1 (0.3)	1 (0.2)
COVID 19 logistical restrictions	1 (0.9)	0	0	0	1 (0.2)
Failure to meet continuation criteria	2 (1.8)	0	0	0	2 (0.5)
Other	6 (5.4)	7 (6.5)	5 (2.4)	12 (3.8)	18 (4.2)
Primary reason for discontinuation					
Adverse event	13 (11.6)	11 (10.3)	17 (8.1)	28 (8.9)	41 (9.6)
Withdrew consent	5 (4.5)	6 (5.6)	10 (4.8)	16 (5.1)	21 (4.9)
Lost to follow up	0	0	0	0	0
COVID 19 infection	0	0	0	0	0
COVID 19 logistical restrictions	1 (0.9)	0	0	0	1 (0.2)
Failure to meet continuation criteria	2 (1.8)	0	0	0	2 (0.5)
Other	5 (4.5)	5 (4.7)	5 (2.4)	10 (3.2)	15 (3.5)

Note: Subject [redacted] was randomized by error and never dosed.
$ Subjects who discontinued study drug are counted under each reason given for discontinuation, therefore, the sum of the counts given for the reasons may be greater than the overall number of discontinuations.
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.

	PBO + 52 WK CS T (N 112) n (%)	7.5 + 26 WK CS T (N 107) n (%)	UPA 15 + 26 WK CS T (N 209) n (%)	Total (N 316) n (%)	Overall Total (N 428) n (%)
Completed study drug in Period 1	71 (63.4)	73 (68.2)	155 (74.2)	228 (72.2)	299 (69.9)
Ongoing study drug in Period 1	0	0	0	0	0
Discontinued study drug in Period 1	41 (36.6)	34 (31.8)	54 (25.8)	88 (27.8)	129 (30.1)
All reasons for discontinuation$					
Adverse event	29 (25.9)	21 (19.6)	36 (17.2)	57 (18.0)	86 (20.1)
Withdrew consent	5 (4.5)	7 (6.5)	9 (4.3)	16 (5.1)	21 (4.9)
Lost to follow up	0	0	0	0	0
Lack of efficacy	11 (9.8)	6 (5.6)	8 (3.8)	14 (4.4)	25 (5.8)
COVID 19 infection	0	0	1 (0.5)	1 (0.3)	1 (0.2)
COVID 19 logistical restrictions	1 (0.9)	0	0	0	1 (0.2)
Other	6 (5.4)	6 (5.6)	10 (4.8)	16 (5.1)	22 (5.1)
Primary reason for discontinuation					
Adverse event	23 (20.5)	18 (16.8)	32 (15.3)	50 (15.8)	73 (17.1)
Withdrew consent	3 (2.7)	7 (6.5)	8 (3.8)	15 (4.7)	18 (4.2)
Lost to follow up	0	0	0	0	0
Lack of efficacy	8 (7.1)	4 (3.7)	7 (3.3)	11 (3.5)	19 (4.4)
COVID 19 infection	0	0	0	0	0
COVID 19 logistical restrictions	1 (0.9)	0	0	0	1 (0.2)
Other	6 (5.4)	5 (4.7)	7 (3.3)	12 (3.8)	18 (4.2)

Note: Subject [redacted] was randomized by error and never dosed.
$ Subjects who discontinued study drug are counted under each reason given for discontinuation, therefore, the sum of the counts given for the reasons may be greater than the overall number of discontinuations.
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.

Cross reference: M16 852 52w CSR Table 14.1 2.1

2.7.3.2.3 有効性の結果

PMDA の多重検定手順に基づく有効性の結果を M16-852 52w CSR Appendix 16.1　9.4 に示した。

主要評価項目及び副次評価項目の結果を表 2.7.3-4 に示す（検定方法の詳細は 2.7.3.1.8 項に示した）。

表 2.7.3-4. 主要評価項目及び副次評価項目の結果（PMDA の多重性を制御した検定手順，M16-852 試験，FAS1）

Endpoint[#] Treatment	N	Within Group PE [95% CI]	Between Group Difference (UPA - PBO) PE [95% CI][$]	P-value	Statistical Significance[@]
Proportion of subjects achieving sustained remission at Week 52 (%)					
PBO + 52 WK CS T	112	29.0 [20.6, 37.5]			
UPA 7.5 + 26 WK CS T	107	41.1 [31.8, 50.4]	12.1 [0.4, 24.6]	0.0579	Not Significant
UPA 15 + 26 WK CS T	209	46.4 [39.6, 53.2]	17.1 [6.3, 27.8]	0.0019**	Significant
Proportion of subjects achieving sustained complete remission from Week 12 through Week 52 (%)					
PBO + 52 WK CS T	112	16.1 [9.3, 22.9]			
UPA 7.5 + 26 WK CS T	107	26.2 [17.8, 34.5]	9.9 [0.8, 20.6]	0.0699	Not Significant
UPA 15 + 26 WK CS T	209	37.1 [30.5, 43.7]	20.7 [11.3, 30.2]	<0.0001***	Not Significant
Cumulative CS exposure through Week 52 (mg)					
PBO + 52 WK CS T	90	2882.0 [2762.00, 3253.00]			
UPA 7.5 + 26 WK CS T	86	1905.0 [1615.00, 2265.00]		<0.0001***	Not Significant
UPA 15 + 26 WK CS T	180	1615.0 [1615.00, 1635.00]		<0.0001***	Not Significant
Time to first GCA flare through Week 52 (days)					
PBO + 52 WK CS T	112	323.0 [249.00, NE]			
UPA 7.5 + 26 WK CS T	107	NE [316.00, NE]	0.75 [0.499, 1.136]	0.1778	Not Significant
UPA 15 + 26 WK CS T	209	NE [NE, NE]	0.57 [0.399, 0.826]	0.0025**	Not Significant

Endpoint[#] Treatment	N	Within Group PE [95% CI]	Between Group Difference (UPA - PBO) PE [95% CI][$]	P-value	Statistical Significance[@]
Proportion of subjects who experience at least 1 GCA flare through Week 52 (%)					
PBO + 52 WK CS T	112	55.6 [42.9, 69.2]			
UPA 7.5 + 26 WK CS T	107	41.3 [32.2, 51.7]	0.60 [0.35, 1.03]	0.0633	Not Significant
UPA 15 + 26 WK CS T	209	34.3 [27.4, 42.4]	0.47 [0.29, 0.74]	0.0014**	Not Significant
Proportion of subjects in complete remission at Week 52 (%)					
PBO + 52 WK CS T	112	19.6 [12.3, 27.0]			
UPA 7.5 + 26 WK CS T	107	43.0 [33.6, 52.4]	23.5 [11.7, 35.3]	<0.0001***	Not Significant
UPA 15 + 26 WK CS T	209	50.2 [43.4, 57.1]	30.3 [20.4, 40.2]	<0.0001***	Not Significant
Proportion of subjects in complete remission at Week 24 (%)					
PBO + 52 WK CS T	112	36.1 [27.2, 45.1]			
UPA 7.5 + 26 WK CS T	107	39.3 [30.0, 48.5]	3.2 [9.6, 16.0]	0.6276	Not Significant
UPA 15 + 26 WK CS T	209	57.2 [50.5, 64.0]	20.8 [9.7, 31.9]	0.0002***	Not Significant
Change from Baseline in the SF 36 PCS at Week 52					
PBO + 52 WK CS T	44	1.2892 [3.3093, 0.7309]			
UPA 7.5 + 26 WK CS T	49	1.3202 [0.6553, 3.2957]	2.6094 [0.1841, 5.4028]	0.0670	Not Significant
UPA 15 + 26 WK CS T	123	2.4634 [1.1707, 3.7561]	3.7526 [1.3932, 6.1119]	0.0019**	Not Significant

Endpoint[#] / Treatment	N	Within Group PE [95% CI]	Between Group Difference (UPA - PBO) PE [95% CI][$]	P-value	Statistical Significance[@]
Number of GCA flares per subject through Week 52					
PBO + 52 WK CS T	112	0.7 [0.5, 0.9]			
UPA 7.5 + 26 WK CS T	107	0.6 [0.4, 0.7]	0.8 [0.6, 1.2]	0.2722	Not Significant
UPA 15 + 26 WK CS T	209	0.4 [0.3, 0.5]	0.6 [0.4, 0.8]	0.0010***	Not Significant
Change from Baseline in FACIT Fatigue at Week 52					
PBO + 52 WK CS T	45	2.4 [4.71, 0.07]			
UPA 7.5 + 26 WK CS T	49	1.1 [1.17, 3.37]	3.5 [0.27, 6.70]	0.0338*	Not Significant
UPA 15 + 26 WK CS T	123	1.7 [0.18, 3.14]	4.0 [1.33, 6.76]	0.0036**	Not Significant
Assessment of TSQM patient global satisfaction subscale at Week 52					
PBO + 52 WK CS T	45	68.8428 [63.8310, 73.8547]			
UPA 7.5 + 26 WK CS T	52	74.2644 [69.4483, 79.0805]	5.4216 [1.4269, 12.2701]	0.1203	Not Significant
UPA 15 + 26 WK CS T	126	71.5753 [68.3375, 74.8131]	2.7325 [3.1020, 8.5670]	0.3573	Not Significant
Rate of CS related AEs through Week 52^ (E/PY)					
PBO + 52 WK CS T	112	1.7 [1.3, 2.3]			
UPA 7.5 + 26 WK CS T	107	1.7 [1.2, 2.2]	0.9 [0.6, 1.4]	0.7749	Not Significant
UPA 15 + 26 WK CS T	209	2.0 [1.7, 2.4]	1.1 [0.8, 1.6]	0.4371	Not Significant

Results for categorical endpoints (except for proportion of subjects who experience at least 1 GCA flare) are based on CMH with non responder imputation incorporating multiple imputation to handle missing data due to COVID 19 (NRI MI).

Number of GCA flares per subject and rate of CS related AEs are assessed as events per patient years based on Poisson model adjusted by stratification factors, with log (duration of study participation in years) as an offset. Robust standard error is used in inference.

Results for continuous endpoints (except for cumulative CS dose) were based on MMRM. Cumulative CS exposure was assessed using van Elteren test stratified by stratification factors. Time to first GCA flare was based on Kaplan Meier Method and P values were based on stratified log rank test.

$ Point estimate and 95% CI for treatment difference are based on CMH for categorical endpoints, MMRM for continuous endpoints (except for cumulative CS exposure), Cox model for time to first GCA flare, and Poisson model for Number of GCA flares per subject and Rate of CS related AEs.

@ Statistical significance is determined via the graphical multiple testing procedure controlling the overall type I error rate of all primary and multiplicity controlled secondary endpoints at the 0.05 level.

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

^ Analysis set for endpoint 'Rate of CS related AEs through Week 52' was SS1.

* P value ≤ 0.05.

** P value ≤ 0.01.

*** P value ≤ 0.001.

Note: Within group estimate: Percentage for categorical endpoints, median for cumulative CS exposure and time to first GCA flare, least squares mean for continuous endpoints, and mean number of event rate per patient year for number of GCA flares per subject and rate of CS related AEs. Between group estimate: hazard ratio for time to first GCA flare, odds ratio for proportion of subjects who experience at least 1 GCA flare, difference in least squares means for continuous endpoints, difference in percentages for categorical endpoints.

Cross reference: M16 852 52w CSR Appendix 16.1 9.4 Table 1

2.7.3.2.3.1 主要評価項目

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（プラセボ群との割合の差 17.1%［$P = 0.0019$］）（表 2.7.3-4）。この評価項目の達成には，被験者は，投与 52 週時の評価までに治験実施計画書に規定された CS 漸減投与を遵守し，CS の併用を必要としない状態にあることが必要であった。

ウパダシチニブ 7.5 mg QD 群の投与 52 週時に寛解維持を達成した被験者の割合（41.1%）は，プラセボ群（29.0%）と比較して数値的に高かった（プラセボ群との割合の差 12.1%［$P = 0.0579$］）が，統計学的に有意ではなかった（表 2.7.3-4）。

2.7.3.2.3.2 副次評価項目

全体として，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）を除き，いずれの副次評価項目でも，プラセボ群と比較してウパダシチニブ 15 mg QD 群及び 7.5 mg QD 群の方が数値的に高い有効性が認められたが，統計学的に有意ではなかった。

なお，有効性の数値的な差は，ウパダシチニブ 7.5 mg QD 群とプラセボ群との差と比較してウパダシチニブ 15 mg QD 群とプラセボ群との差の方がおおむね大きかった（表 2.7.3-4）。

2.7.3.2.3.2.1 完全寛解

<u>完全寛解維持</u>

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は，プラセボ群と比較してウパダシチニブ 15 mg QD 群の方が数値的に高かった（表 2.7.3-4）。この評価項目の達成には，被験者は，投与 52 週時の評価までに治験実施計画書に規定された CS 漸減投与を遵守し，CS の併用を必要としない状態にあることが必要であった。更に，ベースライン時の CS 用量（30 mg 以下，30 mg 超）及び新規発症若しくは再発性のいずれの状態であったかにかかわらず，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は，プラセボ群と比較してウパダシチニブ 15 mg QD 群の方が数値的に高かった（M16-852 52w CSR Table 14.2　3.1）。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は，プラセボ群と比較してウパダシチニブ 7.5 mg QD 群の方が数値的に高かった（表 2.7.3-4）。

投与 12 週時から投与 52 週時までの期間の完全寛解維持の評価項目の各要素の結果（追加解析）は，各要素を考慮した複合評価項目である投与 12 週時から投与 52 週時までの期間の完全寛解維持の結果と同様であった（M16-852 52w CSR Table 14.2　3.2）。

投与 24 週時の完全寛解及び投与 52 週時の完全寛解

投与 24 週時に完全寛解を達成した被験者の割合は，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 群の方が数値的に高かった（表 2.7.3-4，表 2.7.3.6-4）。

投与 52 週時に完全寛解を達成した被験者の割合は，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 群の方が数値的に高かった（表 2.7.3-4，表 2.7.3.6-4）。投与 52 週時の完全寛解の達成には，被験者は，その時点で CS の併用を必要としない状態にあることが必要であった。

2.7.3.2.3.2.2 再燃

投与 52 週時までの最初の再燃までの期間で評価した再燃のリスクは，プラセボ群と比較してウパダシチニブ 15 mg QD 群の方が数値的に低かった（層別ログランク検定）。ウパダシチニブ 15 mg QD 群のプラセボ群に対するハザード比（Cox 回帰モデルにより算出）は，0.57（95%CI：0.399–0.826）であった。投与 52 週時までの最初の再燃までの期間の中央値は，プラセボ群では 323.0 日であった。投与 52 週時までの最初の再燃までの期間の中央値は，プラセボ群と比較してウパダシチニブ 15 mg QD 群及び 7.5 mg QD 群の方が延長したが，第 1 ピリオドでは中央値が未到達であったため，推定しなかった（表 2.7.3-4）。

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は，プラセボ群と比較してウパダシチニブ 15 mg QD 群の方が数値的に低かった（表 2.7.3-4）。同様に，ベースライン時の CS 用量（30 mg 以下，30 mg 超）及び新規発症若しくは再発性のいずれの状態であったかにかかわらず，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は，プラセボ群と比較してウパダシチニブ 15 mg QD 群の方が数値的に低かった（M16-852 52w CSR Table 14.2　6.1）。また，投与 52 週時までの被験者あたりの再燃回数は，プラセボ群と比較してウパダシチニブ 15 mg QD 群の方が数値的に少なかった。これら 2 つの評価項目では，プラセボ群と比較してウパダシチニブ 7.5 mg QD 群でも同様の傾向が認められた（表 2.7.3-4）。

2.7.3.2.3.2.3 副腎皮質ステロイドの曝露量及び関連した有害事象

投与 52 週時までの CS の累積曝露量（中央値）は，プラセボ群（2882.0 mg）と比較してウパダシチニブ 15 mg QD 群（1615.0 mg）及びウパダシチニブ 7.5 mg QD 群（1905.0 mg）の方が数値的に少なかった（表 2.7.3-4，M16-852 52w CSR Table 14.2　4.1）。

また，治験実施計画書に規定された CS 漸減投与以外の追加の CS の累積曝露量（CS エスケープ療法及び治験実施計画書に規定された CS 漸減投与以外の併用薬として記録された CS の両者のみを含む）の追加解析を実施した。投与 52 週時までの治験実施計画書に規定された CS 漸減投与以外の追加の CS の累積曝露量の中央値は，プラセボ群（512.5 mg）と比較してウパダシチニブ 15 mg QD 群（20.0 mg）の方が少なかった（M16-852 52w CSR Table 14.2　4.3）。

投与 52 週時までの CS に関連した有害事象の発現率は，プラセボ群と比較してウパダシチニブ 15 mg QD 群及び 7.5 mg QD 群で同様であった（表 2.7.3-4）。

2.7.3.2.3.2.4 患者報告アウトカム

投与 52 週時の SF-36 PCS のベースラインからの変化量は，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 群の方が数値的に改善した（表 2.7.3-4）。

投与 52 週時の FACIT-Fatigue のベースラインからの変化量は，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 群の方が数値的に改善した（表 2.7.3-4）。

投与 52 週時の TSQM の患者の全般的満足度下位尺度の評価は，プラセボ群と比較してウパダシチニブ 15 mg QD 群及び 7.5 mg QD 群で同様であった（表 2.7.3-4）。

2.7.3.2.3.3 追加評価項目

追加評価項目のうち，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，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の結果を示す。これらの追加評価項目では，ウパダシチニブ群で早期の有効性が認められた。他の追加評価項目の結果は M16-852 52w CSR に示した。

投与 52 週時までの各来院時の寛解

寛解を達成した被験者の割合は，投与 2 週時の早期にウパダシチニブ 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 群の方が数値的に高かった。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は，ベースライン後のいずれの来院時でも，プラセボ群と比較してウパダシチニブ 15 mg QD 群の方が数値的に高かった（表 2.7.3.6-3，M16-852 52w CSR Figure 14.2　26.1）。

投与 12 週時の完全寛解

投与 12 週時に完全寛解を達成した被験者の割合は，プラセボ群と比較してウパダシチニブ 15 mg QD 群及び 7.5 mg QD 群の方が高かった（表 2.7.3.6-4）。

各来院での SF-36

SF-36 PCS のベースラインからの変化量は，投与 12 週時の早期にプラセボ群と比較してウパダシチニブ 15 mg QD 群及び 7.5 mg QD 群の方が数値的に改善した。投与 12 週時に認められた SF-36 PCS の改善は，ウパダシチニブ 15 mg QD 群では投与 52 週時まで持続したが，7.5 mg QD 群では持続しなかった（表 2.7.3.6-5，M16-852 52w CSR Figure 14.2　23.1）。

各来院での FACIT-Fatigue

FACIT-Fatigue のベースラインからの変化量は，投与 8 週時の早期にプラセボ群と比較してウパダシチニブ 15 mg QD 群の方が数値的に改善し，この改善は投与 52 週時まで持続した（表 2.7.3.6-6，M16-852 52w CSR Figure 14.2　24.1）。

2.7.3.2.3.4　部分集団解析

主要評価項目の部分集団解析の結果，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］を含む）を通して，プラセボ群と比較してウパダシチニブ 15 mg QD 群の方が一貫して高い有効性が認められた（M16-852 52w CSR Table 14.2　2.3）。

2.7.3.2.3.5　日本人部分集団の有効性解析

日本人部分集団の解析結果は M16-852 52w JA に示した。

2.7.3.2.3.5.1　人口統計学的特性及びその他のベースラインの特性

M16-852 試験の第 1 ピリオドの日本人被験者の人口統計学的特性を表 2.7.3.6-7 に示す。日本人部分集団では，人口統計学的特性は，全体で，多くの被験者が女性（80.0%［16/20 例］），たばこ製品の使用歴なし（70.0%［14/20 例］），及び 65 歳以上（90.0%［18/20 例］。65 歳以上 75 歳未満が 45.0%［9/20 例］，75 歳以上が 45.0%［9/20 例］）であった。BMI の平均値（SD）は 20.5033 kg/m^2（2.9062）であった。

M16-852 試験の第 1 ピリオドで，日本人部分集団では，ベースラインの疾患特性は，多くの被験者がベースライン時に新規発症 GCA（ウパダシチニブ群合計 86.7%［13/15 例］，プラセボ群 80.0%［4/5 例］），IL-6 阻害薬の前治療歴なし（ウパダシチニブ群合計 100%［15/15 例］，プラセボ群 100%［5/5 例］）であった。ベースライン時の CS 用量の平均値は，ウパダシチニブ群合計が 26.7 mg，プラセボ群が 30.0 mg であった。ベースライン時の CS 用量が 30 mg 以下であった被験者の割合は，ウパダシチニブ群とプラセボ群で同様であった（ウパダシチニブ群合計 80.0%［12/15 例］，プラセボ群 80.0%［4/5 例］）。診断後の罹病期間の中央値（範囲）は，ウパダシチニブ群合計が 36.0 日（22–273），プラセボ群が 42.0 日（16–195）であった（M16-852 52w JA Table 14.1　5.1 J）。

ベースラインでは，CRP の平均値は，ウパダシチニブ群合計が 3.819 mg/L，プラセボ群が 1.028 mg/L であった。ESR の平均値は，ウパダシチニブ群合計が 10.3 mm/hr，プラセボ群が

17.6 mm/hr であった。FACIT-Fatigue の平均値は，ウパダシチニブ群合計が 36.7，プラセボ群が 38.8 であった（M16-852 52w JA Table 14.1　5.1 J）。

2.7.3.2.3.5.2　　被験者の内訳

M16-852 試験の第 1 ピリオドの日本人部分集団の被験者の内訳を表 2.7.3-5 に示す。第 1 ピリオドでは，ランダム化した日本人被験者は 20 例（ウパダシチニブ 15 mg QD 群 10 例，7.5 mg QD 群 5 例，プラセボ群 5 例）であり，全被験者に治験薬を 1 回以上投与した。全体で，第 1 ピリオドを完了した被験者の割合は 90.0%（18/20 例）であった。第 1 ピリオドでは，試験を中止した被験者の割合は，ウパダシチニブ 15 mg QD 群が 10.0%（1/10 例），7.5 mg QD 群が 20.0%（1/5 例），プラセボ群が 0%（0/5 例）であり，試験中止の主な理由はいずれも同意撤回であった。

表 2.7.3-5. 被験者の内訳（M16-852 試験の第 1 ピリオド，FAS1，日本人部分集団）

	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 (%)	Overall Total (N 20) n (%)
Received randomized study drug	5 (100)	5 (100)	10 (100)	15 (100)	20 (100)
Completed Period 1	5 (100)	4 (80.0)	9 (90.0)	13 (86.7)	18 (90.0)
Ongoing in Period 1	0	0	0	0	0
Discontinued study in Period 1	0	1 (20.0)	1 (10.0)	2 (13.3)	2 (10.0)
All reasons for discontinuation$					
Adverse event	0	1 (20.0)	0	1 (6.7)	1 (5.0)
Withdrew consent	0	1 (20.0)	1 (10.0)	2 (13.3)	2 (10.0)
Lost to follow up	0	0	0	0	0
COVID 19 infection	0	0	0	0	0
COVID 19 logistical restrictions	0	0	0	0	0
Failure to meet continuation criteria	0	0	0	0	0
Other	0	1 (20.0)	0	1 (6.7)	1 (5.0)
Primary reason for discontinuation					
Adverse event	0	0	0	0	0
Withdrew consent	0	1 (20.0)	1 (10.0)	2 (13.3)	2 (10.0)
Lost to follow up	0	0	0	0	0
COVID 19 infection	0	0	0	0	0
COVID 19 logistical restrictions	0	0	0	0	0
Failure to meet continuation criteria	0	0	0	0	0
Other	0	0	0	0	0

Note: $ Subjects who discontinued study drug are counted under each reason given for discontinuation, therefore, the sum of the counts given for the reasons may be greater than the overall number of discontinuations.
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.

	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 (%)	Overall Total (N 20) n (%)
Completed study drug in Period 1	5 (100)	4 (80.0)	9 (90.0)	13 (86.7)	18 (90.0)
Ongoing study drug in Period 1	0	0	0	0	0
Discontinued study drug in Period 1	0	1 (20.0)	1 (10.0)	2 (13.3)	2 (10.0)
All reasons for discontinuation$					
Adverse event	0	1 (20.0)	0	1 (6.7)	1 (5.0)
Withdrew consent	0	1 (20.0)	1 (10.0)	2 (13.3)	2 (10.0)
Lost to follow up	0	0	0	0	0
Lack of efficacy	0	1 (20.0)	0	1 (6.7)	1 (5.0)
COVID 19 infection	0	0	0	0	0
COVID 19 logistical restrictions	0	0	0	0	0
Other	0	0	0	0	0
Primary reason for discontinuation					
Adverse event	0	0	0	0	0
Withdrew consent	0	1 (20.0)	1 (10.0)	2 (13.3)	2 (10.0)
Lost to follow up	0	0	0	0	0
Lack of efficacy	0	0	0	0	0
COVID 19 infection	0	0	0	0	0
COVID 19 logistical restrictions	0	0	0	0	0
Other	0	0	0	0	0

Note: $ Subjects who discontinued study drug are counted under each reason given for discontinuation, therefore, the sum of the counts given for the reasons may be greater than the overall number of discontinuations.
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.

Cross reference: M16 852 52w JA Table 14.1 2.1 J

2.7.3.2.3.5.3 有効性の結果

日本人部分集団での主要評価項目及び副次評価項目の結果を表 2.7.3-6 に示す。

表 2.7.3-6. 主要評価項目及び副次評価項目の結果（M16-852 試験，FAS1，日本人部分集団）

Endpoint # / Treatment	N	Within Group Point Estimate [95% CI]	Between Group Difference (UPA Placebo) Point Estimate [95% CI] $
Proportion of subjects achieving sustained remission at Week 52 (%)			
PBO + 52 WK CS T	5	40.0 [0.0, 82.9]	
UPA 7.5 + 26 WK CS T	5	20.0 [0.0, 55.1]	20.0 [75.4, 35.4]
UPA 15 + 26 WK CS T	10	70.0 [41.6, 98.4]	30.0 [21.5, 81.5]
Proportion of subjects achieving sustained complete remission from Week 12 through Week 52 (%)			
PBO + 52 WK CS T	5	20.0 [0.0, 55.1]	
UPA 7.5 + 26 WK CS T	5	0.0 [0.0, 0.0]	20.0 [55.1, 15.1]
UPA 15 + 26 WK CS T	10	70.0 [41.6, 98.4]	50.0 [4.9, 95.1]
Cumulative CS exposure through Week 52 (mg)			
PBO + 52 WK CS T	5	2422.0 [2092.00, 6328.00]	
UPA 7.5 + 26 WK CS T	4	2318.0 [825.00, 4819.00]	
UPA 15 + 26 WK CS T	9	1150.0 [825.00, 1615.00]	
Time to first disease flare through Week 52 (days)			
PBO + 52 WK CS T	5	NE [71.00, NE]	
UPA 7.5 + 26 WK CS T	5	225.0 [8.00, NE]	2.13 [0.351, 12.877]
UPA 15 + 26 WK CS T	10	NE [NE, NE]	0.00 [0.000, NE]
Proportion of subjects who experience at least 1 disease flare through Week 52 (%)			
PBO + 52 WK CS T	5	40.0 [11.8, 87.4]	
UPA 7.5 + 26 WK CS T	5	60.0 [24.7, 94.8]	2.25 [0.18, 28.26]
UPA 15 + 26 WK CS T	10	0.0 [0.0, 0.0]	0.00 [NA, NA]
Proportion of subjects in complete remission at Week 52 (%)			
PBO + 52 WK CS T	5	20.0 [0.0, 55.1]	
UPA 7.5 + 26 WK CS T	5	40.0 [0.0, 82.9]	20.0 [35.4, 75.4]
UPA 15 + 26 WK CS T	10	80.0 [55.2, 100.0]	60.0 [17.1, 100.0]

Endpoint # Treatment	N	Within Group Point Estimate [95% CI]	Between Group Difference (UPA Placebo) Point Estimate [95% CI] $
Proportion of subjects in complete remission at Week 24 (%)			
PBO + 52 WK CS T	5	40.0 [0.0, 82.9]	
UPA 7.5 + 26 WK CS T	5	40.0 [0.0, 82.9]	0.0 [60.7, 60.7]
UPA 15 + 26 WK CS T	10	80.0 [55.2, 100.0]	40.0 [9.6, 89.6]
Change from Baseline in the 36 item Short Form Quality of Life Questionnaire (SF 36) Physical Component Score (PCS) at Week 52			
PBO + 52 WK CS T	3	2.5634 [7.5262, 12.6530]	
UPA 7.5 + 26 WK CS T	1	8.5049 [7.9092, 24.9191]	5.9415 [13.2527, 25.1358]
UPA 15 + 26 WK CS T	8	1.9861 [8.8106, 4.8385]	4.5494 [16.7637, 7.6648]
Number of disease flares per subject through Week 52			
PBO + 52 WK CS T	5	0.4 [0.1, 1.6]	
UPA 7.5 + 26 WK CS T	5	0.7 [0.2, 2.2]	1.7 [0.3, 10.5]
UPA 15 + 26 WK CS T	10	0.0 [0.0, 0.0]	0.0 [0.0, 0.0]
Change from Baseline in Functional Assessment of Chronic Illness Therapy Fatigue (FACIT Fatigue) at Week 52			
PBO + 52 WK CS T	3	0.8 [10.78, 9.20]	
UPA 7.5 + 26 WK CS T	1	3.8 [21.79, 14.20]	3.0 [23.51, 17.50]
UPA 15 + 26 WK CS T	8	2.5 [8.39, 3.40]	1.7 [13.30, 9.90]
Assessment of Treatment Satisfaction Questionnaire for Medication (TSQM) patient global satisfaction subscale at Week 52			
PBO + 52 WK CS T	3	75.8732 [61.0374, 90.7090]	
UPA 7.5 + 26 WK CS T	1	58.6454 [34.6295, 82.6613]	17.2278 [45.4353, 10.9798]
UPA 15 + 26 WK CS T	8	64.7964 [55.1657, 74.4270]	11.0769 [28.7581, 6.6044]
Rate of CS related AEs through Week 52			
PBO + 52 WK CS T	5	0.2 [0.0, 1.1]	
UPA 7.5 + 26 WK CS T	5	0.5 [0.2, 1.3]	2.4 [0.3, 17.5]
UPA 15 + 26 WK CS T	10	1.0 [0.4, 2.3]	5.0 [0.7, 35.0]

Endpoint # Treatment	N	Within Group Point Estimate [95% CI]	Between Group Difference (UPA Placebo) Point Estimate [95% CI] $

Note: Within group estimate: Percentage for categorical endpoints, median for cumulative CS exposure and time to first disease flare, least squares mean for continuous endpoints, and mean number of event rate per patient year for number of disease flares per subject and rate of CS related AEs. Between group estimate: hazard ratio for time to first disease flare, odds ratio for proportion of subjects who experience at least 1 disease flare, difference in least squares means for continuous endpoints, difference in percentages for categorical endpoints.
Results for categorical endpoints (except for proportion of subjects who experience at least 1 disease flare) are based on the normal approximation to the binomial distribution with non responder imputation incorporating multiple imputation to handle missing data due to COVID 19 (NRI MI).
Number of disease flares per subject and rate of CS related AEs are assessed as events per patient years based on Poisson model with log (duration of study participation in years) as an offset. Robust standard error is used in inference (except for number of disease flares per subject).
Results for continuous endpoints (except for cumulative CS dose) are based on MMRM.
Time to first disease flare is based on Kaplan Meier Method.
$ Point estimate and 95% CI for treatment difference are based on the normal approximation to the binomial distribution for categorical endpoints, MMRM for continuous endpoints (except for cumulative CS exposure), Cox model for time to first disease flare, and Poisson model for Number of disease flares per subject and Rate of CS related AEs.
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.

Cross reference: M16 852 52w JA Table 14.2 1.2 J

2.7.3.2.3.5.3.1 主要評価項目

日本人部分集団では，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（40.0%）と比較してウパダシチニブ 15 mg QD 群（70.0%）の方が高かった（プラセボ群との割合の差 30.0%）（表 2.7.3-6）。

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（40.0%）と比較してウパダシチニブ 7.5 mg QD 群（20.0%）の方が低かった（プラセボ群との割合の差–20.0%）（表 2.7.3-6）。

日本人集団での主要評価項目の結果は，プラセボ群と比較し，ウパダシチニブ 15mg 群で数値的に高い有効性を示し，全体集団と同様の傾向が認められた。ウパダシチニブ 7.5mg 群ではプラセボ群より数値的に低かった。なお，日本人集団は症例数が限られており，解釈には注意が必要である。

2.7.3.2.3.5.3.2 副次評価項目

日本人部分集団では，完全寛解，再燃及び CS の累積曝露量に関連した副次評価項目では，プラセボ群と比較してウパダシチニブ 15 mg QD 群の方がおおむね高い有効性が認められた（表 2.7.3-6）。

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は，プラセボ群と比較してウパダシチニブ 15 mg QD 群の方が高かったが，プラセボ群と比較してウパダシチニブ 7.5 mg QD 群の方が低かった（表 2.7.3-6）。

投与 24 週時に完全寛解を達成した被験者の割合は，プラセボ群と比較してウパダシチニブ 15 mg QD 群の方が高かったが，プラセボ群と比較してウパダシチニブ 7.5 mg QD 群で同様であった（表 2.7.3-6，表 2.7.3.6-9）。

投与 52 週時に完全寛解を達成した被験者の割合は，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 群の方が高かった（表 2.7.3-6，表 2.7.3.6-9）。

投与 52 週時までの最初の再燃までの期間の中央値は，ウパダシチニブ 7.5 mg QD 群が 225.0 日と推定されたが，15 mg QD 群及びプラセボ群は再燃をきたした被験者数の影響により，推定できなかった（表 2.7.3-6）。

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は，プラセボ群と比較してウパダシチニブ 15 mg QD 群の方が低かったが，プラセボ群と比較してウパダシチニブ 7.5 mg QD 群の方が高かった（表 2.7.3-6）。

投与 52 週時までの被験者あたりの再燃回数は，プラセボ群と比較してウパダシチニブ 15 mg QD 群の方が少なかったが，プラセボ群と比較してウパダシチニブ 7.5 mg QD 群の方が多かった（表 2.7.3-6）。

投与 52 週時までの CS の累積曝露量（中央値）は，プラセボ群（2422.0 mg）と比較してウパダシチニブ 15 mg QD 群（1150.0 mg）の方が少なかったが，プラセボ群（2422.0 mg）と比較してウパダシチニブ 7.5 mg QD 群（2318.0 mg）で同様であった（表 2.7.3-6，M16-852 52w JA Table 14.2　4.1 J）。

投与 52 週時までの CS に関連した有害事象の発現率は，プラセボ群と比較してウパダシチニブ 15 mg QD 群及び 7.5 mg QD 群でおおむね同様であった（表 2.7.3-6）。

投与 52 週時の SF-36 PCS のベースラインからの変化量は，プラセボ群と比較してウパダシチニブ 15 mg QD 群で改善は認められなかったが，プラセボ群と比較してウパダシチニブ 7.5 mg QD 群の方が改善した（表 2.7.3-6）。

投与 52 週時の FACIT-Fatigue のベースラインからの変化量は，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 群で改善は認められなかった（表 2.7.3-6）。

投与 52 週時の TSQM の患者の全般的満足度下位尺度の評価は，プラセボ群と比較してウパダシチニブ 15 mg QD 群及び 7.5 mg QD 群でおおむね同様であった（表 2.7.3-6）。

日本人集団での主な副次評価項目の結果は，全体集団とおおむね同様の傾向を示した。なお，日本人集団は症例数が限られており，解釈には注意が必要である。

2.7.3.2.3.5.3.3　追加評価項目

追加評価項目のうち，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（表 2.7.3.6-8），投与 12 週時に完全寛解を達成した被験者の割合（表 2.7.3.6-9），各来院での SF-36 のベースラインからの変化量（表 2.7.3.6-10），各来院での FACIT-Fatigue のベースラインからの変化量の結果（表 2.7.3.6-11）を付録に示す。

2.7.3.3　全試験を通しての結果の比較と解析

本承認申請は，評価試験 1 試験の結果に基づくため，本項は該当しない。

2.7.3.4　推奨用法・用量に関する臨床情報の解析

第 III 相試験の用量及び推奨用法用量の設定根拠は 1.8.3 項に示した。

2.7.3.5　効果の持続，耐薬性

本承認申請は，M16-852 試験の投与 52 週時まで（第 1 ピリオド）のみの有効性の結果に基づくため，本項は該当しない。

参考文献

1. Atkinson MJ, Sinha A, Hass SL, et al. Validation of a general measure of treatment satisfaction, the Treatment Satisfaction Questionnaire for Medication (TSQM), using a national panel study of chronic disease. Health Qual Life Outcomes. 2004;2:12.

2.7.3.6 付録

表 2.7.3.6-1. 臨床的有効性試験の要約（評価資料）

試験番号 / 資料番号 / 施設数 / 実施国 / 実施期間	開始日 / 終了日 / 登録例数 / 登録目標例数	デザイン 対照の種類	治験薬及び 対照薬の用量 投与経路及び 投与方法	試験の目的	投与群ごとの 登録例数 / 完了例数	性別： 男性 / 女性 年齢の中央値 （範囲）	診断 選択基準	主要評価項目
M16 852 / 5.3.5.1 1 項 / 100 施設 / 日本を含む 23 ヵ国 / 第 1 ピリオド: 52 週間	2019 年 2 月 6 日（FSFV） / 2024 年 2 月 6 日（LSLV） / 428 例 / 420 例	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	ウパダシチニブ 7.5 mg，15 mg QD 経口 プラセボ QD 経口 prednisone / プレドニゾロン 20 mg，30 mg，40 mg，50 mg 又は 60 mg QD 経口	第 1 ピリオド GCA 患者を対象に，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 QD 及び 15 mg QD と 26 週間の 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。	第 1 ピリオド • ウパダシチニブ 15 mg QD 群 209 例 / 177 例 • ウパダシチニブ 7.5 mg QD 群 107 例 / 85 例 • プラセボ群 112 例 / 86 例	第 1 ピリオド 115 例 / 313 例 72.0 歳（51 88）	ベースライン前 8 週間以内に活動性 GCA（新規発症又は再発性）と診断された 50 歳以上の成人患者	投与 52 週時に寛解維持を達成した被験者の割合

FSFV 最初の被験者の初回来院日，LSLV 最後の被験者の最終来院日

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表 2.7.3.6-2

[redacted]20[redacted] 19:09 <[redacted]>

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

TABLE 14.1__4.1

Demographic Characteristics
(FAS1)

	PBO + 52 WK CS-T (N=112)	UPA 7.5 + 26 WK CS-T (N=107)	UPA 15 + 26 WK CS-T (N=209)	UPA Total (N=316)	Overall Total (N=428)
Sex - n (%)					
Female	77 (68.8)	80 (74.8)	156 (74.6)	236 (74.7)	313 (73.1)
Male	35 (31.3)	27 (25.2)	53 (25.4)	80 (25.3)	115 (26.9)
Race - n (%)					
White	103 (92.0)	99 (92.5)	199 (95.2)	298 (94.3)	401 (93.7)
Black or African American	2 (1.8)	1 (0.9)	0	1 (0.3)	3 (0.7)
Asian	6 (5.4)	6 (5.6)	10 (4.8)	16 (5.1)	22 (5.1)
American Indian or Alaska Native	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	1 (0.9)	0	1 (0.3)	1 (0.2)
Multiple	1 (0.9)	0	0	0	1 (0.2)
Race Group - n (%)					
White	103 (92.0)	99 (92.5)	199 (95.2)	298 (94.3)	401 (93.7)
Non-White	9 (8.0)	8 (7.5)	10 (4.8)	18 (5.7)	27 (6.3)
Ethnicity - n (%)					
Hispanic or Latino	5 (4.5)	2 (1.9)	6 (2.9)	8 (2.5)	13 (3.0)
Not Hispanic or Latino	107 (95.5)	105 (98.1)	203 (97.1)	308 (97.5)	415 (97.0)
Age (year)					
n	112	107	209	316	428
Mean (SD)	71.6 (7.33)	71.1 (7.55)	70.8 (7.31)	70.9 (7.39)	71.1 (7.37)
Median	72.0	72.0	71.0	72.0	72.0
Min, Max	52, 87	54, 88	51, 88	51, 88	51, 88

Note: Percentages calculated on non-missing values.
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 14.1__4.1

Demographic Characteristics
(FAS1)

	PBO + 52 WK CS-T (N=112)	UPA 7.5 + 26 WK CS-T (N=107)	UPA 15 + 26 WK CS-T (N=209)	UPA Total (N=316)	Overall Total (N=428)
Age Group 1 (year) - n (%)					
< 65	17 (15.2)	19 (17.8)	42 (20.1)	61 (19.3)	78 (18.2)
>= 65	95 (84.8)	88 (82.2)	167 (79.9)	255 (80.7)	350 (81.8)
Age Group 2 (year) - n (%)					
< 65	17 (15.2)	19 (17.8)	42 (20.1)	61 (19.3)	78 (18.2)
>= 65 and < 75	59 (52.7)	49 (45.8)	102 (48.8)	151 (47.8)	210 (49.1)
>= 75	36 (32.1)	39 (36.4)	65 (31.1)	104 (32.9)	140 (32.7)
Weight (kg)					
n	112	107	207	314	426
Mean (SD)	71.1325 (16.0343)	67.8694 (15.6592)	68.9875 (15.9459)	68.6065 (15.8327)	69.2706 (15.9060)
Median	68.0000	65.2000	67.0000	66.5000	67.1500
Min, Max	37.600, 160.500	32.700, 117.600	35.380, 159.936	32.700, 159.936	32.700, 160.500
Height (cm)					
n	112	106	206	312	424
Mean (SD)	165.593 (9.8440)	163.803 (9.1333)	164.873 (9.2901)	164.509 (9.2364)	164.796 (9.4011)
Median	165.750	163.000	165.000	164.000	164.000
Min, Max	148.00, 192.00	141.00, 187.96	142.00, 187.00	141.00, 187.96	141.00, 192.00
Body Mass Index (kg/m^2)					
n	112	106	206	312	424
Mean (SD)	25.8012 (4.3233)	25.2169 (5.1322)	25.2650 (4.6390)	25.2487 (4.8040)	25.3946 (4.6832)
Median	25.1227	24.9878	24.7697	24.8469	24.9712
Min, Max	16.039, 45.430	14.475, 43.459	11.959, 47.820	11.959, 47.820	11.959, 47.820

Note: Percentages calculated on non-missing values.
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 14.1__4.1

Demographic Characteristics
(FAS1)

	PBO + 52 WK CS-T (N=112)	UPA 7.5 + 26 WK CS-T (N=107)	UPA 15 + 26 WK CS-T (N=209)	UPA Total (N=316)	Overall Total (N=428)
Body Mass Index (kg/m^2) - n (%)					
< 25	53 (47.3)	53 (50.0)	108 (52.4)	161 (51.6)	214 (50.5)
>= 25 and < 30	41 (36.6)	39 (36.8)	70 (34.0)	109 (34.9)	150 (35.4)
>= 30	18 (16.1)	14 (13.2)	28 (13.6)	42 (13.5)	60 (14.2)
Missing	0	1	3	4	4
Geographic Region - n (%)					
North America	10 (8.9)	12 (11.2)	9 (4.3)	21 (6.6)	31 (7.2)
Western Europe	62 (55.4)	63 (58.9)	135 (64.6)	198 (62.7)	260 (60.7)
Eastern Europe	9 (8.0)	5 (4.7)	16 (7.7)	21 (6.6)	30 (7.0)
Asia	7 (6.3)	6 (5.6)	10 (4.8)	16 (5.1)	23 (5.4)
Japan	5 (4.5)	5 (4.7)	10 (4.8)	15 (4.7)	20 (4.7)
Oceania	24 (21.4)	21 (19.6)	39 (18.7)	60 (19.0)	84 (19.6)
Nicotine User - n(%)					
Current	13 (11.6)	7 (6.5)	32 (15.3)	39 (12.3)	52 (12.1)
Former	33 (29.5)	32 (29.9)	63 (30.1)	95 (30.1)	128 (29.9)
Never	66 (58.9)	68 (63.6)	111 (53.1)	179 (56.6)	245 (57.2)
Unknown	0	0	3 (1.4)	3 (0.9)	3 (0.7)
Alcohol User - n(%)					
Current	58 (51.8)	57 (53.3)	117 (56.0)	174 (55.1)	232 (54.2)
Former	14 (12.5)	13 (12.1)	27 (12.9)	40 (12.7)	54 (12.6)
Never	40 (35.7)	37 (34.6)	60 (28.7)	97 (30.7)	137 (32.0)
Unknown	0	0	5 (2.4)	5 (1.6)	5 (1.2)

Note: Percentages calculated on non-missing values.
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 2.7.3.6-3

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

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Response Rate Diff Compared to Placebo Adjusted Diff(%)	Response Rate Diff Compared to Placebo [95% CI] #	Response Rate Diff Compared to Placebo P-value @
Week 2								
All								
PBO + 52 WK CS-T	112	89 (79.5)	[72.0, 86.9]	0				
UPA 7.5 + 26 WK CS-T	107	79 (73.8)	[65.5, 82.2]	0	-5.6	-5.7	[-16.6, 5.3]	0.3121
UPA 15 + 26 WK CS-T	209	176 (84.2)	[79.3, 89.2]	0	4.7	4.4	[-4.3, 13.1]	0.3226
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	47 (79.7)	[69.4, 89.9]	0				
UPA 7.5 + 26 WK CS-T	55	41 (74.5)	[63.0, 86.1]	0	-5.1		[-20.5, 10.3]	
UPA 15 + 26 WK CS-T	110	93 (84.5)	[77.8, 91.3]	0	4.9		[-7.4, 17.2]	
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	42 (79.2)	[68.3, 90.2]	0				
UPA 7.5 + 26 WK CS-T	52	38 (73.1)	[61.0, 85.1]	0	-6.2		[-22.4, 10.1]	
UPA 15 + 26 WK CS-T	99	83 (83.8)	[76.6, 91.1]	0	4.6		[-8.5, 17.7]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Response Rate Diff Compared to Placebo Adjusted Diff(%)	Response Rate Diff Compared to Placebo [95% CI] #	Response Rate Diff Compared to Placebo P-value @
Week 2								
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	63 (82.9)	[74.4, 91.4]	0				
UPA 7.5 + 26 WK CS-T	75	55 (73.3)	[63.3, 83.3]	0	-9.6		[-22.7, 3.5]	
UPA 15 + 26 WK CS-T	148	128 (86.5)	[81.0, 92.0]	0	3.6		[-6.5, 13.7]	
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	26 (72.2)	[57.6, 86.9]	0				
UPA 7.5 + 26 WK CS-T	32	24 (75.0)	[60.0, 90.0]	0	2.8		[-18.2, 23.7]	
UPA 15 + 26 WK CS-T	61	48 (78.7)	[68.4, 89.0]	0	6.5		[-11.4, 24.3]	
Week 4								
All								
PBO + 52 WK CS-T	112	87 (77.7)	[70.0, 85.4]	0				
UPA 7.5 + 26 WK CS-T	107	80 (74.8)	[66.5, 83.0]	0	-2.9	-2.8	[-13.8, 8.3]	0.6257
UPA 15 + 26 WK CS-T	209	173 (82.8)	[77.7, 87.9]	0	5.1	4.9	[-4.1, 14.0]	0.2830

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	Adjusted [95% CI] #	P-value @
Week 4								
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	48 (81.4)	[71.4, 91.3]	0				
UPA 7.5 + 26 WK CS-T	55	42 (76.4)	[65.1, 87.6]	0	-5.0		[-20.0, 10.0]	
UPA 15 + 26 WK CS-T	110	95 (86.4)	[80.0, 92.8]	0	5.0		[-6.8, 16.8]	
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	39 (73.6)	[61.7, 85.5]	0				
UPA 7.5 + 26 WK CS-T	52	38 (73.1)	[61.0, 85.1]	0	-0.5		[-17.4, 16.4]	
UPA 15 + 26 WK CS-T	99	78 (78.8)	[70.7, 86.8]	0	5.2		[-9.1, 19.5]	
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	59 (77.6)	[68.3, 87.0]	0				
UPA 7.5 + 26 WK CS-T	75	54 (72.0)	[61.8, 82.2]	0	-5.6		[-19.5, 8.2]	
UPA 15 + 26 WK CS-T	148	123 (83.1)	[77.1, 89.1]	0	5.5		[-5.7, 16.6]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 4								
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	28 (77.8)	[64.2, 91.4]	0				
UPA 7.5 + 26 WK CS-T	32	26 (81.3)	[67.7, 94.8]	0	3.5		[-15.7, 22.6]	
UPA 15 + 26 WK CS-T	61	50 (82.0)	[72.3, 91.6]	0	4.2		[-12.5, 20.8]	
Week 8								
All								
PBO + 52 WK CS-T	112	74 (66.1)	[57.3, 74.8]	0				
UPA 7.5 + 26 WK CS-T	107	73 (68.2)	[59.4, 77.0]	0	2.2	2.4	[-9.6, 14.5]	0.6903
UPA 15 + 26 WK CS-T	209	160 (76.5)	[70.8, 82.3]	0	10.4	10.1	[0.0, 20.3]	0.0496*
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	44 (74.6)	[63.5, 85.7]	0				
UPA 7.5 + 26 WK CS-T	55	41 (74.5)	[63.0, 86.1]	0	-0.0		[-16.0, 16.0]	
UPA 15 + 26 WK CS-T	110	89 (80.9)	[73.6, 88.3]	0	6.3		[-7.0, 19.7]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	Adjusted [95% CI] #	P-value @
Week 8								
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	30 (56.6)	[43.3, 69.9]	0				
UPA 7.5 + 26 WK CS-T	52	32 (61.5)	[48.3, 74.8]	0	4.9		[-13.9, 23.7]	
UPA 15 + 26 WK CS-T	99	71 (71.6)	[62.7, 80.5]	0	15.0		[-1.0, 31.1]	
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	51 (67.1)	[56.5, 77.7]	0				
UPA 7.5 + 26 WK CS-T	75	47 (62.7)	[51.7, 73.6]	0	-4.4		[-19.7, 10.8]	
UPA 15 + 26 WK CS-T	148	115 (77.6)	[70.9, 84.4]	0	10.5		[-2.0, 23.1]	
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	23 (63.9)	[48.2, 79.6]	0				
UPA 7.5 + 26 WK CS-T	32	26 (81.3)	[67.7, 94.8]	0	17.4		[-3.4, 38.1]	
UPA 15 + 26 WK CS-T	61	45 (73.8)	[62.7, 84.8]	0	9.9		[-9.3, 29.1]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 12								
All								
PBO + 52 WK CS-T	112	71 (63.4)	[54.5, 72.3]	0				
UPA 7.5 + 26 WK CS-T	107	73 (68.2)	[59.4, 77.0]	0	4.8	5.1	[-7.2, 17.4]	0.4148
UPA 15 + 26 WK CS-T	209	152 (72.6)	[66.6, 78.7]	0	9.3	9.2	[-1.4, 19.8]	0.0897
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	43 (72.9)	[61.5, 84.2]	0				
UPA 7.5 + 26 WK CS-T	55	42 (76.4)	[65.1, 87.6]	0	3.5		[-12.5, 19.4]	
UPA 15 + 26 WK CS-T	110	84 (76.4)	[68.4, 84.3]	0	3.5		[-10.4, 17.3]	
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	28 (52.8)	[39.4, 66.3]	0				
UPA 7.5 + 26 WK CS-T	52	31 (59.6)	[46.3, 73.0]	0	6.8		[-12.1, 25.7]	
UPA 15 + 26 WK CS-T	99	68 (68.5)	[59.3, 77.7]	0	15.7		[-0.6, 32.0]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 12								
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	46 (60.5)	[49.5, 71.5]	0				
UPA 7.5 + 26 WK CS-T	75	49 (65.3)	[54.6, 76.1]	0	4.8		[-10.6, 20.2]	
UPA 15 + 26 WK CS-T	148	109 (73.5)	[66.4, 80.7]	0	13.0		[-0.1, 26.1]	
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	25 (69.4)	[54.4, 84.5]	0				
UPA 7.5 + 26 WK CS-T	32	24 (75.0)	[60.0, 90.0]	0	5.6		[-15.7, 26.8]	
UPA 15 + 26 WK CS-T	61	43 (70.5)	[59.0, 81.9]	0	1.0		[-17.9, 20.0]	
Week 16								
All								
PBO + 52 WK CS-T	112	64 (57.1)	[48.0, 66.3]	0				
UPA 7.5 + 26 WK CS-T	107	68 (63.6)	[54.4, 72.7]	0	6.4	6.7	[-6.1, 19.4]	0.3061
UPA 15 + 26 WK CS-T	209	151 (72.2)	[66.1, 78.3]	0	15.0	14.9	[4.1, 25.8]	0.0071**

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	Adjusted [95% CI] #	P-value @
Week 16								
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	38 (64.4)	[52.2, 76.6]	0				
UPA 7.5 + 26 WK CS-T	55	38 (69.1)	[56.9, 81.3]	0	4.7		[-12.6, 22.0]	
UPA 15 + 26 WK CS-T	110	85 (77.3)	[69.4, 85.1]	0	12.9		[-1.6, 27.4]	
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	26 (49.1)	[35.6, 62.5]	0				
UPA 7.5 + 26 WK CS-T	52	30 (57.7)	[44.3, 71.1]	0	8.6		[-10.4, 27.6]	
UPA 15 + 26 WK CS-T	99	66 (66.5)	[57.2, 75.9]	0	17.5		[1.1, 33.8]	
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	42 (55.3)	[44.1, 66.4]	0				
UPA 7.5 + 26 WK CS-T	75	45 (60.0)	[48.9, 71.1]	0	4.7		[-11.0, 20.5]	
UPA 15 + 26 WK CS-T	148	108 (72.9)	[65.7, 80.1]	0	17.6		[4.3, 30.9]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 16								
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	22 (61.1)	[45.2, 77.0]	0				
UPA 7.5 + 26 WK CS-T	32	23 (71.9)	[56.3, 87.5]	0	10.8		[-11.5, 33.0]	
UPA 15 + 26 WK CS-T	61	43 (70.5)	[59.0, 81.9]	0	9.4		[-10.2, 29.0]	
Week 20								
All								
PBO + 52 WK CS-T	112	63 (56.2)	[47.0, 65.4]	0				
UPA 7.5 + 26 WK CS-T	107	61 (57.0)	[47.6, 66.4]	0	0.8	0.9	[-12.1, 13.9]	0.8904
UPA 15 + 26 WK CS-T	209	139 (66.4)	[60.0, 72.9]	0	10.2	10.1	[-1.0, 21.2]	0.0741
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	37 (62.7)	[50.4, 75.1]	0				
UPA 7.5 + 26 WK CS-T	55	33 (60.0)	[47.1, 72.9]	0	-2.7		[-20.6, 15.2]	
UPA 15 + 26 WK CS-T	110	77 (70.0)	[61.4, 78.6]	0	7.3		[-7.7, 22.3]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	Adjusted [95% CI] #	P-value @
Week 20								
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	26 (49.0)	[35.5, 62.5]	0				
UPA 7.5 + 26 WK CS-T	52	28 (53.8)	[40.3, 67.4]	0	4.9		[-14.3, 24.0]	
UPA 15 + 26 WK CS-T	99	62 (62.5)	[52.9, 72.1]	0	13.5		[-3.0, 30.0]	
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	42 (55.2)	[44.0, 66.4]	0				
UPA 7.5 + 26 WK CS-T	75	43 (57.3)	[46.1, 68.5]	0	2.1		[-13.7, 17.9]	
UPA 15 + 26 WK CS-T	148	99 (66.8)	[59.2, 74.4]	0	11.6		[-1.9, 25.1]	
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	21 (58.3)	[42.2, 74.4]	0				
UPA 7.5 + 26 WK CS-T	32	18 (56.3)	[39.1, 73.4]	0	-2.1		[-25.6, 21.5]	
UPA 15 + 26 WK CS-T	61	40 (65.6)	[53.7, 77.5]	0	7.2		[-12.8, 27.3]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 24								
All								
PBO + 52 WK CS-T	112	60 (53.4)	[44.1, 62.6]	0				
UPA 7.5 + 26 WK CS-T	107	52 (48.6)	[39.1, 58.1]	0	-4.8	-4.6	[-17.7, 8.5]	0.4937
UPA 15 + 26 WK CS-T	209	131 (62.5)	[56.0, 69.1]	0	9.2	8.9	[-2.2, 20.1]	0.1171
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	37 (62.7)	[50.4, 75.1]	0				
UPA 7.5 + 26 WK CS-T	55	28 (50.9)	[37.7, 64.1]	0	-11.8		[-29.9, 6.3]	
UPA 15 + 26 WK CS-T	110	75 (68.2)	[59.5, 76.9]	0	5.5		[-9.6, 20.6]	
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	23 (43.0)	[29.5, 56.4]	0				
UPA 7.5 + 26 WK CS-T	52	24 (46.2)	[32.6, 59.7]	0	3.2		[-15.9, 22.3]	
UPA 15 + 26 WK CS-T	99	56 (56.3)	[46.4, 66.1]	0	13.3		[-3.3, 30.0]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 24								
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	38 (49.7)	[38.4, 61.0]	0				
UPA 7.5 + 26 WK CS-T	75	37 (49.3)	[38.0, 60.6]	0	-0.4		[-16.3, 15.6]	
UPA 15 + 26 WK CS-T	148	96 (64.7)	[56.9, 72.4]	0	15.0		[1.3, 28.7]	
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	22 (61.1)	[45.2, 77.0]	0				
UPA 7.5 + 26 WK CS-T	32	15 (46.9)	[29.6, 64.2]	0	-14.2		[-37.7, 9.3]	
UPA 15 + 26 WK CS-T	61	35 (57.4)	[45.0, 69.8]	0	-3.7		[-23.9, 16.5]	
Week 28								
All								
PBO + 52 WK CS-T	112	57 (50.8)	[41.5, 60.1]	0				
UPA 7.5 + 26 WK CS-T	107	50 (46.7)	[37.3, 56.2]	0	-4.0	-3.8	[-16.9, 9.3]	0.5677
UPA 15 + 26 WK CS-T	209	124 (59.6)	[52.9, 66.2]	0	8.8	8.6	[-2.7, 19.8]	0.1359

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	Adjusted [95% CI] #	P-value @
Week 28								
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	35 (59.3)	[46.8, 71.9]	0				
UPA 7.5 + 26 WK CS-T	55	28 (50.9)	[37.7, 64.1]	0	-8.4		[-26.6, 9.8]	
UPA 15 + 26 WK CS-T	110	70 (63.5)	[54.5, 72.6]	0	4.2		[-11.2, 19.7]	
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	22 (41.3)	[27.9, 54.6]	0				
UPA 7.5 + 26 WK CS-T	52	22 (42.3)	[28.9, 55.7]	0	1.0		[-17.9, 20.0]	
UPA 15 + 26 WK CS-T	99	55 (55.1)	[45.3, 65.0]	0	13.9		[-2.7, 30.4]	
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	37 (48.5)	[37.2, 59.8]	0				
UPA 7.5 + 26 WK CS-T	75	34 (45.3)	[34.1, 56.6]	0	-3.2		[-19.1, 12.8]	
UPA 15 + 26 WK CS-T	148	90 (61.1)	[53.2, 69.0]	0	12.6		[-1.1, 26.4]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 28								
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	20 (55.6)	[39.3, 71.8]	0				
UPA 7.5 + 26 WK CS-T	32	16 (50.0)	[32.7, 67.3]	0	-5.6		[-29.3, 18.2]	
UPA 15 + 26 WK CS-T	61	34 (55.7)	[43.3, 68.2]	0	0.2		[-20.3, 20.6]	
Week 36								
All								
PBO + 52 WK CS-T	112	51 (45.3)	[36.1, 54.6]	0				
UPA 7.5 + 26 WK CS-T	107	50 (46.7)	[37.3, 56.2]	0	1.4	1.6	[-11.5, 14.7]	0.8089
UPA 15 + 26 WK CS-T	209	120 (57.6)	[50.9, 64.4]	0	12.3	12.1	[0.9, 23.4]	0.0350*
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	32 (54.2)	[41.5, 66.9]	0				
UPA 7.5 + 26 WK CS-T	55	28 (50.9)	[37.7, 64.1]	0	-3.3		[-21.7, 15.0]	
UPA 15 + 26 WK CS-T	110	68 (61.7)	[52.6, 70.8]	0	7.5		[-8.1, 23.1]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	Adjusted [95% CI] #	P-value @
Week 36								
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	19 (35.4)	[22.4, 48.4]	0				
UPA 7.5 + 26 WK CS-T	52	22 (42.3)	[28.9, 55.7]	0	6.9		[-11.8, 25.6]	
UPA 15 + 26 WK CS-T	99	53 (53.1)	[43.2, 63.0]	0	17.7		[1.4, 34.0]	
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	33 (43.1)	[31.9, 54.3]	0				
UPA 7.5 + 26 WK CS-T	75	34 (45.3)	[34.1, 56.6]	0	2.2		[-13.7, 18.1]	
UPA 15 + 26 WK CS-T	148	87 (59.1)	[51.1, 67.1]	0	16.0		[2.3, 29.7]	
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	18 (50.0)	[33.7, 66.3]	0				
UPA 7.5 + 26 WK CS-T	32	16 (50.0)	[32.7, 67.3]	0	0.0		[-23.8, 23.8]	
UPA 15 + 26 WK CS-T	61	33 (54.1)	[41.6, 66.6]	0	4.1		[-16.5, 24.7]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Response Rate Diff Compared to Placebo Adjusted Diff(%)	Response Rate Diff Compared to Placebo [95% CI] #	Response Rate Diff Compared to Placebo P-value @
Week 44								
All								
PBO + 52 WK CS-T	112	42 (37.2)	[28.2, 46.2]	0				
UPA 7.5 + 26 WK CS-T	107	51 (47.7)	[38.2, 57.1]	0	10.5	10.6	[-2.3, 23.5]	0.1072
UPA 15 + 26 WK CS-T	209	117 (56.1)	[49.3, 62.9]	0	18.9	18.6	[7.5, 29.6]	0.0010***
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	25 (42.4)	[29.8, 55.0]	0				
UPA 7.5 + 26 WK CS-T	55	29 (52.7)	[39.5, 65.9]	0	10.4		[-7.9, 28.6]	
UPA 15 + 26 WK CS-T	110	67 (60.7)	[51.5, 69.9]	0	18.3		[2.7, 33.9]	
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	17 (31.4)	[18.8, 44.0]	0				
UPA 7.5 + 26 WK CS-T	52	22 (42.3)	[28.9, 55.7]	0	10.9		[-7.5, 29.4]	
UPA 15 + 26 WK CS-T	99	51 (51.0)	[41.1, 60.9]	0	19.6		[3.6, 35.7]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 44								
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	30 (39.0)	[28.0, 50.0]	0				
UPA 7.5 + 26 WK CS-T	75	35 (46.7)	[35.4, 58.0]	0	7.7		[-8.1, 23.5]	
UPA 15 + 26 WK CS-T	148	85 (57.7)	[49.6, 65.7]	0	18.7		[5.0, 32.3]	
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	12 (33.3)	[17.9, 48.7]	0				
UPA 7.5 + 26 WK CS-T	32	16 (50.0)	[32.7, 67.3]	0	16.7		[-6.5, 39.8]	
UPA 15 + 26 WK CS-T	61	32 (52.3)	[39.8, 64.9]	0	19.0		[-0.9, 38.9]	
Week 52								
All								
PBO + 52 WK CS-T	112	37 (32.7)	[24.0, 41.4]	0				
UPA 7.5 + 26 WK CS-T	107	50 (46.7)	[37.3, 56.2]	0	14.0	14.0	[1.3, 26.8]	0.0305*
UPA 15 + 26 WK CS-T	209	111 (53.2)	[46.4, 60.0]	0	20.5	20.1	[9.2, 31.0]	0.0003***

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Response Rate Diff Compared to Placebo Adjusted Diff(%)	Response Rate Diff Compared to Placebo [95% CI] #	Response Rate Diff Compared to Placebo P-value @
Week 52								
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	21 (35.6)	[23.4, 47.8]	0				
UPA 7.5 + 26 WK CS-T	55	29 (52.7)	[39.5, 65.9]	0	17.1		[-0.8, 35.1]	
UPA 15 + 26 WK CS-T	110	67 (60.7)	[51.5, 69.8]	0	25.1		[9.8, 40.3]	
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	16 (29.5)	[17.1, 41.9]	0				
UPA 7.5 + 26 WK CS-T	52	21 (40.4)	[27.0, 53.7]	0	10.9		[-7.3, 29.1]	
UPA 15 + 26 WK CS-T	99	44 (44.8)	[35.0, 54.7]	0	15.4		[-0.5, 31.2]	
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	28 (36.4)	[25.5, 47.2]	0				
UPA 7.5 + 26 WK CS-T	75	34 (45.3)	[34.1, 56.6]	0	9.0		[-6.7, 24.6]	
UPA 15 + 26 WK CS-T	148	80 (54.2)	[46.2, 62.3]	0	17.9		[4.3, 31.4]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__17.1

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	Adjusted [95% CI] #	P-value @
Week 52								
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	9 (25.0)	[10.9, 39.1]	0				
UPA 7.5 + 26 WK CS-T	32	16 (50.0)	[32.7, 67.3]	0	25.0		[2.6, 47.4]	
UPA 15 + 26 WK CS-T	61	31 (50.6)	[38.0, 63.2]	0	25.6		[6.7, 44.5]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表 2.7.3.6-4

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

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 2								
All								
PBO + 52 WK CS-T	112	72 (63.8)	[54.9, 72.8]	1				
UPA 7.5 + 26 WK CS-T	107	68 (63.4)	[54.2, 72.6]	1	-0.4	-0.4	[-13.1, 12.2]	0.9462
UPA 15 + 26 WK CS-T	209	153 (73.2)	[67.2, 79.2]	0	9.4	8.9	[-1.7, 19.5]	0.0987
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	40 (66.9)	[54.8, 79.1]	1				
UPA 7.5 + 26 WK CS-T	55	36 (65.2)	[52.5, 77.8]	1	-1.8		[-19.3, 15.7]	
UPA 15 + 26 WK CS-T	110	79 (71.8)	[63.4, 80.2]	0	4.9		[-9.9, 19.6]	
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	32 (60.4)	[47.2, 73.5]	0				
UPA 7.5 + 26 WK CS-T	52	32 (61.5)	[48.3, 74.8]	0	1.2		[-17.5, 19.8]	
UPA 15 + 26 WK CS-T	99	74 (74.7)	[66.2, 83.3]	0	14.4		[-1.3, 30.1]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 2								
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	51 (67.1)	[56.5, 77.7]	0				
UPA 7.5 + 26 WK CS-T	75	47 (62.4)	[51.4, 73.4]	1	-4.7		[-19.9, 10.6]	
UPA 15 + 26 WK CS-T	148	114 (77.0)	[70.2, 83.8]	0	9.9		[-2.6, 22.5]	
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	21 (56.9)	[40.5, 73.4]	1				
UPA 7.5 + 26 WK CS-T	32	21 (65.6)	[49.2, 82.1]	0	8.7		[-14.6, 31.9]	
UPA 15 + 26 WK CS-T	61	39 (63.9)	[51.9, 76.0]	0	7.0		[-13.4, 27.4]	
Week 4								
All								
PBO + 52 WK CS-T	112	59 (52.3)	[43.0, 61.6]	1				
UPA 7.5 + 26 WK CS-T	107	68 (63.8)	[54.6, 72.9]	1	11.5	11.7	[-1.2, 24.6]	0.0750
UPA 15 + 26 WK CS-T	209	146 (69.9)	[63.6, 76.1]	0	17.6	17.6	[6.5, 28.6]	0.0018**

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Response Rate Diff Compared to Placebo Adjusted Diff(%)	Response Rate Diff Compared to Placebo [95% CI] #	Response Rate Diff Compared to Placebo P-value @
Week 4								
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	35 (58.5)	[45.8, 71.2]	1				
UPA 7.5 + 26 WK CS-T	55	36 (65.5)	[52.9, 78.0]	0	6.9		[-10.9, 24.8]	
UPA 15 + 26 WK CS-T	110	80 (72.7)	[64.4, 81.0]	0	14.2		[-1.0, 29.4]	
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	24 (45.3)	[31.9, 58.7]	0				
UPA 7.5 + 26 WK CS-T	52	32 (62.0)	[48.7, 75.3]	1	16.7		[-2.2, 35.6]	
UPA 15 + 26 WK CS-T	99	66 (66.7)	[57.4, 76.0]	0	21.4		[5.1, 37.7]	
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	39 (51.3)	[40.1, 62.6]	0				
UPA 7.5 + 26 WK CS-T	75	45 (60.3)	[49.2, 71.4]	1	9.0		[-6.8, 24.8]	
UPA 15 + 26 WK CS-T	148	103 (69.6)	[62.2, 77.0]	0	18.3		[4.8, 31.7]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 4								
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	20 (54.3)	[37.8, 70.8]	1				
UPA 7.5 + 26 WK CS-T	32	23 (71.9)	[56.3, 87.5]	0	17.6		[-5.1, 40.3]	
UPA 15 + 26 WK CS-T	61	43 (70.5)	[59.0, 81.9]	0	16.2		[-3.9, 36.3]	
Week 8								
All								
PBO + 52 WK CS-T	112	53 (47.3)	[38.1, 56.6]	0				
UPA 7.5 + 26 WK CS-T	107	61 (57.3)	[47.8, 66.7]	1	9.9	10.1	[-3.0, 23.2]	0.1291
UPA 15 + 26 WK CS-T	209	141 (67.4)	[61.1, 73.8]	0	20.1	19.7	[8.7, 30.8]	0.0005***
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	31 (52.5)	[39.8, 65.3]	0				
UPA 7.5 + 26 WK CS-T	55	34 (61.8)	[49.0, 74.7]	0	9.3		[-8.8, 27.4]	
UPA 15 + 26 WK CS-T	110	78 (70.9)	[62.4, 79.4]	0	18.4		[3.1, 33.7]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 8								
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	22 (41.5)	[28.2, 54.8]	0				
UPA 7.5 + 26 WK CS-T	52	27 (52.4)	[38.8, 66.1]	1	10.9		[-8.1, 30.0]	
UPA 15 + 26 WK CS-T	99	63 (63.5)	[54.0, 73.0]	0	22.0		[5.7, 38.3]	
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	35 (46.1)	[34.8, 57.3]	0				
UPA 7.5 + 26 WK CS-T	75	41 (55.0)	[43.7, 66.3]	1	9.0		[-7.0, 24.9]	
UPA 15 + 26 WK CS-T	148	106 (71.6)	[64.3, 78.8]	0	25.5		[12.1, 38.9]	
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	18 (50.0)	[33.7, 66.3]	0				
UPA 7.5 + 26 WK CS-T	32	20 (62.5)	[45.7, 79.3]	0	12.5		[-10.9, 35.9]	
UPA 15 + 26 WK CS-T	61	35 (57.4)	[45.0, 69.8]	0	7.4		[-13.1, 27.9]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 12								
All								
PBO + 52 WK CS-T	112	44 (39.3)	[30.2, 48.3]	0				
UPA 7.5 + 26 WK CS-T	107	63 (58.9)	[49.6, 68.2]	0	19.6	19.7	[6.8, 32.5]	0.0027**
UPA 15 + 26 WK CS-T	209	129 (61.6)	[55.0, 68.2]	2	22.3	22.2	[11.0, 33.3]	<0.0001***
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	24 (40.7)	[28.1, 53.2]	0				
UPA 7.5 + 26 WK CS-T	55	37 (67.3)	[54.9, 79.7]	0	26.6		[9.0, 44.2]	
UPA 15 + 26 WK CS-T	110	73 (66.3)	[57.4, 75.1]	1	25.6		[10.2, 40.9]	
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	20 (37.7)	[24.7, 50.8]	0				
UPA 7.5 + 26 WK CS-T	52	26 (50.0)	[36.4, 63.6]	0	12.3		[-6.6, 31.1]	
UPA 15 + 26 WK CS-T	99	56 (56.5)	[46.7, 66.3]	1	18.7		[2.4, 35.0]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 12								
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	30 (39.5)	[28.5, 50.5]	0				
UPA 7.5 + 26 WK CS-T	75	44 (58.7)	[47.5, 69.8]	0	19.2		[3.5, 34.8]	
UPA 15 + 26 WK CS-T	148	93 (62.7)	[54.9, 70.5]	2	23.2		[9.7, 36.7]	
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	14 (38.9)	[23.0, 54.8]	0				
UPA 7.5 + 26 WK CS-T	32	19 (59.4)	[42.4, 76.4]	0	20.5		[-2.8, 43.8]	
UPA 15 + 26 WK CS-T	61	36 (59.0)	[46.7, 71.4]	0	20.1		[-0.0, 40.3]	
Week 16								
All								
PBO + 52 WK CS-T	112	44 (39.3)	[30.2, 48.3]	0				
UPA 7.5 + 26 WK CS-T	107	54 (50.5)	[41.0, 59.9]	0	11.2	11.2	[-1.8, 24.2]	0.0907
UPA 15 + 26 WK CS-T	209	133 (63.6)	[57.1, 70.1]	0	24.3	24.3	[13.2, 35.3]	<0.0001***

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Response Rate Diff Compared to Placebo Adjusted Diff(%)	Response Rate Diff Compared to Placebo [95% CI] #	Response Rate Diff Compared to Placebo P-value @
Week 16								
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	26 (44.1)	[31.4, 56.7]	0				
UPA 7.5 + 26 WK CS-T	55	30 (54.5)	[41.4, 67.7]	0	10.5		[-7.8, 28.7]	
UPA 15 + 26 WK CS-T	110	77 (70.0)	[61.4, 78.6]	0	25.9		[10.6, 41.2]	
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	18 (34.0)	[21.2, 46.7]	0				
UPA 7.5 + 26 WK CS-T	52	24 (46.2)	[32.6, 59.7]	0	12.2		[-6.4, 30.8]	
UPA 15 + 26 WK CS-T	99	56 (56.5)	[46.7, 66.3]	0	22.5		[6.4, 38.6]	
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	28 (36.8)	[26.0, 47.7]	0				
UPA 7.5 + 26 WK CS-T	75	39 (52.0)	[40.7, 63.3]	0	15.2		[-0.5, 30.8]	
UPA 15 + 26 WK CS-T	148	94 (63.4)	[55.7, 71.2]	0	26.6		[13.3, 39.9]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 16								
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	16 (44.4)	[28.2, 60.7]	0				
UPA 7.5 + 26 WK CS-T	32	15 (46.9)	[29.6, 64.2]	0	2.4		[-21.3, 26.1]	
UPA 15 + 26 WK CS-T	61	39 (63.9)	[51.9, 76.0]	0	19.5		[-0.7, 39.7]	
Week 20								
All								
PBO + 52 WK CS-T	112	46 (41.0)	[31.9, 50.1]	1				
UPA 7.5 + 26 WK CS-T	107	51 (47.8)	[38.3, 57.3]	2	6.8	7.0	[-6.0, 20.0]	0.2939
UPA 15 + 26 WK CS-T	209	126 (60.1)	[53.5, 66.8]	1	19.1	19.0	[7.9, 30.1]	0.0008***
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	30 (50.7)	[37.9, 63.5]	1				
UPA 7.5 + 26 WK CS-T	55	28 (50.9)	[37.7, 64.1]	0	0.2		[-18.2, 18.6]	
UPA 15 + 26 WK CS-T	110	70 (63.6)	[54.6, 72.6]	1	12.9		[-2.8, 28.5]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Response Rate Diff Compared to Placebo Adjusted Diff(%)	Response Rate Diff Compared to Placebo [95% CI] #	Response Rate Diff Compared to Placebo P-value @
Week 20								
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	16 (30.2)	[17.8, 42.5]	0				
UPA 7.5 + 26 WK CS-T	52	23 (44.6)	[31.0, 58.1]	2	14.4		[-4.0, 32.7]	
UPA 15 + 26 WK CS-T	99	56 (56.3)	[46.5, 66.1]	0	26.1		[10.3, 41.9]	
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	30 (39.5)	[28.5, 50.5]	0				
UPA 7.5 + 26 WK CS-T	75	35 (46.9)	[35.6, 58.2]	2	7.4		[-8.4, 23.2]	
UPA 15 + 26 WK CS-T	148	90 (60.6)	[52.7, 68.5]	1	21.1		[7.6, 34.7]	
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	16 (44.3)	[28.0, 60.5]	1				
UPA 7.5 + 26 WK CS-T	32	16 (50.0)	[32.7, 67.3]	0	5.7		[-18.0, 29.5]	
UPA 15 + 26 WK CS-T	61	36 (59.0)	[46.7, 71.4]	0	14.8		[-5.7, 35.2]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	[95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 24								
All								
PBO + 52 WK CS-T	112	40 (36.1)	[27.2, 45.1]	1				
UPA 7.5 + 26 WK CS-T	107	42 (39.3)	[30.0, 48.5]	2	3.2	3.2	[-9.6, 16.0]	0.6276
UPA 15 + 26 WK CS-T	209	120 (57.2)	[50.5, 64.0]	0	21.1	20.8	[9.7, 31.9]	0.0002***
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	25 (42.0)	[29.4, 54.7]	1				
UPA 7.5 + 26 WK CS-T	55	23 (41.8)	[28.8, 54.9]	0	-0.2		[-18.4, 18.0]	
UPA 15 + 26 WK CS-T	110	68 (61.8)	[52.7, 70.9]	0	19.8		[4.2, 35.4]	
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	16 (29.6)	[17.1, 42.0]	0				
UPA 7.5 + 26 WK CS-T	52	19 (36.6)	[23.5, 49.7]	2	7.0		[-11.0, 25.1]	
UPA 15 + 26 WK CS-T	99	52 (52.2)	[42.3, 62.0]	0	22.6		[6.7, 38.4]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 24								
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	28 (36.4)	[25.5, 47.3]	0				
UPA 7.5 + 26 WK CS-T	75	30 (40.0)	[28.9, 51.1]	2	3.6		[-11.9, 19.2]	
UPA 15 + 26 WK CS-T	148	88 (59.2)	[51.3, 67.2]	0	22.8		[9.3, 36.3]	
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	13 (35.6)	[19.8, 51.3]	1				
UPA 7.5 + 26 WK CS-T	32	12 (37.5)	[20.7, 54.3]	0	1.9		[-21.1, 25.0]	
UPA 15 + 26 WK CS-T	61	32 (52.5)	[39.9, 65.0]	0	16.9		[-3.3, 37.1]	
Week 28								
All								
PBO + 52 WK CS-T	112	36 (31.8)	[23.1, 40.5]	0				
UPA 7.5 + 26 WK CS-T	107	37 (34.6)	[25.6, 43.7]	1	2.9	2.8	[-9.5, 15.1]	0.6561
UPA 15 + 26 WK CS-T	209	112 (53.5)	[46.8, 60.3]	0	21.7	21.4	[10.6, 32.2]	0.0001***

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Response Rate Diff Compared to Placebo Adjusted Diff(%)	Response Rate Diff Compared to Placebo [95% CI] #	Response Rate Diff Compared to Placebo P-value @
Week 28								
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	23 (39.0)	[26.5, 51.4]	0				
UPA 7.5 + 26 WK CS-T	55	20 (36.4)	[23.7, 49.1]	0	-2.6		[-20.4, 15.2]	
UPA 15 + 26 WK CS-T	110	63 (57.2)	[47.9, 66.4]	0	18.2		[2.7, 33.7]	
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	13 (23.8)	[12.2, 35.4]	0				
UPA 7.5 + 26 WK CS-T	52	17 (32.8)	[20.0, 45.6]	1	9.0		[-8.2, 26.3]	
UPA 15 + 26 WK CS-T	99	49 (49.5)	[39.6, 59.3]	0	25.7		[10.5, 40.9]	
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	27 (35.0)	[24.2, 45.8]	0				
UPA 7.5 + 26 WK CS-T	75	26 (34.8)	[24.0, 45.6]	1	-0.2		[-15.5, 15.0]	
UPA 15 + 26 WK CS-T	148	81 (54.6)	[46.6, 62.7]	0	19.6		[6.2, 33.1]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 28								
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	9 (25.0)	[10.9, 39.1]	0				
UPA 7.5 + 26 WK CS-T	32	11 (34.4)	[17.9, 50.8]	0	9.4		[-12.3, 31.1]	
UPA 15 + 26 WK CS-T	61	31 (50.8)	[38.3, 63.4]	0	25.8		[6.9, 44.7]	
Week 36								
All								
PBO + 52 WK CS-T	112	38 (34.3)	[25.5, 43.1]	0				
UPA 7.5 + 26 WK CS-T	107	41 (38.3)	[29.1, 47.5]	0	4.0	4.2	[-8.4, 16.7]	0.5156
UPA 15 + 26 WK CS-T	209	110 (52.5)	[45.7, 59.2]	0	18.2	18.0	[7.0, 28.9]	0.0013**
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	26 (44.1)	[31.4, 56.7]	0				
UPA 7.5 + 26 WK CS-T	55	22 (40.0)	[27.1, 52.9]	0	-4.1		[-22.2, 14.0]	
UPA 15 + 26 WK CS-T	110	61 (55.1)	[45.8, 64.5]	0	11.1		[-4.7, 26.8]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Response Rate Diff Compared to Placebo Adjusted Diff(%)	Response Rate Diff Compared to Placebo [95% CI] #	Response Rate Diff Compared to Placebo P-value @
Week 36								
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	12 (23.4)	[11.8, 34.9]	0				
UPA 7.5 + 26 WK CS-T	52	19 (36.5)	[23.5, 49.6]	0	13.1		[-4.3, 30.6]	
UPA 15 + 26 WK CS-T	99	49 (49.5)	[39.6, 59.3]	0	26.1		[10.9, 41.3]	
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	24 (32.1)	[21.5, 42.7]	0				
UPA 7.5 + 26 WK CS-T	75	28 (37.3)	[26.4, 48.3]	0	5.2		[-10.0, 20.4]	
UPA 15 + 26 WK CS-T	148	81 (54.5)	[46.4, 62.5]	0	22.4		[9.1, 35.7]	
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	14 (38.9)	[23.0, 54.8]	0				
UPA 7.5 + 26 WK CS-T	32	13 (40.6)	[23.6, 57.6]	0	1.7		[-21.6, 25.0]	
UPA 15 + 26 WK CS-T	61	29 (47.5)	[35.0, 60.1]	0	8.7		[-11.6, 28.9]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 44								
All								
PBO + 52 WK CS-T	112	28 (25.0)	[17.0, 33.0]	0				
UPA 7.5 + 26 WK CS-T	107	45 (42.1)	[32.7, 51.4]	0	17.1	17.1	[4.9, 29.3]	0.0059**
UPA 15 + 26 WK CS-T	209	110 (52.7)	[45.9, 59.5]	0	27.7	27.3	[16.9, 37.6]	<0.0001***
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	17 (28.8)	[17.3, 40.4]	0				
UPA 7.5 + 26 WK CS-T	55	25 (45.5)	[32.3, 58.6]	0	16.6		[-0.9, 34.2]	
UPA 15 + 26 WK CS-T	110	65 (58.8)	[49.6, 68.1]	0	30.0		[15.2, 44.8]	
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	11 (20.8)	[9.8, 31.7]	0				
UPA 7.5 + 26 WK CS-T	52	20 (38.5)	[25.2, 51.7]	0	17.7		[0.6, 34.9]	
UPA 15 + 26 WK CS-T	99	45 (45.9)	[36.0, 55.8]	0	25.1		[10.4, 39.9]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 44								
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	21 (27.6)	[17.6, 37.7]	0				
UPA 7.5 + 26 WK CS-T	75	31 (41.3)	[30.2, 52.5]	0	13.7		[-1.3, 28.7]	
UPA 15 + 26 WK CS-T	148	81 (54.9)	[46.8, 62.9]	0	27.2		[14.3, 40.1]	
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	7 (19.4)	[6.5, 32.4]	0				
UPA 7.5 + 26 WK CS-T	32	14 (43.8)	[26.6, 60.9]	0	24.3		[2.8, 45.8]	
UPA 15 + 26 WK CS-T	61	29 (47.4)	[34.9, 60.0]	0	28.0		[10.0, 46.0]	
Week 52								
All								
PBO + 52 WK CS-T	112	22 (19.6)	[12.3, 27.0]	0				
UPA 7.5 + 26 WK CS-T	107	46 (43.0)	[33.6, 52.4]	0	23.3	23.5	[11.7, 35.3]	<0.0001***
UPA 15 + 26 WK CS-T	209	105 (50.2)	[43.4, 57.1]	0	30.6	30.3	[20.4, 40.2]	<0.0001***

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Response Rate Diff Compared to Placebo Adjusted Diff(%)	Response Rate Diff Compared to Placebo [95% CI] #	Response Rate Diff Compared to Placebo P-value @
Week 52								
Baseline CS Dose <= 30 mg								
PBO + 52 WK CS-T	59	14 (23.7)	[12.9, 34.6]	0				
UPA 7.5 + 26 WK CS-T	55	27 (49.1)	[35.9, 62.3]	0	25.4		[8.3, 42.5]	
UPA 15 + 26 WK CS-T	110	64 (57.9)	[48.6, 67.2]	0	34.1		[19.9, 48.4]	
Baseline CS Dose > 30 mg								
PBO + 52 WK CS-T	53	8 (15.1)	[5.5, 24.7]	0				
UPA 7.5 + 26 WK CS-T	52	19 (36.5)	[23.5, 49.6]	0	21.4		[5.2, 37.7]	
UPA 15 + 26 WK CS-T	99	41 (41.8)	[31.9, 51.6]	0	26.7		[12.9, 40.4]	
New Onset Disease at Baseline								
PBO + 52 WK CS-T	76	16 (21.1)	[11.9, 30.2]	0				
UPA 7.5 + 26 WK CS-T	75	30 (40.0)	[28.9, 51.1]	0	18.9		[4.6, 33.3]	
UPA 15 + 26 WK CS-T	148	76 (51.4)	[43.3, 59.6]	0	30.4		[18.1, 42.6]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2__7

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1)

Visit / Strata / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo: Diff(%)	Adjusted Diff(%)	[95% CI] #	P-value @
Week 52								
Relapsing Disease at Baseline								
PBO + 52 WK CS-T	36	6 (16.7)	[4.5, 28.8]	0				
UPA 7.5 + 26 WK CS-T	32	16 (50.0)	[32.7, 67.3]	0	33.3		[12.2, 54.5]	
UPA 15 + 26 WK CS-T	61	29 (47.4)	[34.8, 59.9]	0	30.7		[13.2, 48.2]	

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# @ Across the strata, 95% CI for adjusted difference and p-value are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (Baseline CS dose (prednisone or prednisolone > 30 mg or <= 30 mg) and disease status (new onset or relapsing disease)) for the comparison of two treatment groups. Within each stratum, 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表 2.7.3.6-5

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

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Bodily Pain Scale										
Week 8										
All										
PBO + 52 WK CS-T	85	48.7490	50.3192	1.9449	[0.0896, 3.8002]	0.9433				
UPA 7.5 + 26 WK CS-T	79	48.0847	48.7023	0.6417	[-1.2979, 2.5814]	0.9861	-1.3032	[-3.9345, 1.3281]	1.3377	0.3307
UPA 15 + 26 WK CS-T	170	46.6618	49.2566	1.7893	[0.4246, 3.1541]	0.6939	-0.1556	[-2.3938, 2.0826]	1.1379	0.8913

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Bodily Pain Scale										
Week 8										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	51	48.5893	49.4827	1.0472	[-1.3842, 3.4786]	1.2326				
UPA 7.5 + 26 WK CS-T	43	48.0076	49.1235	0.9192	[-1.7625, 3.6008]	1.3592	-0.1280	[-3.7447, 3.4887]	1.8333	0.9444
UPA 15 + 26 WK CS-T	93	47.7816	51.5016	3.5492	[1.7326, 5.3659]	0.9209	2.5020	[-0.5307, 5.5347]	1.5374	0.1053

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Bodily Pain Scale										
Week 8										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	34	48.9886	51.5739	3.3602	[0.4165, 6.3038]	1.4901				
UPA 7.5 + 26 WK CS-T	36	48.1769	48.1993	0.2836	[-2.6098, 3.1770]	1.4646	-3.0765	[-6.8737, 0.7206]	1.9213	0.1115
UPA 15 + 26 WK CS-T	77	45.3093	46.5452	-0.3529	[-2.6473, 1.9416]	1.1618	-3.7130	[-7.0130, -0.4131]	1.6699	0.0277*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Bodily Pain Scale										
Week 8										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	55	50.5542	51.8298	2.4300	[0.2417, 4.6183]	1.1107				
UPA 7.5 + 26 WK CS-T	55	48.7874	49.5279	0.9507	[-1.2491, 3.1505]	1.1164	-1.4793	[-4.5801, 1.6216]	1.5738	0.3482
UPA 15 + 26 WK CS-T	120	47.6404	48.9912	0.8774	[-0.6174, 2.3722]	0.7587	-1.5526	[-4.2054, 1.1001]	1.3464	0.2500

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Bodily Pain Scale										
Week 8										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	30	45.4396	47.5497	1.9733	[-1.5021, 5.4488]	1.7532				
UPA 7.5 + 26 WK CS-T	24	46.4745	46.8105	0.6333	[-3.1716, 4.4381]	1.9185	-1.3401	[-6.2689, 3.5888]	2.4845	0.5908
UPA 15 + 26 WK CS-T	50	44.3133	49.8937	4.8282	[1.9741, 7.6823]	1.4403	2.8549	[-1.2894, 6.9991]	2.0891	0.1748

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Bodily Pain Scale										
Week 12										
All										
PBO + 52 WK CS-T	77	48.7340	49.1006	0.3571	[-1.7621, 2.4763]	1.0773				
UPA 7.5 + 26 WK CS-T	73	48.3441	49.3439	1.5084	[-0.6869, 3.7038]	1.1159	1.1514	[-1.8537, 4.1564]	1.5274	0.4515
UPA 15 + 26 WK CS-T	161	46.5684	48.9150	1.0919	[-0.4328, 2.6166]	0.7751	0.7348	[-1.8172, 3.2868]	1.2972	0.5715

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Bodily Pain Scale										
Week 12										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	47	48.3575	47.9629	-0.4295	[-3.2098, 2.3509]	1.4094				
UPA 7.5 + 26 WK CS-T	41	47.9545	50.0001	1.8737	[-1.1566, 4.9041]	1.5357	2.3032	[-1.8065, 6.4129]	2.0829	0.2703
UPA 15 + 26 WK CS-T	89	47.7543	50.1690	2.0940	[0.0443, 4.1438]	1.0388	2.5235	[-0.9283, 5.9753]	1.7496	0.1509

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Bodily Pain Scale										
Week 12										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	30	49.3238	50.8829	1.7486	[-1.6362, 5.1334]	1.7126				
UPA 7.5 + 26 WK CS-T	32	48.8433	48.5031	1.0232	[-2.2711, 4.3175]	1.6666	-0.7254	[-5.1669, 3.7161]	2.2453	0.7471
UPA 15 + 26 WK CS-T	72	45.1024	47.3649	-0.0923	[-2.6165, 2.4320]	1.2786	-1.8409	[-5.6769, 1.9950]	1.9395	0.3442

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Bodily Pain Scale										
Week 12										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	50	50.0388	51.0952	1.6912	[-0.8234, 4.2058]	1.2760				
UPA 7.5 + 26 WK CS-T	49	49.2599	49.7865	1.4127	[-1.1277, 3.9532]	1.2891	-0.2785	[-3.8513, 3.2944]	1.8129	0.8781
UPA 15 + 26 WK CS-T	114	47.2490	48.4834	0.1054	[-1.5821, 1.7929]	0.8562	-1.5858	[-4.6168, 1.4452]	1.5380	0.3036

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Bodily Pain Scale										
Week 12										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	27	46.3177	45.4067	-1.2425	[-5.1336, 2.6487]	1.9630				
UPA 7.5 + 26 WK CS-T	24	46.4745	48.4401	2.2629	[-1.8992, 6.4249]	2.0971	3.5054	[-1.9890, 8.9997]	2.7679	0.2084
UPA 15 + 26 WK CS-T	47	44.9174	49.9618	4.2564	[1.1220, 7.3909]	1.5822	5.4989	[0.8249, 10.1729]	2.3554	0.0216*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Bodily Pain Scale										
Week 24										
All										
PBO + 52 WK CS-T	63	48.0073	49.3065	0.8066	[-1.5382, 3.1514]	1.1916				
UPA 7.5 + 26 WK CS-T	57	49.2863	46.1668	-2.0842	[-4.5427, 0.3742]	1.2494	-2.8908	[-6.2468, 0.4652]	1.7053	0.0911
UPA 15 + 26 WK CS-T	143	46.9355	49.1348	1.1703	[-0.4546, 2.7951]	0.8258	0.3637	[-2.4364, 3.1637]	1.4227	0.7984

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Bodily Pain Scale										
Week 24										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	37	47.4716	49.1607	0.9616	[-1.9399, 3.8630]	1.4698				
UPA 7.5 + 26 WK CS-T	31	48.8742	46.2859	-2.5463	[-5.7291, 0.6364]	1.6123	-3.5079	[-7.8123, 0.7965]	2.1805	0.1095
UPA 15 + 26 WK CS-T	81	48.3984	49.9913	1.6212	[-0.4009, 3.6432]	1.0239	0.6596	[-2.8748, 4.1941]	1.7902	0.7130

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Bodily Pain Scale										
Week 24										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	26	48.7697	49.5140	0.5943	[-3.4707, 4.6592]	2.0557				
UPA 7.5 + 26 WK CS-T	26	49.7777	46.0247	-1.2672	[-5.2902, 2.7558]	2.0349	-1.8615	[-7.3432, 3.6203]	2.7696	0.5028
UPA 15 + 26 WK CS-T	62	45.0242	48.0158	0.5953	[-2.3099, 3.5005]	1.4712	0.0010	[-4.6730, 4.6751]	2.3614	0.9996

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Bodily Pain Scale										
Week 24										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	41	50.1673	50.8262	1.4501	[-1.4663, 4.3665]	1.4794				
UPA 7.5 + 26 WK CS-T	40	49.9017	45.9301	-2.6785	[-5.6179, 0.2609]	1.4910	-4.1285	[-8.2671, 0.0100]	2.0993	0.0506
UPA 15 + 26 WK CS-T	100	47.5026	49.3534	0.8457	[-1.0607, 2.7520]	0.9668	-0.6044	[-4.0901, 2.8813]	1.7680	0.7328

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Bodily Pain Scale										
Week 24										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	22	43.9819	46.4745	0.7673	[-3.3199, 4.8546]	2.0592				
UPA 7.5 + 26 WK CS-T	17	47.8383	46.7235	0.0427	[-4.4931, 4.5785]	2.2837	-0.7246	[-6.6375, 5.1883]	2.9752	0.8082
UPA 15 + 26 WK CS-T	43	45.6165	48.6265	2.6519	[-0.4665, 5.7703]	1.5716	1.8845	[-2.9317, 6.7008]	2.4226	0.4388

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Bodily Pain Scale										
Week 52										
All										
PBO + 52 WK CS-T	44	48.1056	48.2522	-1.1007	[-3.6593, 1.4579]	1.2992				
UPA 7.5 + 26 WK CS-T	49	49.5150	49.0130	0.5185	[-1.9584, 2.9955]	1.2576	1.6192	[-1.9001, 5.1386]	1.7867	0.3657
UPA 15 + 26 WK CS-T	123	47.0170	49.6919	1.7882	[0.1667, 3.4098]	0.8235	2.8889	[-0.0890, 5.8668]	1.5119	0.0572

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Bodily Pain Scale										
Week 52										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	26	49.2039	47.0638	-2.9371	[-6.3302, 0.4561]	1.7164				
UPA 7.5 + 26 WK CS-T	29	48.6226	47.9135	-0.0738	[-3.3737, 3.2262]	1.6688	2.8633	[-1.8672, 7.5938]	2.3926	0.2334
UPA 15 + 26 WK CS-T	70	48.5193	50.5814	2.2222	[0.0824, 4.3619]	1.0820	5.1593	[1.1500, 9.1685]	2.0279	0.0120*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Bodily Pain Scale										
Week 52										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	18	46.5193	49.9689	1.5521	[-2.4538, 5.5580]	2.0225				
UPA 7.5 + 26 WK CS-T	20	50.8090	50.6074	1.2935	[-2.5506, 5.1376]	1.9410	-0.2586	[-5.5640, 5.0468]	2.6753	0.9232
UPA 15 + 26 WK CS-T	53	45.0328	48.5171	1.2547	[-1.4390, 3.9483]	1.3622	-0.2974	[-4.7823, 4.1875]	2.2614	0.8956

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Bodily Pain Scale										
Week 52										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	29	50.1937	50.1381	-0.2509	[-3.2775, 2.7756]	1.5336				
UPA 7.5 + 26 WK CS-T	34	50.1982	51.1707	2.3305	[-0.5193, 5.1802]	1.4437	2.5814	[-1.5731, 6.7359]	2.1049	0.2217
UPA 15 + 26 WK CS-T	87	47.5752	50.1984	1.8300	[0.0153, 3.6446]	0.9191	2.0809	[-1.4497, 5.6115]	1.7889	0.2463

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Bodily Pain Scale										
Week 52										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	15	44.0687	44.6063	-1.8159	[-6.6593, 3.0276]	2.4326				
UPA 7.5 + 26 WK CS-T	15	47.9663	44.1224	-2.7230	[-7.5849, 2.1389]	2.4407	-0.9072	[-7.5943, 5.7800]	3.3538	0.7876
UPA 15 + 26 WK CS-T	36	45.6680	48.4681	2.4490	[-0.8947, 5.7928]	1.6813	4.2649	[-1.3483, 9.8782]	2.8149	0.1342

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
General Health Scale										
Week 8										
All										
PBO + 52 WK CS-T	85	49.3428	48.8841	0.0757	[-1.2827, 1.4342]	0.6906				
UPA 7.5 + 26 WK CS-T	79	46.8721	46.2883	-0.5017	[-1.9218, 0.9183]	0.7219	-0.5775	[-2.5056, 1.3506]	0.9802	0.5562
UPA 15 + 26 WK CS-T	170	46.3668	46.8507	0.2292	[-0.7751, 1.2334]	0.5106	0.1534	[-1.4926, 1.7995]	0.8368	0.8546

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
General Health Scale										
Week 8										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	51	48.2725	48.2632	0.2458	[-1.5413, 2.0329]	0.9059				
UPA 7.5 + 26 WK CS-T	43	45.9761	46.9382	0.6576	[-1.3187, 2.6340]	1.0017	0.4118	[-2.2559, 3.0796]	1.3522	0.7610
UPA 15 + 26 WK CS-T	93	46.6671	47.7306	0.9474	[-0.3886, 2.2834]	0.6772	0.7016	[-1.5308, 2.9340]	1.1316	0.5360

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
General Health Scale										
Week 8										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	34	50.9483	49.8155	-0.1055	[-2.2922, 2.0811]	1.1067				
UPA 7.5 + 26 WK CS-T	36	47.9423	45.5120	-1.8893	[-4.0266, 0.2480]	1.0817	-1.7838	[-4.5954, 1.0278]	1.4226	0.2119
UPA 15 + 26 WK CS-T	77	46.0041	45.7880	-0.4761	[-2.1744, 1.2221]	0.8597	-0.3706	[-2.8461, 2.1049]	1.2527	0.7678

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
General Health Scale										
Week 8										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	55	51.5693	50.5578	-0.2371	[-1.8077, 1.3335]	0.7972				
UPA 7.5 + 26 WK CS-T	55	47.9123	46.0535	-1.8334	[-3.3986, -0.2682]	0.7944	-1.5963	[-3.8184, 0.6258]	1.1278	0.1583
UPA 15 + 26 WK CS-T	120	47.4325	47.3334	-0.4034	[-1.4701, 0.6634]	0.5414	-0.1662	[-2.0770, 1.7446]	0.9699	0.8641

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
General Health Scale										
Week 8										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	30	45.2611	45.8158	0.4881	[-2.2278, 3.2041]	1.3696				
UPA 7.5 + 26 WK CS-T	24	44.4884	46.8262	2.0518	[-0.9150, 5.0187]	1.4955	1.5637	[-2.2797, 5.4071]	1.9368	0.4214
UPA 15 + 26 WK CS-T	50	43.8092	45.6922	1.1532	[-1.0585, 3.3649]	1.1157	0.6651	[-2.5722, 3.9024]	1.6315	0.6844

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
General Health Scale										
Week 12										
All										
PBO + 52 WK CS-T	77	49.0424	47.3627	-1.2664	[-2.8534, 0.3206]	0.8068				
UPA 7.5 + 26 WK CS-T	73	47.0110	46.8222	-0.0289	[-1.6741, 1.6162]	0.8363	1.2374	[-1.0161, 3.4910]	1.1455	0.2808
UPA 15 + 26 WK CS-T	161	46.2307	46.9071	0.2930	[-0.8534, 1.4395]	0.5829	1.5594	[-0.3597, 3.4785]	0.9755	0.1109

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
General Health Scale										
Week 12										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	47	47.9555	46.6100	-0.9370	[-3.0197, 1.1457]	1.0557				
UPA 7.5 + 26 WK CS-T	41	45.8216	47.4684	1.2207	[-1.0559, 3.4973]	1.1537	2.1576	[-0.9302, 5.2454]	1.5650	0.1697
UPA 15 + 26 WK CS-T	89	46.4115	47.2663	0.6358	[-0.9018, 2.1734]	0.7792	1.5728	[-1.0167, 4.1623]	1.3125	0.2323

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
General Health Scale										
Week 12										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	30	50.7451	48.5420	-1.5604	[-4.1033, 0.9826]	1.2869				
UPA 7.5 + 26 WK CS-T	32	48.5350	45.9941	-1.5695	[-4.0359, 0.8968]	1.2480	-0.0092	[-3.3399, 3.3215]	1.6842	0.9957
UPA 15 + 26 WK CS-T	72	46.0073	46.4630	0.0518	[-1.8361, 1.9397]	0.9563	1.6122	[-1.2928, 4.5171]	1.4692	0.2744

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
General Health Scale										
Week 12										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	50	51.0653	49.2964	-1.1365	[-3.0449, 0.7720]	0.9684				
UPA 7.5 + 26 WK CS-T	49	48.2466	46.6358	-1.3330	[-3.2523, 0.5863]	0.9739	-0.1966	[-2.9061, 2.5130]	1.3749	0.8865
UPA 15 + 26 WK CS-T	114	47.2798	47.3215	-0.5894	[-1.8702, 0.6913]	0.6498	0.5470	[-1.7611, 2.8551]	1.1713	0.6409

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
General Health Scale										
Week 12										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	27	45.2963	43.7817	-1.7129	[-4.6632, 1.2375]	1.4885				
UPA 7.5 + 26 WK CS-T	24	44.4884	47.2027	2.4283	[-0.7061, 5.5627]	1.5795	4.1412	[0.0062, 8.2761]	2.0834	0.0497*
UPA 15 + 26 WK CS-T	47	43.6862	45.9018	1.8367	[-0.5322, 4.2056]	1.1958	3.5496	[0.0237, 7.0754]	1.7771	0.0485*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
General Health Scale										
Week 24										
All										
PBO + 52 WK CS-T	63	49.1782	48.5518	-0.3169	[-2.0372, 1.4033]	0.8740				
UPA 7.5 + 26 WK CS-T	57	47.7637	46.4456	-0.9763	[-2.7743, 0.8217]	0.9135	-0.6593	[-3.1178, 1.7991]	1.2489	0.5980
UPA 15 + 26 WK CS-T	143	46.7053	47.7826	1.0891	[-0.1057, 2.2838]	0.6070	1.4060	[-0.6528, 3.4648]	1.0458	0.1799

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
General Health Scale										
Week 24										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	37	48.5981	48.2382	0.0709	[-2.2786, 2.4205]	1.1897				
UPA 7.5 + 26 WK CS-T	31	46.8818	47.3266	0.3184	[-2.2511, 2.8878]	1.3011	0.2474	[-3.2368, 3.7317]	1.7643	0.8886
UPA 15 + 26 WK CS-T	81	47.0163	48.0201	1.2787	[-0.3512, 2.9086]	0.8249	1.2077	[-1.6530, 4.0684]	1.4483	0.4056

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
General Health Scale										
Week 24										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	26	50.0038	48.9980	-0.7502	[-3.3724, 1.8720]	1.3251				
UPA 7.5 + 26 WK CS-T	26	48.8151	45.3952	-2.6005	[-5.1829, -0.0180]	1.3055	-1.8503	[-5.3207, 1.6201]	1.7520	0.2931
UPA 15 + 26 WK CS-T	62	46.2990	47.4724	1.0398	[-0.8796, 2.9593]	0.9712	1.7900	[-1.1997, 4.7798]	1.5093	0.2381

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
General Health Scale										
Week 24										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	41	51.5391	50.0779	-1.0694	[-3.2002, 1.0615]	1.0803				
UPA 7.5 + 26 WK CS-T	40	48.9541	46.7073	-2.0518	[-4.1852, 0.0815]	1.0816	-0.9825	[-3.9987, 2.0337]	1.5292	0.5213
UPA 15 + 26 WK CS-T	100	47.5609	48.3169	0.4411	[-0.9416, 1.8237]	0.7008	1.5104	[-1.0380, 4.0589]	1.2920	0.2438

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
General Health Scale										
Week 24										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	22	44.7784	45.7077	0.8290	[-2.2593, 3.9172]	1.5551				
UPA 7.5 + 26 WK CS-T	17	44.9627	45.8298	0.9316	[-2.4800, 4.3433]	1.7174	0.1027	[-4.3358, 4.5412]	2.2324	0.9634
UPA 15 + 26 WK CS-T	43	44.7155	46.5401	1.9941	[-0.3742, 4.3624]	1.1930	1.1651	[-2.4721, 4.8023]	1.8287	0.5258

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
General Health Scale										
Week 52										
All										
PBO + 52 WK CS-T	44	49.5225	47.9987	-1.6812	[-3.8723, 0.5099]	1.1128				
UPA 7.5 + 26 WK CS-T	49	47.3345	49.2753	1.7139	[-0.4201, 3.8479]	1.0836	3.3951	[0.3607, 6.4295]	1.5407	0.0285*
UPA 15 + 26 WK CS-T	123	46.7223	48.7364	2.1166	[0.7184, 3.5148]	0.7100	3.7978	[1.2268, 6.3689]	1.3055	0.0039**

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
General Health Scale										
Week 52										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	26	49.5466	46.7485	-3.1296	[-5.8295, -0.4297]	1.3668				
UPA 7.5 + 26 WK CS-T	29	46.7586	48.3982	1.9991	[-0.6939, 4.6920]	1.3623	5.1287	[1.3127, 8.9447]	1.9313	0.0088**
UPA 15 + 26 WK CS-T	70	47.5887	49.1443	2.0272	[0.2755, 3.7789]	0.8860	5.1568	[1.9374, 8.3761]	1.6294	0.0019**

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
General Health Scale										
Week 52										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	18	49.4877	49.8047	0.5639	[-3.1755, 4.3033]	1.8867				
UPA 7.5 + 26 WK CS-T	20	48.1695	50.5470	1.7235	[-1.8516, 5.2986]	1.8040	1.1596	[-3.8679, 6.1872]	2.5339	0.6482
UPA 15 + 26 WK CS-T	53	45.5781	48.1978	2.3531	[-0.0567, 4.7630]	1.2180	1.7892	[-2.4755, 6.0540]	2.1499	0.4072

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
General Health Scale										
Week 52										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	29	51.3660	49.4804	-1.8891	[-4.5941, 0.8159]	1.3708				
UPA 7.5 + 26 WK CS-T	34	48.1793	49.6617	0.9744	[-1.5724, 3.5212]	1.2902	2.8635	[-0.8540, 6.5811]	1.8837	0.1303
UPA 15 + 26 WK CS-T	87	47.3980	49.2836	1.6585	[0.0312, 3.2859]	0.8242	3.5476	[0.3838, 6.7115]	1.6032	0.0282*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
General Health Scale										
Week 52										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	15	45.9584	45.1343	-1.5096	[-5.4705, 2.4512]	1.9902				
UPA 7.5 + 26 WK CS-T	15	45.4196	48.3993	2.8837	[-1.1402, 6.9076]	2.0198	4.3933	[-1.1217, 9.9083]	2.7664	0.1167
UPA 15 + 26 WK CS-T	36	45.0893	47.4140	2.6660	[-0.1001, 5.4322]	1.3903	4.1757	[-0.4594, 8.8107]	2.3252	0.0767

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Component Summary										
Week 8										
All										
PBO + 52 WK CS-T	85	50.4921	52.0652	2.4526	[0.8023, 4.1029]	0.8390				
UPA 7.5 + 26 WK CS-T	79	47.0491	49.0339	1.4817	[-0.2397, 3.2031]	0.8750	-0.9709	[-3.3190, 1.3771]	1.1935	0.4165
UPA 15 + 26 WK CS-T	170	47.9256	49.1794	0.9035	[-0.2967, 2.1037]	0.6102	-1.5491	[-3.5412, 0.4430]	1.0126	0.1270

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Component Summary										
Week 8										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	51	49.3894	51.2811	2.1628	[0.0899, 4.2357]	1.0506				
UPA 7.5 + 26 WK CS-T	43	45.6918	48.9049	2.1749	[-0.1091, 4.4590]	1.1575	0.0121	[-3.0768, 3.1009]	1.5654	0.9938
UPA 15 + 26 WK CS-T	93	48.7397	50.2753	1.7644	[0.2212, 3.3077]	0.7821	-0.3984	[-2.9787, 2.1819]	1.3077	0.7610

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Component Summary										
Week 8										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	34	52.1462	53.2413	2.5578	[-0.2475, 5.3632]	1.4198				
UPA 7.5 + 26 WK CS-T	36	48.6703	49.1881	0.3870	[-2.3611, 3.1350]	1.3908	-2.1709	[-5.8088, 1.4671]	1.8404	0.2401
UPA 15 + 26 WK CS-T	77	46.9423	47.8557	-0.3639	[-2.5075, 1.7798]	1.0853	-2.9217	[-6.0901, 0.2467]	1.6031	0.0704

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Mental Component Summary										
Week 8										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	55	51.6406	53.2985	2.8345	[0.8696, 4.7995]	0.9972				
UPA 7.5 + 26 WK CS-T	55	48.6232	50.0521	1.4459	[-0.5219, 3.4137]	0.9985	-1.3886	[-4.1698, 1.3926]	1.4113	0.3262
UPA 15 + 26 WK CS-T	120	48.2656	49.4233	0.8123	[-0.5234, 2.1481]	0.6778	-2.0222	[-4.4005, 0.3561]	1.2069	0.0952

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Component Summary										
Week 8										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	30	48.3867	49.8041	1.9119	[-1.1994, 5.0232]	1.5690				
UPA 7.5 + 26 WK CS-T	24	43.4419	46.7006	1.6509	[-1.7862, 5.0880]	1.7326	-0.2610	[-4.7361, 4.2141]	2.2552	0.9081
UPA 15 + 26 WK CS-T	50	47.1094	48.5940	1.2408	[-1.2730, 3.7546]	1.2682	-0.6711	[-4.4098, 3.0676]	1.8839	0.7224

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Component Summary										
Week 12										
All										
PBO + 52 WK CS-T	77	49.7391	52.2605	3.2294	[1.5360, 4.9229]	0.8608				
UPA 7.5 + 26 WK CS-T	73	46.5795	48.7730	1.5198	[-0.2302, 3.2699]	0.8895	-1.7096	[-4.1088, 0.6896]	1.2194	0.1619
UPA 15 + 26 WK CS-T	161	47.6469	50.0121	1.7209	[0.5092, 2.9327]	0.6160	-1.5085	[-3.5416, 0.5246]	1.0333	0.1453

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Component Summary										
Week 12										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	47	48.7837	50.5274	2.3377	[0.2151, 4.4604]	1.0758				
UPA 7.5 + 26 WK CS-T	41	45.2951	48.0609	1.5533	[-0.7583, 3.8649]	1.1714	-0.7844	[-3.9260, 2.3571]	1.5921	0.6228
UPA 15 + 26 WK CS-T	89	48.4194	50.7008	2.2984	[0.7410, 3.8557]	0.7892	-0.0394	[-2.6689, 2.5902]	1.3326	0.9765

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Mental Component Summary										
Week 12										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	30	51.2360	54.9758	4.4081	[1.5033, 7.3130]	1.4697				
UPA 7.5 + 26 WK CS-T	32	48.2250	49.6853	1.2799	[-1.5303, 4.0901]	1.4217	-3.1282	[-6.8934, 0.6370]	1.9038	0.1027
UPA 15 + 26 WK CS-T	72	46.6919	49.1607	0.7404	[-1.4419, 2.9226]	1.1051	-3.6678	[-6.9323, -0.4033]	1.6508	0.0279*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Mental Component Summary										
Week 12										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	50	50.2658	53.3573	3.7646	[1.7101, 5.8191]	1.0423				
UPA 7.5 + 26 WK CS-T	49	48.1163	49.8880	1.6097	[-0.4631, 3.6826]	1.0516	-2.1549	[-5.0745, 0.7648]	1.4813	0.1472
UPA 15 + 26 WK CS-T	114	48.2757	50.1704	1.2733	[-0.1013, 2.6478]	0.6973	-2.4913	[-4.9650, -0.0177]	1.2550	0.0484*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Component Summary										
Week 12										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	27	48.7638	50.2295	2.4466	[-0.6251, 5.5184]	1.5497				
UPA 7.5 + 26 WK CS-T	24	43.4419	46.4965	1.4468	[-1.8160, 4.7097]	1.6446	-0.9998	[-5.3118, 3.3122]	2.1731	0.6465
UPA 15 + 26 WK CS-T	47	46.1216	49.6280	2.9272	[0.4587, 5.3957]	1.2461	0.4806	[-3.1750, 4.1362]	1.8425	0.7948

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
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Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Mental Component Summary										
Week 24										
All										
PBO + 52 WK CS-T	63	49.0273	53.0341	3.6543	[1.7927, 5.5160]	0.9458				
UPA 7.5 + 26 WK CS-T	57	47.1209	49.1060	1.5089	[-0.4450, 3.4628]	0.9928	-2.1454	[-4.8109, 0.5200]	1.3541	0.1142
UPA 15 + 26 WK CS-T	143	47.8981	49.5340	1.4137	[0.1273, 2.7002]	0.6536	-2.2406	[-4.4589, -0.0224]	1.1269	0.0477*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Component Summary										
Week 24										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	37	47.7623	52.8987	4.0469	[1.6926, 6.4012]	1.1918				
UPA 7.5 + 26 WK CS-T	31	45.3671	49.3608	2.4237	[-0.1624, 5.0098]	1.3092	-1.6232	[-5.1213, 1.8749]	1.7709	0.3608
UPA 15 + 26 WK CS-T	81	48.6220	50.2488	2.0714	[0.4468, 3.6959]	0.8220	-1.9755	[-4.8342, 0.8831]	1.4469	0.1742

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Component Summary										
Week 24										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	26	50.8276	53.2266	2.9532	[-0.2214, 6.1278]	1.6056				
UPA 7.5 + 26 WK CS-T	26	49.2119	48.8023	0.1992	[-2.9308, 3.3292]	1.5835	-2.7540	[-6.9523, 1.4443]	2.1214	0.1966
UPA 15 + 26 WK CS-T	62	46.9524	48.6002	0.2194	[-2.1027, 2.5416]	1.1757	-2.7338	[-6.3295, 0.8619]	1.8169	0.1349

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Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Component Summary										
Week 24										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	41	49.9950	53.6589	3.6984	[1.4680, 5.9287]	1.1310				
UPA 7.5 + 26 WK CS-T	40	48.0505	49.6689	1.3163	[-0.9381, 3.5707]	1.1432	-2.3820	[-5.5538, 0.7897]	1.6084	0.1402
UPA 15 + 26 WK CS-T	100	48.4150	49.4256	0.7091	[-0.7425, 2.1607]	0.7359	-2.9893	[-5.6508, -0.3278]	1.3495	0.0279*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Component Summary										
Week 24										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	22	47.2240	51.8697	3.7555	[0.2790, 7.2321]	1.7501				
UPA 7.5 + 26 WK CS-T	17	44.9335	47.7818	1.9686	[-1.8949, 5.8321]	1.9444	-1.7870	[-6.8301, 3.2562]	2.5359	0.4830
UPA 15 + 26 WK CS-T	43	46.6960	49.7861	3.1771	[0.5248, 5.8294]	1.3357	-0.5785	[-4.6962, 3.5393]	2.0697	0.7806

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Component Summary										
Week 52										
All										
PBO + 52 WK CS-T	44	49.4518	52.3159	2.5713	[0.1898, 4.9529]	1.2092				
UPA 7.5 + 26 WK CS-T	49	46.9796	50.6111	2.6724	[0.3711, 4.9736]	1.1684	0.1011	[-3.1826, 3.3848]	1.6670	0.9517
UPA 15 + 26 WK CS-T	123	47.8698	50.1696	1.8014	[0.3049, 3.2978]	0.7599	-0.7699	[-3.5465, 2.0066]	1.4095	0.5854

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

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Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
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Mental Component Summary										
Week 52										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	26	49.2736	51.1524	1.8540	[-1.0247, 4.7326]	1.4553				
UPA 7.5 + 26 WK CS-T	29	45.0770	47.5006	1.2752	[-1.4970, 4.0474]	1.4014	-0.5788	[-4.5785, 3.4209]	2.0222	0.7751
UPA 15 + 26 WK CS-T	70	48.9850	51.2086	2.7633	[0.9748, 4.5518]	0.9040	0.9093	[-2.4765, 4.2950]	1.7116	0.5961

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Program Source Code: [redacted]

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Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
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Mental Component Summary										
Week 52										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	18	49.7092	53.9965	3.7381	[-0.4165, 7.8927]	2.0977				
UPA 7.5 + 26 WK CS-T	20	49.7383	55.1213	3.8372	[-0.1496, 7.8240]	2.0131	0.0991	[-5.4623, 5.6605]	2.8045	0.9719
UPA 15 + 26 WK CS-T	53	46.3969	48.7973	0.0002	[-2.7554, 2.7558]	1.3936	-3.7379	[-8.4627, 0.9869]	2.3828	0.1197

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Program Source Code: [redacted]

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Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
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Mental Component Summary										
Week 52										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	29	49.3886	52.6011	2.9989	[-0.1093, 6.1070]	1.5742				
UPA 7.5 + 26 WK CS-T	34	47.7991	51.6508	2.8736	[-0.0322, 5.7793]	1.4715	-0.1253	[-4.3809, 4.1303]	2.1553	0.9537
UPA 15 + 26 WK CS-T	87	48.4439	50.1190	1.0910	[-0.7497, 2.9317]	0.9321	-1.9079	[-5.5203, 1.7046]	1.8295	0.2986

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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Program Source Code: [redacted]

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Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
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Mental Component Summary										
Week 52										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	15	49.5739	51.7644	2.2388	[-1.4203, 5.8979]	1.8390				
UPA 7.5 + 26 WK CS-T	15	45.1220	48.2546	2.3067	[-1.4173, 6.0306]	1.8699	0.0679	[-4.9998, 5.1356]	2.5429	0.9788
UPA 15 + 26 WK CS-T	36	46.4825	50.2919	3.4719	[0.8889, 6.0549]	1.2987	1.2331	[-3.0064, 5.4727]	2.1274	0.5639

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

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Mental Health Scale										
Week 8										
All										
PBO + 52 WK CS-T	85	50.5907	51.6371	2.1456	[0.5747, 3.7165]	0.7986				
UPA 7.5 + 26 WK CS-T	79	47.4900	49.2120	1.6552	[0.0207, 3.2897]	0.8309	-0.4904	[-2.7182, 1.7374]	1.1324	0.6652
UPA 15 + 26 WK CS-T	170	46.6820	48.4979	1.2531	[0.1072, 2.3991]	0.5826	-0.8925	[-2.7928, 1.0079]	0.9661	0.3562

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Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 8										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	51	49.9957	51.0729	1.8468	[-0.1062, 3.7998]	0.9899				
UPA 7.5 + 26 WK CS-T	43	45.7573	48.2517	1.8369	[-0.3055, 3.9793]	1.0857	-0.0099	[-2.9166, 2.8968]	1.4733	0.9946
UPA 15 + 26 WK CS-T	93	47.2109	49.7144	2.3881	[0.9391, 3.8371]	0.7344	0.5413	[-1.8910, 2.9736]	1.2328	0.6611

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 8										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	34	51.4832	52.4835	2.1014	[-0.6236, 4.8265]	1.3790				
UPA 7.5 + 26 WK CS-T	36	49.5597	50.3590	0.8764	[-1.7970, 3.5498]	1.3528	-1.2250	[-4.7280, 2.2780]	1.7719	0.4905
UPA 15 + 26 WK CS-T	77	46.0433	47.0286	-0.7183	[-2.8310, 1.3944]	1.0694	-2.8198	[-5.8871, 0.2476]	1.5519	0.0713

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 8										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	55	51.6763	52.9129	2.5550	[0.6482, 4.4617]	0.9677				
UPA 7.5 + 26 WK CS-T	55	49.2029	50.5823	1.7928	[-0.1167, 3.7022]	0.9689	-0.7622	[-3.4529, 1.9285]	1.3655	0.5773
UPA 15 + 26 WK CS-T	120	46.9218	48.5569	1.0020	[-0.2968, 2.3008]	0.6591	-1.5530	[-3.8696, 0.7636]	1.1757	0.1879

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 8										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	30	48.6005	49.2981	1.1192	[-1.7130, 3.9514]	1.4285				
UPA 7.5 + 26 WK CS-T	24	43.5646	46.0716	1.0316	[-2.0850, 4.1483]	1.5713	-0.0876	[-4.1499, 3.9747]	2.0475	0.9660
UPA 15 + 26 WK CS-T	50	46.1065	48.3563	1.5272	[-0.7642, 3.8187]	1.1561	0.4080	[-2.9875, 3.8035]	1.7114	0.8120

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 12										
All										
PBO + 52 WK CS-T	77	49.6446	51.6151	2.8170	[1.1611, 4.4729]	0.8418				
UPA 7.5 + 26 WK CS-T	73	47.1766	49.1834	1.9713	[0.2644, 3.6782]	0.8676	-0.8457	[-3.1868, 1.4953]	1.1899	0.4777
UPA 15 + 26 WK CS-T	161	46.5293	49.4053	2.0139	[0.8265, 3.2013]	0.6036	-0.8031	[-2.7964, 1.1902]	1.0132	0.4286

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 12										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	47	49.2535	50.6450	2.2072	[0.2229, 4.1914]	1.0057				
UPA 7.5 + 26 WK CS-T	41	45.5080	47.9964	1.8535	[-0.2982, 4.0053]	1.0904	-0.3536	[-3.2876, 2.5803]	1.4870	0.8123
UPA 15 + 26 WK CS-T	89	47.0171	50.2210	2.8869	[1.4341, 4.3396]	0.7362	0.6797	[-1.7797, 3.1391]	1.2465	0.5862

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 12										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	30	50.2573	53.1349	3.3931	[0.4149, 6.3713]	1.5071				
UPA 7.5 + 26 WK CS-T	32	49.3144	50.7042	1.6042	[-1.2809, 4.4893]	1.4599	-1.7889	[-5.6511, 2.0733]	1.9530	0.3613
UPA 15 + 26 WK CS-T	72	45.9263	48.3970	0.2670	[-1.9679, 2.5019]	1.1320	-3.1261	[-6.4849, 0.2327]	1.6987	0.0679

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 12										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	50	50.1875	52.5419	3.3248	[1.2955, 5.3540]	1.0296				
UPA 7.5 + 26 WK CS-T	49	48.9457	50.3872	1.9706	[-0.0702, 4.0114]	1.0355	-1.3541	[-4.2270, 1.5187]	1.4577	0.3539
UPA 15 + 26 WK CS-T	114	47.0354	49.1237	1.1197	[-0.2392, 2.4787]	0.6895	-2.2050	[-4.6543, 0.2442]	1.2427	0.0774

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 12										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	27	48.6392	49.8988	1.7533	[-1.1321, 4.6388]	1.4560				
UPA 7.5 + 26 WK CS-T	24	43.5646	46.7256	1.6856	[-1.3805, 4.7518]	1.5456	-0.0677	[-4.1263, 3.9909]	2.0457	0.9737
UPA 15 + 26 WK CS-T	47	45.3017	50.0884	3.7768	[1.4615, 6.0921]	1.1689	2.0235	[-1.4182, 5.4652]	1.7351	0.2463

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 24										
All										
PBO + 52 WK CS-T	63	49.1652	52.0304	2.9680	[1.2203, 4.7157]	0.8880				
UPA 7.5 + 26 WK CS-T	57	47.6091	48.3893	0.7277	[-1.1039, 2.5593]	0.9307	-2.2403	[-4.7367, 0.2561]	1.2683	0.0784
UPA 15 + 26 WK CS-T	143	46.8613	49.1298	1.8558	[0.6428, 3.0687]	0.6163	-1.1122	[-3.1974, 0.9730]	1.0594	0.2947

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 24										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	37	48.6052	52.4939	3.6108	[1.4431, 5.7786]	1.0974				
UPA 7.5 + 26 WK CS-T	31	45.7200	47.8297	0.9575	[-1.4185, 3.3335]	1.2028	-2.6534	[-5.8750, 0.5683]	1.6310	0.1058
UPA 15 + 26 WK CS-T	81	47.3151	49.8665	2.6167	[1.1245, 4.1090]	0.7551	-0.9941	[-3.6259, 1.6376]	1.3322	0.4567

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 24										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	26	49.9621	51.3708	1.7728	[-1.2855, 4.8311]	1.5468				
UPA 7.5 + 26 WK CS-T	26	49.8615	49.0566	0.0411	[-2.9808, 3.0631]	1.5287	-1.7317	[-5.7483, 2.2850]	2.0296	0.3952
UPA 15 + 26 WK CS-T	62	46.2685	48.1673	0.1424	[-2.1275, 2.4124]	1.1491	-1.6304	[-5.0819, 1.8211]	1.7440	0.3517

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
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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.
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Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 24										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	41	49.9744	52.5904	2.9686	[0.8305, 5.1067]	1.0843				
UPA 7.5 + 26 WK CS-T	40	48.9057	49.3635	0.7951	[-1.3619, 2.9521]	1.0939	-2.1735	[-5.2053, 0.8584]	1.5375	0.1590
UPA 15 + 26 WK CS-T	100	47.3360	48.9318	1.1151	[-0.2796, 2.5099]	0.7071	-1.8535	[-4.4112, 0.7043]	1.2970	0.1546

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 24										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	22	47.6571	50.9866	2.8367	[-0.2899, 5.9633]	1.5736				
UPA 7.5 + 26 WK CS-T	17	44.5584	46.0973	0.2464	[-3.2226, 3.7154]	1.7454	-2.5903	[-7.1151, 1.9346]	2.2748	0.2581
UPA 15 + 26 WK CS-T	43	45.7573	49.5901	3.1983	[0.8099, 5.5866]	1.2024	0.3616	[-3.3298, 4.0530]	1.8551	0.8459

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 52										
All										
PBO + 52 WK CS-T	44	49.3218	52.1162	2.5756	[0.2557, 4.8954]	1.1780				
UPA 7.5 + 26 WK CS-T	49	47.3441	50.2804	2.1408	[-0.1033, 4.3849]	1.1395	-0.4347	[-3.6342, 2.7647]	1.6244	0.7892
UPA 15 + 26 WK CS-T	123	46.4651	49.4852	2.2739	[0.8064, 3.7414]	0.7452	-0.3017	[-3.0141, 2.4107]	1.3772	0.8268

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 52										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	26	49.7609	51.1695	1.0473	[-1.8645, 3.9591]	1.4728				
UPA 7.5 + 26 WK CS-T	29	45.0042	46.9887	0.6300	[-2.1898, 3.4497]	1.4259	-0.4173	[-4.4765, 3.6419]	2.0531	0.8392
UPA 15 + 26 WK CS-T	70	47.6537	50.6434	3.2933	[1.4662, 5.1203]	0.9237	2.2460	[-1.1909, 5.6829]	1.7383	0.1985

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 52										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	18	48.6877	53.4837	4.8401	[0.9971, 8.6830]	1.9410				
UPA 7.5 + 26 WK CS-T	20	50.7369	55.0533	3.1650	[-0.5231, 6.8531]	1.8629	-1.6750	[-6.7782, 3.4281]	2.5741	0.5166
UPA 15 + 26 WK CS-T	53	44.8952	47.9555	0.3606	[-2.2299, 2.9511]	1.3106	-4.4795	[-8.8265, -0.1324]	2.1930	0.0435*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 52										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	29	48.9733	52.5816	3.3441	[0.3420, 6.3463]	1.5210				
UPA 7.5 + 26 WK CS-T	34	48.7133	51.7140	2.4958	[-0.3185, 5.3101]	1.4256	-0.8483	[-4.9606, 3.2640]	2.0833	0.6844
UPA 15 + 26 WK CS-T	87	46.8384	49.0635	1.3938	[-0.3957, 3.1833]	0.9064	-1.9503	[-5.4490, 1.5484]	1.7725	0.2727

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Mental Health Scale										
Week 52										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	15	49.9957	51.2165	1.3118	[-2.2171, 4.8407]	1.7737				
UPA 7.5 + 26 WK CS-T	15	44.2404	47.0308	1.2578	[-2.3228, 4.8383]	1.7981	-0.0540	[-4.9509, 4.8428]	2.4576	0.9825
UPA 15 + 26 WK CS-T	36	45.5630	50.5043	3.9938	[1.5084, 6.4793]	1.2496	2.6820	[-1.4247, 6.7887]	2.0610	0.1972

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Component Summary										
Week 8										
All										
PBO + 52 WK CS-T	85	45.2218	45.4918	0.1396	[-1.2447, 1.5240]	0.7038				
UPA 7.5 + 26 WK CS-T	79	44.3642	44.9681	0.3787	[-1.0741, 1.8314]	0.7385	0.2390	[-1.7241, 2.2022]	0.9980	0.8108
UPA 15 + 26 WK CS-T	170	44.1813	45.6459	1.0765	[0.0546, 2.0984]	0.5196	0.9369	[-0.7298, 2.6036]	0.8473	0.2696

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Component Summary										
Week 8										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	51	44.2875	44.7434	0.1779	[-1.6626, 2.0185]	0.9331				
UPA 7.5 + 26 WK CS-T	43	42.9727	45.2508	1.5938	[-0.4548, 3.6424]	1.0384	1.4158	[-1.3309, 4.1626]	1.3923	0.3105
UPA 15 + 26 WK CS-T	93	45.2193	47.4698	2.3635	[0.9852, 3.7418]	0.6987	2.1855	[-0.1118, 4.4828]	1.1646	0.0621

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Component Summary										
Week 8										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	34	46.6231	46.6144	0.2226	[-1.9607, 2.4060]	1.1051				
UPA 7.5 + 26 WK CS-T	36	46.0264	44.6304	-1.1227	[-3.2723, 1.0269]	1.0880	-1.3453	[-4.1468, 1.4562]	1.4175	0.3442
UPA 15 + 26 WK CS-T	77	42.9276	43.4430	-0.4823	[-2.2103, 1.2456]	0.8748	-0.7050	[-3.1573, 1.7474]	1.2410	0.5709

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Component Summary										
Week 8										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	55	47.0318	47.0366	0.3114	[-1.3579, 1.9808]	0.8474				
UPA 7.5 + 26 WK CS-T	55	44.5616	45.0828	0.3347	[-1.3533, 2.0228]	0.8568	0.0233	[-2.3545, 2.4011]	1.2069	0.9846
UPA 15 + 26 WK CS-T	120	45.2437	45.9785	0.7109	[-0.4343, 1.8561]	0.5812	0.3994	[-1.6262, 2.4250]	1.0282	0.6980

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Component Summary										
Week 8										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	30	41.9034	42.6597	0.1219	[-2.4207, 2.6646]	1.2823				
UPA 7.5 + 26 WK CS-T	24	43.9120	44.7051	0.6856	[-2.0847, 3.4559]	1.3966	0.5637	[-3.0101, 4.1374]	1.8014	0.7550
UPA 15 + 26 WK CS-T	50	41.6316	44.8479	2.2978	[0.2019, 4.3937]	1.0572	2.1759	[-0.8188, 5.1706]	1.5096	0.1526

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Physical Component Summary										
Week 12										
All										
PBO + 52 WK CS-T	77	45.2835	44.1945	-1.1709	[-2.8105, 0.4687]	0.8337				
UPA 7.5 + 26 WK CS-T	73	44.2694	45.5722	1.1665	[-0.5408, 2.8739]	0.8680	2.3375	[0.0071, 4.6678]	1.1847	0.0493*
UPA 15 + 26 WK CS-T	161	44.3103	45.6262	0.8582	[-0.3259, 2.0423]	0.6021	2.0291	[0.0529, 4.0054]	1.0047	0.0442*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Component Summary										
Week 12										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	47	44.2680	43.5056	-0.7858	[-2.9370, 1.3654]	1.0906				
UPA 7.5 + 26 WK CS-T	41	42.6269	46.4009	2.8818	[0.5125, 5.2511]	1.2009	3.6676	[0.4738, 6.8614]	1.6189	0.0246*
UPA 15 + 26 WK CS-T	89	45.2285	46.7621	1.6790	[0.0851, 3.2730]	0.8079	2.4648	[-0.2108, 5.1405]	1.3563	0.0708

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Component Summary										
Week 12										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	30	46.8744	45.2737	-1.5540	[-4.1821, 1.0741]	1.3305				
UPA 7.5 + 26 WK CS-T	32	46.3739	44.5103	-0.9645	[-3.5282, 1.5992]	1.2978	0.5895	[-2.8640, 4.0430]	1.7470	0.7363
UPA 15 + 26 WK CS-T	72	43.1753	44.2220	-0.1348	[-2.0988, 1.8293]	0.9952	1.4193	[-1.5786, 4.4171]	1.5167	0.3510

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Physical Component Summary										
Week 12										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	50	46.7287	46.0149	-0.2082	[-2.1744, 1.7580]	0.9980				
UPA 7.5 + 26 WK CS-T	49	44.4445	45.3229	0.8261	[-1.1662, 2.8184]	1.0112	1.0343	[-1.7680, 3.8366]	1.4223	0.4678
UPA 15 + 26 WK CS-T	114	45.1420	46.0473	0.5928	[-0.7365, 1.9222]	0.6746	0.8010	[-1.5735, 3.1756]	1.2052	0.5069

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Physical Component Summary										
Week 12										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	27	42.6071	40.8233	-2.5590	[-5.5810, 0.4630]	1.5249				
UPA 7.5 + 26 WK CS-T	24	43.9120	46.0812	2.0617	[-1.1849, 5.3082]	1.6362	4.6207	[0.3429, 8.8984]	2.1557	0.0345*
UPA 15 + 26 WK CS-T	47	42.2931	44.6048	1.8509	[-0.5796, 4.2814]	1.2270	4.4099	[0.7860, 8.0338]	1.8267	0.0176*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Physical Component Summary										
Week 24										
All										
PBO + 52 WK CS-T	63	44.7172	45.5979	-0.0122	[-1.7946, 1.7702]	0.9058				
UPA 7.5 + 26 WK CS-T	57	45.0791	43.7633	-1.3568	[-3.2196, 0.5059]	0.9467	-1.3447	[-3.8888, 1.1995]	1.2928	0.2991
UPA 15 + 26 WK CS-T	143	44.8277	46.7251	1.6155	[0.3804, 2.8506]	0.6277	1.6276	[-0.4981, 3.7534]	1.0801	0.1329

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Component Summary										
Week 24										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	37	44.0208	46.0348	1.0052	[-1.2887, 3.2992]	1.1619				
UPA 7.5 + 26 WK CS-T	31	44.0652	43.7663	-0.9665	[-3.4884, 1.5553]	1.2773	-1.9718	[-5.3755, 1.4319]	1.7240	0.2544
UPA 15 + 26 WK CS-T	81	45.9675	47.2402	1.7995	[0.1917, 3.4074]	0.8140	0.7943	[-2.0063, 3.5949]	1.4183	0.5762

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Component Summary										
Week 24										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	26	45.7081	44.9761	-1.2551	[-4.1865, 1.6764]	1.4827				
UPA 7.5 + 26 WK CS-T	26	46.2881	43.7597	-1.8124	[-4.6926, 1.0678]	1.4573	-0.5573	[-4.4688, 3.3541]	1.9766	0.7784
UPA 15 + 26 WK CS-T	62	43.3385	46.0523	1.3760	[-0.7350, 3.4870]	1.0692	2.6311	[-0.7207, 5.9829]	1.6936	0.1228

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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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Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Component Summary										
Week 24										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	41	46.6645	47.3931	0.4743	[-1.7284, 2.6770]	1.1172				
UPA 7.5 + 26 WK CS-T	40	45.1948	43.8654	-1.2494	[-3.4580, 0.9592]	1.1203	-1.7237	[-4.8452, 1.3978]	1.5833	0.2776
UPA 15 + 26 WK CS-T	100	45.5659	47.4713	1.6483	[0.2155, 3.0811]	0.7266	1.1740	[-1.4540, 3.8020]	1.3328	0.3794

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Physical Component Summary										
Week 24										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	22	41.0881	42.2522	-0.5160	[-3.6877, 2.6557]	1.5980				
UPA 7.5 + 26 WK CS-T	17	44.8071	43.5228	-1.5011	[-5.0104, 2.0083]	1.7671	-0.9850	[-5.5669, 3.5968]	2.3057	0.6703
UPA 15 + 26 WK CS-T	43	43.1107	44.9900	1.7683	[-0.6690, 4.2055]	1.2280	2.2843	[-1.4658, 6.0344]	1.8861	0.2292

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Component Summary										
Week 52										
All										
PBO + 52 WK CS-T	44	45.7034	45.3722	-1.2892	[-3.3093, 0.7309]	1.0260				
UPA 7.5 + 26 WK CS-T	49	45.2233	46.6241	1.3202	[-0.6553, 3.2957]	1.0032	2.6094	[-0.1841, 5.4028]	1.4185	0.0670
UPA 15 + 26 WK CS-T	123	45.0748	47.6393	2.4634	[1.1707, 3.7561]	0.6565	3.7526	[1.3932, 6.1119]	1.1981	0.0019**

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Component Summary										
Week 52										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	26	45.6059	44.9778	-1.6286	[-4.1455, 0.8882]	1.2736				
UPA 7.5 + 26 WK CS-T	29	44.8652	46.3071	1.9775	[-0.5214, 4.4765]	1.2637	3.6062	[0.0628, 7.1496]	1.7925	0.0461*
UPA 15 + 26 WK CS-T	70	46.4896	48.4307	2.6481	[1.0274, 4.2689]	0.8195	4.2768	[1.2848, 7.2687]	1.5137	0.0054**

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Physical Component Summary										
Week 52										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	18	45.8442	45.9418	-0.6672	[-4.1077, 2.7733]	1.7376				
UPA 7.5 + 26 WK CS-T	20	45.7425	47.0836	0.0601	[-3.2441, 3.3642]	1.6690	0.7272	[-3.8734, 5.3278]	2.3210	0.7546
UPA 15 + 26 WK CS-T	53	43.2061	46.5942	2.0916	[-0.1931, 4.3763]	1.1557	2.7587	[-1.1463, 6.6637]	1.9701	0.1643

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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Program Source Code: [redacted]

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Physical Component Summary										
Week 52										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	29	48.0670	47.7946	-0.6852	[-3.1668, 1.7964]	1.2576				
UPA 7.5 + 26 WK CS-T	34	44.9139	47.3555	2.1747	[-0.1808, 4.5303]	1.1932	2.8599	[-0.5648, 6.2847]	1.7352	0.1011
UPA 15 + 26 WK CS-T	87	45.8032	48.4414	2.5554	[1.0522, 4.0585]	0.7612	3.2405	[0.3388, 6.1423]	1.4702	0.0288*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Component Summary										
Week 52										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	15	41.1339	40.6888	-2.3985	[-6.0396, 1.2427]	1.8315				
UPA 7.5 + 26 WK CS-T	15	45.9245	44.9662	-0.6441	[-4.3397, 3.0514]	1.8575	1.7543	[-3.2976, 6.8062]	2.5376	0.4914
UPA 15 + 26 WK CS-T	36	43.3146	45.7011	2.3518	[-0.2097, 4.9133]	1.2889	4.7502	[0.5163, 8.9841]	2.1263	0.0284*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Physical Functioning Scale										
Week 8										
All										
PBO + 52 WK CS-T	85	45.7657	45.5404	-0.4002	[-1.8372, 1.0368]	0.7306				
UPA 7.5 + 26 WK CS-T	79	44.7260	45.2831	0.3205	[-1.1875, 1.8284]	0.7666	0.7207	[-1.3199, 2.7613]	1.0374	0.4877
UPA 15 + 26 WK CS-T	170	45.0340	45.7206	0.3561	[-0.6999, 1.4122]	0.5370	0.7564	[-0.9745, 2.4873]	0.8800	0.3906

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
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Physical Functioning Scale										
Week 8										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	51	44.5949	44.8198	-0.1951	[-2.1172, 1.7269]	0.9744				
UPA 7.5 + 26 WK CS-T	43	42.4086	45.1683	1.7224	[-0.4233, 3.8681]	1.0876	1.9175	[-0.9534, 4.7885]	1.4553	0.1892
UPA 15 + 26 WK CS-T	93	46.0379	47.3138	1.4736	[0.0346, 2.9125]	0.7294	1.6687	[-0.7316, 4.0690]	1.2168	0.1719

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Physical Functioning Scale										
Week 8										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	34	47.5219	46.6212	-0.8087	[-3.0423, 1.4249]	1.1306				
UPA 7.5 + 26 WK CS-T	36	47.4939	45.4203	-1.7258	[-3.9250, 0.4734]	1.1131	-0.9171	[-3.8010, 1.9667]	1.4591	0.5306
UPA 15 + 26 WK CS-T	77	43.8214	43.7964	-1.1851	[-2.9383, 0.5681]	0.8878	-0.3764	[-2.8940, 2.1411]	1.2739	0.7680

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Functioning Scale										
Week 8										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	55	47.8330	47.2762	-0.2153	[-1.9375, 1.5069]	0.8742				
UPA 7.5 + 26 WK CS-T	55	45.8844	45.7103	-0.0670	[-1.8061, 1.6721]	0.8826	0.1483	[-2.3004, 2.5970]	1.2428	0.9051
UPA 15 + 26 WK CS-T	120	45.8831	46.1859	0.2288	[-0.9522, 1.4098]	0.5994	0.4441	[-1.6452, 2.5333]	1.0604	0.6758

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Functioning Scale										
Week 8										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	30	41.9755	42.3580	-0.6183	[-3.3008, 2.0641]	1.3531				
UPA 7.5 + 26 WK CS-T	24	42.0714	44.3041	1.3401	[-1.5985, 4.2787]	1.4817	1.9584	[-1.8368, 5.7536]	1.9130	0.3084
UPA 15 + 26 WK CS-T	50	42.9960	44.6038	0.6797	[-1.5003, 2.8597]	1.1000	1.2981	[-1.8906, 4.4867]	1.6074	0.4212

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Physical Functioning Scale										
Week 12										
All										
PBO + 52 WK CS-T	77	45.2381	44.6662	-0.6394	[-2.2030, 0.9242]	0.7950				
UPA 7.5 + 26 WK CS-T	73	44.1970	45.8487	1.1346	[-0.4927, 2.7618]	0.8273	1.7740	[-0.4432, 3.9912]	1.1271	0.1165
UPA 15 + 26 WK CS-T	161	45.2263	46.1416	0.6301	[-0.4992, 1.7593]	0.5741	1.2695	[-0.6098, 3.1487]	0.9553	0.1848

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Functioning Scale										
Week 12										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	47	44.3888	43.9405	-0.4419	[-2.4980, 1.6143]	1.0423				
UPA 7.5 + 26 WK CS-T	41	41.8105	45.9184	2.7035	[0.4335, 4.9735]	1.1505	3.1454	[0.0931, 6.1976]	1.5471	0.0435*
UPA 15 + 26 WK CS-T	89	46.1445	47.4990	1.6547	[0.1326, 3.1768]	0.7714	2.0966	[-0.4614, 4.6547]	1.2967	0.1076

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Functioning Scale										
Week 12										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	30	46.5687	45.8030	-0.9827	[-3.4722, 1.5069]	1.2605				
UPA 7.5 + 26 WK CS-T	32	47.2547	45.7594	-1.1014	[-3.5270, 1.3242]	1.2280	-0.1187	[-3.3683, 3.1308]	1.6441	0.9425
UPA 15 + 26 WK CS-T	72	44.0913	44.4636	-0.7784	[-2.6604, 1.1036]	0.9536	0.2043	[-2.6131, 3.0216]	1.4255	0.8862

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Functioning Scale										
Week 12										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	50	46.7090	46.2112	-0.0858	[-1.9723, 1.8007]	0.9575				
UPA 7.5 + 26 WK CS-T	49	45.2381	46.4101	0.9428	[-0.9667, 2.8523]	0.9692	1.0286	[-1.6570, 3.7143]	1.3631	0.4512
UPA 15 + 26 WK CS-T	114	46.0417	46.6963	0.5184	[-0.7564, 1.7932]	0.6469	0.6042	[-1.6733, 2.8817]	1.1559	0.6017

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Physical Functioning Scale										
Week 12										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	27	42.5142	41.8050	-1.4999	[-4.3690, 1.3691]	1.4474				
UPA 7.5 + 26 WK CS-T	24	42.0714	44.7026	1.7385	[-1.3312, 4.8082]	1.5468	3.2384	[-0.7884, 7.2652]	2.0288	0.1137
UPA 15 + 26 WK CS-T	47	43.2486	44.7959	0.9556	[-1.3480, 3.2592]	1.1627	2.4556	[-0.9645, 5.8756]	1.7236	0.1574

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

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Physical Functioning Scale										
Week 24										
All										
PBO + 52 WK CS-T	63	44.4178	46.5443	0.7237	[-1.0650, 2.5124]	0.9089				
UPA 7.5 + 26 WK CS-T	57	44.9840	44.6819	-0.6945	[-2.5626, 1.1735]	0.9493	-1.4182	[-3.9693, 1.1330]	1.2962	0.2748
UPA 15 + 26 WK CS-T	143	45.5632	47.6109	1.8563	[0.6225, 3.0901]	0.6269	1.1326	[-0.9970, 3.2623]	1.0819	0.2961

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
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Physical Functioning Scale										
Week 24										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	37	43.7823	47.4548	1.9476	[-0.1623, 4.0576]	1.0684				
UPA 7.5 + 26 WK CS-T	31	43.5272	44.9474	0.0767	[-2.2524, 2.4058]	1.1793	-1.8709	[-5.0037, 1.2618]	1.5862	0.2400
UPA 15 + 26 WK CS-T	81	46.6256	48.2087	2.2797	[0.7960, 3.7635]	0.7508	0.3321	[-2.2484, 2.9126]	1.3065	0.7997

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
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Physical Functioning Scale										
Week 24										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	26	45.3223	45.2485	-0.8224	[-3.9967, 2.3520]	1.6056				
UPA 7.5 + 26 WK CS-T	26	46.7210	44.3653	-1.9088	[-5.0247, 1.2070]	1.5765	-1.0865	[-5.3538, 3.1808]	2.1565	0.6153
UPA 15 + 26 WK CS-T	62	44.1753	46.8300	1.1218	[-1.1210, 3.3647]	1.1361	1.9442	[-1.6960, 5.5843]	1.8393	0.2925

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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Physical Functioning Scale										
Week 24										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	41	46.3850	48.2522	1.0859	[-1.1570, 3.3288]	1.1375				
UPA 7.5 + 26 WK CS-T	40	45.5321	45.0059	-0.5041	[-2.7483, 1.7401]	1.1383	-1.5900	[-4.7637, 1.5837]	1.6096	0.3244
UPA 15 + 26 WK CS-T	100	46.2690	48.5273	2.0156	[0.5613, 3.4698]	0.7374	0.9297	[-1.7431, 3.6025]	1.3554	0.4936

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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Program Source Code: [redacted]

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Physical Functioning Scale										
Week 24										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	22	40.7518	43.3613	0.2870	[-2.7483, 3.3224]	1.5286				
UPA 7.5 + 26 WK CS-T	17	43.6945	43.9195	-0.9700	[-4.3241, 2.3842]	1.6881	-1.2570	[-5.6161, 3.1021]	2.1924	0.5679
UPA 15 + 26 WK CS-T	43	43.9219	45.4799	1.4592	[-0.8652, 3.7837]	1.1705	1.1722	[-2.4001, 4.7445]	1.7960	0.5158

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
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Physical Functioning Scale										
Week 52										
All										
PBO + 52 WK CS-T	44	45.7537	47.0587	0.1980	[-1.7400, 2.1359]	0.9842				
UPA 7.5 + 26 WK CS-T	49	44.9649	47.3474	1.6070	[-0.2989, 3.5130]	0.9677	1.4091	[-1.2745, 4.0926]	1.3625	0.3021
UPA 15 + 26 WK CS-T	123	45.8872	47.8322	1.9955	[0.7482, 3.2427]	0.6333	1.7975	[-0.4656, 4.0606]	1.1491	0.1190

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

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Physical Functioning Scale										
Week 52										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	26	45.4692	46.9417	0.0728	[-2.3436, 2.4892]	1.2225				
UPA 7.5 + 26 WK CS-T	29	44.8706	45.9263	1.3640	[-1.0599, 3.7879]	1.2251	1.2912	[-2.1248, 4.7072]	1.7274	0.4561
UPA 15 + 26 WK CS-T	70	47.5896	48.9565	2.6130	[1.0448, 4.1812]	0.7926	2.5402	[-0.3409, 5.4212]	1.4572	0.0835

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Physical Functioning Scale										
Week 52										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	18	46.1648	47.2277	0.6694	[-2.6033, 3.9421]	1.6527				
UPA 7.5 + 26 WK CS-T	20	45.1015	49.4080	1.5414	[-1.6032, 4.6859]	1.5882	0.8720	[-3.4892, 5.2331]	2.1997	0.6926
UPA 15 + 26 WK CS-T	53	43.6388	46.3473	0.9744	[-1.2260, 3.1749]	1.1130	0.3050	[-3.3971, 4.0071]	1.8672	0.8706

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Physical Functioning Scale										
Week 52										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	29	47.7742	49.4239	0.8886	[-1.6012, 3.3785]	1.2615				
UPA 7.5 + 26 WK CS-T	34	44.7637	47.7473	1.7433	[-0.6278, 4.1145]	1.2009	0.8547	[-2.5857, 4.2950]	1.7427	0.6245
UPA 15 + 26 WK CS-T	87	46.5864	48.3902	1.7275	[0.2138, 3.2413]	0.7664	0.8389	[-2.0748, 3.7526]	1.4759	0.5705

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Physical Functioning Scale										
Week 52										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	15	41.8476	42.4860	-0.8485	[-4.0026, 2.3057]	1.5858				
UPA 7.5 + 26 WK CS-T	15	45.4208	46.4410	0.9455	[-2.2672, 4.1582]	1.6133	1.7939	[-2.5427, 6.1306]	2.1765	0.4124
UPA 15 + 26 WK CS-T	36	44.1975	46.4836	2.3900	[0.1429, 4.6370]	1.1296	3.2384	[-0.3933, 6.8701]	1.8228	0.0797

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 8										
All										
PBO + 52 WK CS-T	85	47.6891	48.8360	1.7547	[0.0931, 3.4164]	0.8447				
UPA 7.5 + 26 WK CS-T	79	45.6348	46.8688	0.9202	[-0.8164, 2.6568]	0.8828	-0.8345	[-3.1984, 1.5293]	1.2016	0.4878
UPA 15 + 26 WK CS-T	170	46.8494	48.0577	1.3329	[0.1235, 2.5423]	0.6149	-0.4218	[-2.4273, 1.5836]	1.0194	0.6793

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 8										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	51	46.7470	48.3171	1.3260	[-0.6633, 3.3153]	1.0083				
UPA 7.5 + 26 WK CS-T	43	44.5084	47.0184	1.2659	[-0.9268, 3.4585]	1.1113	-0.0601	[-3.0173, 2.8971]	1.4988	0.9681
UPA 15 + 26 WK CS-T	93	48.1189	48.9800	1.5985	[0.1143, 3.0826]	0.7522	0.2725	[-2.2078, 2.7528]	1.2571	0.8286

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 8										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	34	49.1022	49.6143	2.2238	[-0.7332, 5.1808]	1.4965				
UPA 7.5 + 26 WK CS-T	36	46.9802	46.6901	0.3028	[-2.6027, 3.2083]	1.4705	-1.9210	[-5.7889, 1.9470]	1.9563	0.3278
UPA 15 + 26 WK CS-T	77	45.3160	46.9438	1.0403	[-1.2085, 3.2891]	1.1388	-1.1835	[-4.5387, 2.1718]	1.6972	0.4868

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 8										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	55	49.4579	49.7744	1.3309	[-0.7146, 3.3764]	1.0380				
UPA 7.5 + 26 WK CS-T	55	47.5587	47.0523	-0.3277	[-2.3816, 1.7262]	1.0422	-1.6586	[-4.5560, 1.2388]	1.4703	0.2605
UPA 15 + 26 WK CS-T	120	47.2607	48.2182	0.7439	[-0.6497, 2.1374]	0.7071	-0.5870	[-3.0617, 1.8876]	1.2558	0.6406

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 8										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	30	44.4463	47.1156	2.3586	[-0.5648, 5.2821]	1.4747				
UPA 7.5 + 26 WK CS-T	24	41.2257	46.4483	3.3758	[0.1395, 6.6121]	1.6321	1.0172	[-3.1643, 5.1987]	2.1077	0.6304
UPA 15 + 26 WK CS-T	50	45.8622	47.6727	2.1968	[-0.1594, 4.5530]	1.1890	-0.1618	[-3.6743, 3.3506]	1.7705	0.9274

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 12										
All										
PBO + 52 WK CS-T	77	47.0794	48.9786	2.3374	[0.5765, 4.0984]	0.8951				
UPA 7.5 + 26 WK CS-T	73	45.1506	46.8199	1.0753	[-0.7450, 2.8956]	0.9252	-1.2621	[-3.7565, 1.2323]	1.2677	0.3202
UPA 15 + 26 WK CS-T	161	46.5879	48.5559	1.7551	[0.4985, 3.0117]	0.6388	-0.5823	[-2.6965, 1.5319]	1.0745	0.5882

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 12										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	47	46.3156	47.2045	0.9547	[-1.2897, 3.1991]	1.1374				
UPA 7.5 + 26 WK CS-T	41	43.9396	46.1475	0.4640	[-1.9742, 2.9022]	1.2354	-0.4907	[-3.8001, 2.8187]	1.6770	0.7702
UPA 15 + 26 WK CS-T	89	47.7963	49.2046	1.8288	[0.1822, 3.4755]	0.8344	0.8741	[-1.9089, 3.6572]	1.4103	0.5362

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 12										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	30	48.2762	51.7579	4.2833	[1.3840, 7.1825]	1.4667				
UPA 7.5 + 26 WK CS-T	32	46.7022	47.6814	1.5310	[-1.2884, 4.3503]	1.4261	-2.7523	[-6.5172, 1.0126]	1.9032	0.1505
UPA 15 + 26 WK CS-T	72	45.0943	47.7539	1.7724	[-0.4274, 3.9723]	1.1138	-2.5108	[-5.7618, 0.7402]	1.6435	0.1290

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 12										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	50	48.2994	50.3188	2.4348	[0.3207, 4.5489]	1.0724				
UPA 7.5 + 26 WK CS-T	49	47.0730	47.9967	0.8498	[-1.2840, 2.9837]	1.0825	-1.5849	[-4.5886, 1.4188]	1.5238	0.2995
UPA 15 + 26 WK CS-T	114	47.1889	48.6549	0.8614	[-0.5533, 2.2760]	0.7176	-1.5734	[-4.1173, 0.9704]	1.2904	0.2241

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 12										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	27	44.8202	46.4966	2.0600	[-1.2000, 5.3201]	1.6445				
UPA 7.5 + 26 WK CS-T	24	41.2257	44.4173	1.3448	[-2.1250, 4.8146]	1.7489	-0.7152	[-5.3093, 3.8788]	2.3145	0.7580
UPA 15 + 26 WK CS-T	47	45.1303	48.3157	3.2283	[0.6443, 5.8124]	1.3044	1.1683	[-2.7546, 5.0912]	1.9766	0.5558

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 24										
All										
PBO + 52 WK CS-T	63	46.1650	49.4257	2.2672	[0.3636, 4.1708]	0.9671				
UPA 7.5 + 26 WK CS-T	57	45.7840	47.1889	1.1449	[-0.8567, 3.1465]	1.0169	-1.1223	[-3.8489, 1.6043]	1.3850	0.4185
UPA 15 + 26 WK CS-T	143	46.5994	47.3786	0.7710	[-0.5437, 2.0857]	0.6679	-1.4962	[-3.7647, 0.7723]	1.1523	0.1952

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 24										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	37	45.2524	49.0164	1.9371	[-0.4333, 4.3075]	1.1996				
UPA 7.5 + 26 WK CS-T	31	44.1505	48.0815	2.2808	[-0.3219, 4.8836]	1.3173	0.3437	[-3.1706, 3.8581]	1.7785	0.8470
UPA 15 + 26 WK CS-T	81	47.7862	48.1300	1.0343	[-0.5978, 2.6664]	0.8256	-0.9028	[-3.7815, 1.9759]	1.4567	0.5364

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 24										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	26	47.4638	50.0081	2.5881	[-0.6805, 5.8567]	1.6530				
UPA 7.5 + 26 WK CS-T	26	47.7316	46.1247	-0.4193	[-3.6650, 2.8264]	1.6418	-3.0074	[-7.3605, 1.3456]	2.1993	0.1740
UPA 15 + 26 WK CS-T	62	45.0490	46.3968	0.3937	[-2.0083, 2.7957]	1.2161	-2.1944	[-5.9080, 1.5192]	1.8761	0.2444

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 24										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	41	47.8459	50.1388	1.7094	[-0.5975, 4.0163]	1.1696				
UPA 7.5 + 26 WK CS-T	40	46.9415	46.9415	-0.2748	[-2.6113, 2.0617]	1.1846	-1.9842	[-5.2669, 1.2985]	1.6643	0.2347
UPA 15 + 26 WK CS-T	100	46.9763	47.0808	-0.5308	[-2.0379, 0.9763]	0.7639	-2.2402	[-4.9951, 0.5146]	1.3966	0.1104

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 24										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	22	43.0325	48.0968	3.0346	[-0.4390, 6.5081]	1.7489				
UPA 7.5 + 26 WK CS-T	17	43.0604	47.7710	4.0309	[0.1582, 7.9037]	1.9490	0.9964	[-4.0466, 6.0394]	2.5357	0.6954
UPA 15 + 26 WK CS-T	43	45.7229	48.0711	3.1982	[0.5797, 5.8167]	1.3188	0.1636	[-3.9603, 4.2876]	2.0731	0.9373

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 52										
All										
PBO + 52 WK CS-T	44	47.2264	49.5212	1.8589	[-0.4370, 4.1548]	1.1655				
UPA 7.5 + 26 WK CS-T	49	45.7940	48.2809	2.2408	[0.0294, 4.4523]	1.1226	0.3819	[-2.7735, 3.5374]	1.6016	0.8117
UPA 15 + 26 WK CS-T	123	46.8835	48.6385	1.8368	[0.4014, 3.2722]	0.7288	-0.0221	[-2.6908, 2.6466]	1.3545	0.9870

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 52										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	26	47.3299	48.9368	1.0139	[-1.8469, 3.8748]	1.4462				
UPA 7.5 + 26 WK CS-T	29	45.0026	45.7229	0.0790	[-2.6787, 2.8368]	1.3937	-0.9349	[-4.9061, 3.0363]	2.0073	0.6422
UPA 15 + 26 WK CS-T	70	48.4586	49.8015	2.3580	[0.5738, 4.1423]	0.9016	1.3441	[-2.0262, 4.7144]	1.7036	0.4316

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 52										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	18	47.0769	50.3652	2.5101	[-1.3996, 6.4197]	1.9727				
UPA 7.5 + 26 WK CS-T	20	46.9415	51.9900	5.1713	[1.4175, 8.9252]	1.8945	2.6613	[-2.5426, 7.8651]	2.6221	0.3127
UPA 15 + 26 WK CS-T	53	44.8032	47.1025	1.3359	[-1.2579, 3.9297]	1.3116	-1.1741	[-5.5746, 3.2263]	2.2175	0.5977

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 52										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	29	48.0040	50.6454	2.1869	[-0.7186, 5.0923]	1.4716				
UPA 7.5 + 26 WK CS-T	34	46.4397	48.7950	1.8942	[-0.8262, 4.6146]	1.3777	-0.2927	[-4.2731, 3.6877]	2.0160	0.8847
UPA 15 + 26 WK CS-T	87	47.4438	48.7244	1.0540	[-0.6723, 2.7802]	0.8741	-1.1329	[-4.5118, 2.2460]	1.7113	0.5089

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Emotional Scale										
Week 52										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	15	45.7229	47.3477	1.1930	[-2.5815, 4.9675]	1.8936				
UPA 7.5 + 26 WK CS-T	15	44.3302	47.1156	2.6983	[-1.1143, 6.5110]	1.9113	1.5053	[-3.7103, 6.7209]	2.6122	0.5664
UPA 15 + 26 WK CS-T	36	45.5295	48.4309	3.1075	[0.5169, 5.6982]	1.3009	1.9145	[-2.4589, 6.2879]	2.1907	0.3853

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 8										
All										
PBO + 52 WK CS-T	85	42.1240	43.2864	1.0287	[-0.3794, 2.4368]	0.7158				
UPA 7.5 + 26 WK CS-T	79	40.4424	43.0857	2.0591	[0.5846, 3.5335]	0.7496	1.0304	[-0.9662, 3.0269]	1.0149	0.3107
UPA 15 + 26 WK CS-T	170	41.3315	43.7223	2.0124	[0.9796, 3.0451]	0.5251	0.9837	[-0.7093, 2.6766]	0.8606	0.2539

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 8										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	51	41.0410	42.7140	1.1815	[-0.7160, 3.0790]	0.9618				
UPA 7.5 + 26 WK CS-T	43	38.4085	42.6382	2.7159	[0.5986, 4.8332]	1.0731	1.5344	[-1.3022, 4.3711]	1.4378	0.2873
UPA 15 + 26 WK CS-T	93	42.7893	45.4452	3.1776	[1.7549, 4.6002]	0.7211	1.9961	[-0.3742, 4.3664]	1.2015	0.0983

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 8										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	34	43.7487	44.1449	0.8472	[-1.2888, 2.9833]	1.0812				
UPA 7.5 + 26 WK CS-T	36	42.8718	43.6203	0.9570	[-1.1400, 3.0539]	1.0614	0.1097	[-2.6486, 2.8681]	1.3956	0.9374
UPA 15 + 26 WK CS-T	77	39.5709	41.6413	1.0733	[-0.5866, 2.7332]	0.8404	0.2261	[-2.1853, 2.6374]	1.2202	0.8533

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 8										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	55	43.0702	44.2134	1.3697	[-0.3377, 3.0772]	0.8666				
UPA 7.5 + 26 WK CS-T	55	40.2941	43.2335	2.4258	[0.6982, 4.1535]	0.8768	1.0561	[-1.3774, 3.4896]	1.2350	0.3934
UPA 15 + 26 WK CS-T	120	41.9799	44.0943	2.1760	[1.0065, 3.3455]	0.5935	0.8063	[-1.2625, 2.8751]	1.0499	0.4433

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 8										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	30	40.3893	41.5869	0.8485	[-1.6885, 3.3855]	1.2795				
UPA 7.5 + 26 WK CS-T	24	40.7823	42.7470	1.7510	[-1.0176, 4.5197]	1.3957	0.9025	[-2.6782, 4.4832]	1.8046	0.6181
UPA 15 + 26 WK CS-T	50	39.7756	42.8294	2.3900	[0.3111, 4.4689]	1.0487	1.5415	[-1.4713, 4.5543]	1.5185	0.3125

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 12										
All										
PBO + 52 WK CS-T	77	42.2537	43.0119	0.9931	[-0.6257, 2.6119]	0.8230				
UPA 7.5 + 26 WK CS-T	73	40.0530	43.1905	2.5105	[0.8315, 4.1895]	0.8536	1.5174	[-0.7784, 3.8132]	1.1671	0.1944
UPA 15 + 26 WK CS-T	161	41.4093	44.2266	2.3048	[1.1431, 3.4664]	0.5906	1.3117	[-0.6333, 3.2567]	0.9888	0.1856

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 12										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	47	41.0072	42.0583	1.1562	[-1.0382, 3.3506]	1.1124				
UPA 7.5 + 26 WK CS-T	41	37.8774	43.2445	3.5976	[1.1832, 6.0119]	1.2238	2.4413	[-0.8157, 5.6984]	1.6510	0.1409
UPA 15 + 26 WK CS-T	89	42.5978	45.1964	2.9819	[1.3596, 4.6043]	0.8223	1.8257	[-0.9021, 4.5535]	1.3827	0.1883

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 12										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	30	44.2066	44.5060	0.8725	[-1.5292, 3.2741]	1.2153				
UPA 7.5 + 26 WK CS-T	32	42.8406	43.1213	0.8431	[-1.4904, 3.1766]	1.1807	-0.0294	[-3.1703, 3.1115]	1.5881	0.9853
UPA 15 + 26 WK CS-T	72	39.9403	43.0277	1.9319	[0.1387, 3.7251]	0.9083	1.0594	[-1.6676, 3.7864]	1.3790	0.4437

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group ----- Change from Baseline ----- LS Mean	[95% CI]	SE	Between Groups Difference -------- Compared to Placebo -------- LS Mean	[95% CI]	SE	P-value
Role Physical Scale										
Week 12										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	50	42.8743	44.3114	2.2074	[0.2679, 4.1470]	0.9844				
UPA 7.5 + 26 WK CS-T	49	39.6959	42.9953	2.6920	[0.7264, 4.6575]	0.9976	0.4845	[-2.2812, 3.2503]	1.4037	0.7303
UPA 15 + 26 WK CS-T	114	41.9887	44.6675	2.4240	[1.1162, 3.7318]	0.6636	0.2166	[-2.1221, 2.5553]	1.1869	0.8554

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 12										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	27	41.1045	40.6056	-0.6148	[-3.6104, 2.3807]	1.5114				
UPA 7.5 + 26 WK CS-T	24	40.7823	43.5891	2.5931	[-0.5735, 5.7597]	1.5961	3.2079	[-1.0001, 7.4159]	2.1204	0.1335
UPA 15 + 26 WK CS-T	47	40.0040	43.1571	2.6957	[0.3013, 5.0900]	1.2089	3.3105	[-0.2878, 6.9088]	1.8136	0.0709

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 24										
All										
PBO + 52 WK CS-T	63	41.4016	44.1103	1.5455	[-0.2786, 3.3697]	0.9269				
UPA 7.5 + 26 WK CS-T	57	40.5705	42.3433	0.9096	[-1.0000, 2.8193]	0.9704	-0.6359	[-3.2442, 1.9724]	1.3252	0.6317
UPA 15 + 26 WK CS-T	143	41.9868	43.9025	1.7746	[0.5156, 3.0336]	0.6397	0.2290	[-1.9454, 2.4035]	1.1047	0.8359

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 24										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	37	40.4055	44.6536	2.6335	[0.1903, 5.0767]	1.2372				
UPA 7.5 + 26 WK CS-T	31	38.4674	41.5096	1.0390	[-1.6560, 3.7340]	1.3648	-1.5945	[-5.2259, 2.0370]	1.8389	0.3872
UPA 15 + 26 WK CS-T	81	43.2668	44.5697	2.1412	[0.4323, 3.8502]	0.8650	-0.4923	[-3.4741, 2.4895]	1.5098	0.7448

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 24										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	26	42.8190	43.3372	0.1381	[-2.6430, 2.9191]	1.4062				
UPA 7.5 + 26 WK CS-T	26	43.0781	43.3372	0.4491	[-2.2938, 3.1920]	1.3874	0.3110	[-3.4134, 4.0354]	1.8815	0.8690
UPA 15 + 26 WK CS-T	62	40.3145	43.0307	1.7841	[-0.2089, 3.7772]	1.0092	1.6461	[-1.5370, 4.8292]	1.6079	0.3080

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 24										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	41	42.2039	45.3256	2.3286	[0.0454, 4.6119]	1.1579				
UPA 7.5 + 26 WK CS-T	40	40.2584	42.7283	1.5356	[-0.7684, 3.8395]	1.1685	-0.7931	[-4.0395, 2.4533]	1.6464	0.6305
UPA 15 + 26 WK CS-T	100	42.5150	43.9970	1.5915	[0.1019, 3.0811]	0.7553	-0.7371	[-3.4621, 1.9878]	1.3818	0.5943

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 24										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	22	39.9062	41.8455	0.6870	[-2.4162, 3.7903]	1.5621				
UPA 7.5 + 26 WK CS-T	17	41.3051	41.4372	-0.2330	[-3.6744, 3.2083]	1.7315	-0.9201	[-5.4087, 3.5685]	2.2565	0.6845
UPA 15 + 26 WK CS-T	43	40.7584	43.6826	2.8779	[0.5120, 5.2438]	1.1914	2.1909	[-1.4778, 5.8596]	1.8436	0.2382

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 52										
All										
PBO + 52 WK CS-T	44	42.8661	44.3461	0.8089	[-1.2894, 2.9071]	1.0656				
UPA 7.5 + 26 WK CS-T	49	40.9790	44.1867	2.7239	[0.6724, 4.7755]	1.0417	1.9151	[-0.9899, 4.8200]	1.4750	0.1954
UPA 15 + 26 WK CS-T	123	42.1127	45.9828	3.5311	[2.1886, 4.8735]	0.6817	2.7222	[0.2686, 5.1758]	1.2458	0.0298*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 52										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	26	42.3872	44.4599	0.9473	[-1.8163, 3.7108]	1.3986				
UPA 7.5 + 26 WK CS-T	29	39.5015	43.2955	3.3366	[0.5521, 6.1210]	1.4081	2.3893	[-1.5298, 6.3083]	1.9828	0.2302
UPA 15 + 26 WK CS-T	70	43.6506	47.0829	3.9335	[2.1245, 5.7426]	0.9147	2.9862	[-0.3158, 6.2883]	1.6708	0.0760

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 52										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	18	43.5579	44.1816	0.7383	[-2.6435, 4.1201]	1.7065				
UPA 7.5 + 26 WK CS-T	20	43.1213	45.4790	1.6896	[-1.5477, 4.9269]	1.6338	0.9513	[-3.5796, 5.4822]	2.2837	0.6779
UPA 15 + 26 WK CS-T	53	40.0815	44.5300	3.3788	[1.1798, 5.5778]	1.1117	2.6405	[-1.1961, 6.4771]	1.9340	0.1752

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 52										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	29	43.9924	46.3926	2.2887	[-0.2662, 4.8437]	1.2945				
UPA 7.5 + 26 WK CS-T	34	40.3145	44.6733	3.6805	[1.2544, 6.1066]	1.2288	1.3918	[-2.1352, 4.9187]	1.7868	0.4371
UPA 15 + 26 WK CS-T	87	42.7793	46.4443	3.7249	[2.1752, 5.2746]	0.7846	1.4361	[-1.5508, 4.4231]	1.5131	0.3439

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Role Physical Scale										
Week 52										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	15	40.6887	40.3893	-1.3943	[-5.1542, 2.3656]	1.8906				
UPA 7.5 + 26 WK CS-T	15	42.4851	43.0839	0.7775	[-3.0657, 4.6207]	1.9305	2.1718	[-3.0812, 7.4247]	2.6372	0.4128
UPA 15 + 26 WK CS-T	36	40.5016	44.8677	3.7619	[1.1239, 6.3998]	1.3271	5.1562	[0.7543, 9.5580]	2.2102	0.0223*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 8										
All										
PBO + 52 WK CS-T	85	46.6052	48.4336	1.7235	[-0.1067, 3.5537]	0.9304				
UPA 7.5 + 26 WK CS-T	79	43.6958	46.9322	1.7172	[-0.1963, 3.6307]	0.9727	-0.0063	[-2.6149, 2.6024]	1.3260	0.9962
UPA 15 + 26 WK CS-T	170	45.8680	47.0181	0.5714	[-0.7579, 1.9007]	0.6758	-1.1521	[-3.3615, 1.0573]	1.1231	0.3057

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 8										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	51	45.3470	47.7062	1.9645	[-0.4847, 4.4137]	1.2411				
UPA 7.5 + 26 WK CS-T	43	42.2997	47.4296	3.0300	[0.3203, 5.7397]	1.3731	1.0655	[-2.5841, 4.7151]	1.8494	0.5652
UPA 15 + 26 WK CS-T	93	46.7200	48.3911	2.1113	[0.2828, 3.9398]	0.9265	0.1468	[-2.9076, 3.2013]	1.5478	0.9245

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 8										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	34	48.4926	49.5247	1.3960	[-1.4520, 4.2440]	1.4418				
UPA 7.5 + 26 WK CS-T	36	45.3634	46.3382	-0.0452	[-2.8339, 2.7434]	1.4117	-1.4412	[-5.1631, 2.2806]	1.8831	0.4453
UPA 15 + 26 WK CS-T	77	44.8389	45.3598	-1.2732	[-3.4082, 0.8618]	1.0814	-2.6692	[-5.8870, 0.5485]	1.6282	0.1033

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 8										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	55	47.3130	49.9563	3.2236	[1.1090, 5.3383]	1.0731				
UPA 7.5 + 26 WK CS-T	55	43.8493	47.9510	3.2102	[1.0802, 5.3401]	1.0808	-0.0134	[-3.0201, 2.9932]	1.5257	0.9930
UPA 15 + 26 WK CS-T	120	46.4357	47.5637	1.5379	[0.0963, 2.9795]	0.7315	-1.6857	[-4.2423, 0.8709]	1.2973	0.1952

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 8										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	30	45.3077	45.6419	-0.0239	[-3.6914, 3.6437]	1.8490				
UPA 7.5 + 26 WK CS-T	24	43.3442	44.5975	-0.1783	[-4.2171, 3.8604]	2.0351	-0.1545	[-5.4106, 5.1017]	2.6474	0.9536
UPA 15 + 26 WK CS-T	50	44.5056	45.7088	-0.1147	[-3.0803, 2.8510]	1.4959	-0.0908	[-4.5051, 4.3235]	2.2235	0.9675

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 12										
All										
PBO + 52 WK CS-T	77	46.3364	48.7453	2.4340	[0.5497, 4.3183]	0.9579				
UPA 7.5 + 26 WK CS-T	73	43.2612	47.5190	2.5330	[0.5815, 4.4846]	0.9920	0.0990	[-2.5756, 2.7737]	1.3595	0.9420
UPA 15 + 26 WK CS-T	161	45.7249	47.5621	1.1099	[-0.2357, 2.4556]	0.6841	-1.3241	[-3.5868, 0.9387]	1.1502	0.2505

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 12										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	47	45.2864	47.3130	2.2745	[-0.3032, 4.8523]	1.3064				
UPA 7.5 + 26 WK CS-T	41	41.9329	47.8021	3.5528	[0.7394, 6.3663]	1.4257	1.2783	[-2.5343, 5.0908]	1.9321	0.5091
UPA 15 + 26 WK CS-T	89	46.4681	48.3832	2.4096	[0.5136, 4.3055]	0.9607	0.1350	[-3.0631, 3.3331]	1.6207	0.9337

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 12										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	30	47.9814	50.9894	2.9083	[0.0826, 5.7340]	1.4299				
UPA 7.5 + 26 WK CS-T	32	44.9630	47.1563	1.2366	[-1.4899, 3.9631]	1.3797	-1.6717	[-5.3328, 1.9893]	1.8514	0.3681
UPA 15 + 26 WK CS-T	72	44.8064	46.5471	-0.4607	[-2.5610, 1.6396]	1.0637	-3.3690	[-6.5253, -0.2127]	1.5961	0.0366*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 12										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	50	46.3103	49.8196	3.9772	[1.8038, 6.1506]	1.1028				
UPA 7.5 + 26 WK CS-T	49	43.2205	48.5407	4.0648	[1.8613, 6.2683]	1.1182	0.0876	[-3.0114, 3.1866]	1.5725	0.9556
UPA 15 + 26 WK CS-T	114	46.3455	48.2365	2.0631	[0.6067, 3.5195]	0.7389	-1.9141	[-4.5287, 0.7005]	1.3266	0.1505

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 12										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	27	46.3846	46.7560	0.6400	[-3.1217, 4.4018]	1.8977				
UPA 7.5 + 26 WK CS-T	24	43.3442	45.4330	0.6572	[-3.3272, 4.6417]	2.0080	0.0172	[-5.2631, 5.2975]	2.6605	0.9949
UPA 15 + 26 WK CS-T	47	44.2197	45.9263	0.5103	[-2.4997, 3.5203]	1.5195	-0.1297	[-4.6350, 4.3755]	2.2705	0.9546

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 24										
All										
PBO + 52 WK CS-T	63	45.0849	50.8143	4.4983	[2.5553, 6.4414]	0.9872				
UPA 7.5 + 26 WK CS-T	57	43.8829	47.5768	2.1290	[0.0875, 4.1704]	1.0373	-2.3693	[-5.1487, 0.4100]	1.4119	0.0944
UPA 15 + 26 WK CS-T	143	46.2613	48.7153	2.2634	[0.9259, 3.6009]	0.6796	-2.2349	[-4.5434, 0.0736]	1.1727	0.0577

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 24										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	37	43.7902	50.8358	5.4871	[2.9182, 8.0560]	1.3005				
UPA 7.5 + 26 WK CS-T	31	42.4615	48.6067	3.7503	[0.9268, 6.5738]	1.4295	-1.7368	[-5.5459, 2.0723]	1.9284	0.3692
UPA 15 + 26 WK CS-T	81	47.2511	49.6649	3.5696	[1.8027, 5.3364]	0.8943	-1.9175	[-5.0377, 1.2026]	1.5795	0.2266

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 24										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	26	46.9274	50.7837	3.1995	[0.1005, 6.2984]	1.5672				
UPA 7.5 + 26 WK CS-T	26	45.5776	46.3489	0.1662	[-2.8953, 3.2277]	1.5488	-3.0333	[-7.1399, 1.0734]	2.0749	0.1463
UPA 15 + 26 WK CS-T	62	44.9681	47.4747	0.6602	[-1.5847, 2.9050]	1.1366	-2.5393	[-6.0321, 0.9535]	1.7646	0.1527

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 24										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	41	45.6012	52.0817	5.9759	[3.7090, 8.2429]	1.1492				
UPA 7.5 + 26 WK CS-T	40	43.5531	48.3156	3.5779	[1.2843, 5.8716]	1.1629	-2.3980	[-5.6239, 0.8279]	1.6354	0.1442
UPA 15 + 26 WK CS-T	100	46.6111	49.3183	3.1678	[1.6987, 4.6369]	0.7446	-2.8082	[-5.5073, -0.1090]	1.3682	0.0415*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 24										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	22	44.1227	48.4524	2.6168	[-1.2299, 6.4635]	1.9377				
UPA 7.5 + 26 WK CS-T	17	44.6589	45.8385	1.0077	[-3.2690, 5.2845]	2.1531	-1.6091	[-7.1604, 3.9422]	2.7927	0.5660
UPA 15 + 26 WK CS-T	43	45.4476	47.3130	1.7316	[-1.2010, 4.6642]	1.4780	-0.8852	[-5.4092, 3.6389]	2.2756	0.6982

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Social Functioning Scale										
Week 52										
All										
PBO + 52 WK CS-T	44	45.6039	48.9081	2.1610	[-0.2893, 4.6113]	1.2442				
UPA 7.5 + 26 WK CS-T	49	44.3460	48.9500	3.0505	[0.6774, 5.4236]	1.2049	0.8895	[-2.4885, 4.2675]	1.7149	0.6045
UPA 15 + 26 WK CS-T	123	46.6201	49.7177	2.9845	[1.4429, 4.5260]	0.7828	0.8235	[-2.0298, 3.6768]	1.4486	0.5702

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 52										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	26	45.3848	47.5058	1.6793	[-1.3098, 4.6684]	1.5120				
UPA 7.5 + 26 WK CS-T	29	43.1641	47.3130	3.6355	[0.7151, 6.5559]	1.4769	1.9562	[-2.2185, 6.1310]	2.1115	0.3558
UPA 15 + 26 WK CS-T	70	47.8143	50.5358	4.0309	[2.1419, 5.9199]	0.9553	2.3516	[-1.1836, 5.8868]	1.7882	0.1906

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 52										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	18	45.9204	50.9337	2.7473	[-1.5207, 7.0154]	2.1553				
UPA 7.5 + 26 WK CS-T	20	46.0597	51.3236	2.4888	[-1.5959, 6.5735]	2.0629	-0.2585	[-5.9884, 5.4713]	2.8904	0.9289
UPA 15 + 26 WK CS-T	53	45.0428	48.6372	0.9964	[-1.7896, 3.7824]	1.4088	-1.7509	[-6.6039, 3.1020]	2.4479	0.4760

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 52										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	29	45.9300	49.3874	3.1235	[0.1361, 6.1108]	1.5131				
UPA 7.5 + 26 WK CS-T	34	43.6268	49.8196	4.2998	[1.4928, 7.1069]	1.4216	1.1764	[-2.9245, 5.2773]	2.0770	0.5719
UPA 15 + 26 WK CS-T	87	46.9673	50.0789	3.4457	[1.6684, 5.2229]	0.8999	0.3222	[-3.1519, 3.7963]	1.7595	0.8549

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Social Functioning Scale										
Week 52										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	15	44.9735	47.9814	1.5483	[-2.9771, 6.0738]	2.2752				
UPA 7.5 + 26 WK CS-T	15	45.9761	46.9788	2.1305	[-2.4556, 6.7166]	2.3045	0.5822	[-5.6816, 6.8460]	3.1446	0.8536
UPA 15 + 26 WK CS-T	36	45.7812	48.8448	3.4186	[0.2534, 6.5838]	1.5929	1.8702	[-3.3910, 7.1315]	2.6415	0.4811

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 8										
All										
PBO + 52 WK CS-T	85	50.1858	51.5138	1.6226	[-0.0300, 3.2752]	0.8401				
UPA 7.5 + 26 WK CS-T	79	46.7314	47.7842	0.2204	[-1.5136, 1.9544]	0.8815	-1.4022	[-3.7548, 0.9505]	1.1959	0.2419
UPA 15 + 26 WK CS-T	170	47.5473	48.6132	0.2930	[-0.9204, 1.5065]	0.6169	-1.3296	[-3.3240, 0.6648]	1.0138	0.1906

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 8										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	51	48.0540	49.7432	1.3503	[-0.8597, 3.5603]	1.1202				
UPA 7.5 + 26 WK CS-T	43	44.7909	48.2450	1.9939	[-0.4717, 4.4594]	1.2496	0.6436	[-2.6661, 3.9533]	1.6775	0.7017
UPA 15 + 26 WK CS-T	93	48.8281	50.9362	2.3631	[0.7085, 4.0178]	0.8386	1.0128	[-1.7445, 3.7702]	1.3976	0.4696

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 8										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	34	53.3835	54.1698	2.0882	[-0.3919, 4.5683]	1.2550				
UPA 7.5 + 26 WK CS-T	36	49.0491	47.2337	-2.0180	[-4.4453, 0.4093]	1.2282	-4.1062	[-7.2964, -0.9159]	1.6138	0.0120*
UPA 15 + 26 WK CS-T	77	46.0003	45.8074	-1.6339	[-3.5828, 0.3151]	0.9865	-3.7221	[-6.5475, -0.8967]	1.4296	0.0102*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 8										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	55	52.1651	53.5693	2.4049	[0.4594, 4.3505]	0.9874				
UPA 7.5 + 26 WK CS-T	55	47.5743	48.6005	0.4922	[-1.4687, 2.4532]	0.9950	-1.9127	[-4.6862, 0.8609]	1.4075	0.1755
UPA 15 + 26 WK CS-T	120	48.7355	49.1811	0.2110	[-1.1167, 1.5388]	0.6737	-2.1939	[-4.5531, 0.1653]	1.1973	0.0682

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 8										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	30	46.5571	47.7453	1.0938	[-2.0797, 4.2672]	1.6004				
UPA 7.5 + 26 WK CS-T	24	44.7996	45.9135	0.5606	[-2.9176, 4.0388]	1.7533	-0.5332	[-5.0486, 3.9822]	2.2753	0.8152
UPA 15 + 26 WK CS-T	50	44.6956	47.2503	1.6139	[-0.9662, 4.1940]	1.3017	0.5201	[-3.2781, 4.3183]	1.9141	0.7864

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 12										
All										
PBO + 52 WK CS-T	77	49.8967	50.1668	0.4427	[-1.4130, 2.2984]	0.9434				
UPA 7.5 + 26 WK CS-T	73	46.1678	47.0631	-0.1177	[-2.0493, 1.8139]	0.9819	-0.5604	[-3.2006, 2.0798]	1.3421	0.6765
UPA 15 + 26 WK CS-T	161	47.5049	49.2761	0.8481	[-0.4888, 2.1850]	0.6797	0.4054	[-1.8302, 2.6409]	1.1364	0.7215

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 12										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	47	47.5410	47.9834	0.4698	[-2.0100, 2.9497]	1.2571				
UPA 7.5 + 26 WK CS-T	41	44.1928	47.8154	1.9212	[-0.8090, 4.6514]	1.3838	1.4514	[-2.2333, 5.1361]	1.8677	0.4381
UPA 15 + 26 WK CS-T	89	48.7255	50.7615	2.2177	[0.3841, 4.0513]	0.9294	1.7479	[-1.3338, 4.8296]	1.5621	0.2646

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 12										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	30	53.5873	53.5873	0.5638	[-2.2913, 3.4189]	1.4448				
UPA 7.5 + 26 WK CS-T	32	48.6984	46.0992	-2.6486	[-5.4217, 0.1246]	1.4030	-3.2123	[-6.9524, 0.5277]	1.8911	0.0917
UPA 15 + 26 WK CS-T	72	45.9960	47.4400	-0.2869	[-2.4320, 1.8583]	1.0865	-0.8507	[-4.1260, 2.4247]	1.6567	0.6084

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 12										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	50	51.2307	52.3595	1.7802	[-0.3852, 3.9455]	1.0989				
UPA 7.5 + 26 WK CS-T	49	46.8380	46.5955	-1.0582	[-3.2548, 1.1385]	1.1148	-2.8383	[-5.9327, 0.2560]	1.5704	0.0720
UPA 15 + 26 WK CS-T	114	48.7668	50.1999	0.9537	[-0.5063, 2.4137]	0.7408	-0.8265	[-3.4411, 1.7881]	1.3268	0.5340

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 12										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	27	47.4263	46.1061	-1.1313	[-4.6608, 2.3983]	1.7812				
UPA 7.5 + 26 WK CS-T	24	44.7996	48.0176	2.6647	[-1.0947, 6.4241]	1.8950	3.7959	[-1.1835, 8.7754]	2.5096	0.1336
UPA 15 + 26 WK CS-T	47	44.4441	47.0354	1.7159	[-1.1050, 4.5369]	1.4244	2.8472	[-1.3979, 7.0922]	2.1401	0.1864

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 24										
All										
PBO + 52 WK CS-T	63	49.4381	51.9842	1.8752	[-0.1593, 3.9097]	1.0338				
UPA 7.5 + 26 WK CS-T	57	47.1773	46.4477	-1.3357	[-3.4710, 0.7995]	1.0850	-3.2110	[-6.1250, -0.2969]	1.4806	0.0309*
UPA 15 + 26 WK CS-T	143	48.0687	50.0837	1.2959	[-0.1126, 2.7044]	0.7157	-0.5794	[-3.0070, 1.8482]	1.2333	0.6389

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 24										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	37	46.9773	52.2760	3.5222	[0.9112, 6.1331]	1.3224				
UPA 7.5 + 26 WK CS-T	31	45.5063	45.7937	-1.0510	[-3.9373, 1.8352]	1.4618	-4.5732	[-8.4614, -0.6850]	1.9692	0.0214*
UPA 15 + 26 WK CS-T	81	49.2233	50.4335	1.7179	[-0.1081, 3.5438]	0.9244	-1.8043	[-4.9891, 1.3805]	1.6128	0.2649

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 24										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	26	52.9399	51.5689	-0.1491	[-3.4669, 3.1687]	1.6779				
UPA 7.5 + 26 WK CS-T	26	49.1697	47.2274	-1.5388	[-4.7949, 1.7174]	1.6473	-1.3897	[-5.8296, 3.0503]	2.2434	0.5368
UPA 15 + 26 WK CS-T	62	46.5603	49.6267	1.2586	[-1.1242, 3.6415]	1.2068	1.4078	[-2.4184, 5.2339]	1.9335	0.4679

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 24										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	41	51.5829	53.7564	2.6645	[0.1295, 5.1995]	1.2855				
UPA 7.5 + 26 WK CS-T	40	47.3988	46.8789	-1.0006	[-3.5530, 1.5519]	1.2944	-3.6651	[-7.2710, -0.0591]	1.8286	0.0464*
UPA 15 + 26 WK CS-T	100	49.4484	50.9634	1.3033	[-0.3423, 2.9488]	0.8343	-1.3612	[-4.3846, 1.6621]	1.5330	0.3757

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 24										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	22	45.4409	48.6815	1.4718	[-2.0217, 4.9652]	1.7593				
UPA 7.5 + 26 WK CS-T	17	46.6562	45.4330	-1.2972	[-5.1680, 2.5737]	1.9486	-2.7689	[-7.8000, 2.2622]	2.5307	0.2770
UPA 15 + 26 WK CS-T	43	44.8600	48.0378	2.3521	[-0.3375, 5.0418]	1.3549	0.8804	[-3.2435, 5.0043]	2.0736	0.6722

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 52										
All										
PBO + 52 WK CS-T	44	50.5043	50.9094	0.0769	[-2.1130, 2.2667]	1.1122				
UPA 7.5 + 26 WK CS-T	49	46.8380	50.2935	2.3011	[0.1578, 4.4445]	1.0885	2.2243	[-0.8055, 5.2541]	1.5385	0.1495
UPA 15 + 26 WK CS-T	123	48.2501	50.1821	1.0686	[-0.3366, 2.4738]	0.7137	0.9917	[-1.5653, 3.5488]	1.2985	0.4457

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 52										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	26	48.8269	49.9694	0.4264	[-2.3196, 3.1724]	1.3899				
UPA 7.5 + 26 WK CS-T	29	45.1197	48.0902	2.2401	[-0.5014, 4.9816]	1.3869	1.8137	[-2.0662, 5.6936]	1.9635	0.3571
UPA 15 + 26 WK CS-T	70	49.4145	51.1968	2.1692	[0.3901, 3.9483]	0.8998	1.7428	[-1.5255, 5.0111]	1.6540	0.2937

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 52										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	18	52.9272	52.2671	0.0427	[-3.6835, 3.7689]	1.8815				
UPA 7.5 + 26 WK CS-T	20	49.3296	53.4883	2.0971	[-1.4797, 5.6739]	1.8061	2.0544	[-2.9232, 7.0321]	2.5104	0.4150
UPA 15 + 26 WK CS-T	53	46.7122	48.8420	0.1654	[-2.3207, 2.6515]	1.2572	0.1228	[-4.1230, 4.3685]	2.1417	0.9544

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 52										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	29	52.6996	52.8020	0.8834	[-1.8485, 3.6153]	1.3845				
UPA 7.5 + 26 WK CS-T	34	46.9183	51.3740	3.4234	[0.8313, 6.0155]	1.3133	2.5400	[-1.2358, 6.3158]	1.9135	0.1861
UPA 15 + 26 WK CS-T	87	49.7974	51.2997	1.1462	[-0.5075, 2.8000]	0.8376	0.2629	[-2.9316, 3.4573]	1.6187	0.8712

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Vitality Scale										
Week 52										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	15	46.2601	47.2503	-0.4032	[-4.2170, 3.4106]	1.9169				
UPA 7.5 + 26 WK CS-T	15	46.6562	47.8444	0.7145	[-3.1396, 4.5686]	1.9360	1.1177	[-4.1214, 6.3568]	2.6292	0.6720
UPA 15 + 26 WK CS-T	36	44.5108	47.4813	1.9738	[-0.7166, 4.6642]	1.3532	2.3770	[-2.0294, 6.7835]	2.2116	0.2859

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 8										
All										
PBO + 52 WK CS-T	85	0.7018	0.7160	0.0184	[0.0002, 0.0366]	0.0093				
UPA 7.5 + 26 WK CS-T	79	0.6699	0.6811	0.0064	[-0.0126, 0.0254]	0.0097	-0.0120	[-0.0378, 0.0137]	0.0131	0.3588
UPA 15 + 26 WK CS-T	170	0.6672	0.6931	0.0174	[0.0040, 0.0307]	0.0068	-0.0011	[-0.0230, 0.0209]	0.0112	0.9235

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 8										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	51	0.6880	0.7051	0.0196	[-0.0042, 0.0434]	0.0121				
UPA 7.5 + 26 WK CS-T	43	0.6540	0.6751	0.0122	[-0.0141, 0.0385]	0.0133	-0.0074	[-0.0429, 0.0281]	0.0180	0.6824
UPA 15 + 26 WK CS-T	93	0.6765	0.7152	0.0390	[0.0212, 0.0568]	0.0090	0.0194	[-0.0102, 0.0491]	0.0150	0.1983

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 8										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	34	0.7226	0.7323	0.0190	[-0.0101, 0.0481]	0.0147				
UPA 7.5 + 26 WK CS-T	36	0.6890	0.6883	-0.0014	[-0.0299, 0.0271]	0.0144	-0.0204	[-0.0577, 0.0170]	0.0189	0.2822
UPA 15 + 26 WK CS-T	77	0.6560	0.6664	-0.0076	[-0.0303, 0.0150]	0.0115	-0.0266	[-0.0595, 0.0062]	0.0166	0.1111

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 8										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	55	0.7189	0.7385	0.0308	[0.0086, 0.0531]	0.0113				
UPA 7.5 + 26 WK CS-T	55	0.6827	0.6972	0.0171	[-0.0051, 0.0394]	0.0113	-0.0137	[-0.0452, 0.0177]	0.0160	0.3911
UPA 15 + 26 WK CS-T	120	0.6752	0.6951	0.0172	[0.0021, 0.0323]	0.0077	-0.0136	[-0.0406, 0.0133]	0.0137	0.3198

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 8										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	30	0.6705	0.6747	-0.0006	[-0.0327, 0.0314]	0.0162				
UPA 7.5 + 26 WK CS-T	24	0.6407	0.6441	-0.0104	[-0.0456, 0.0247]	0.0177	-0.0098	[-0.0551, 0.0355]	0.0228	0.6676
UPA 15 + 26 WK CS-T	50	0.6480	0.6880	0.0253	[-0.0010, 0.0516]	0.0133	0.0259	[-0.0121, 0.0639]	0.0192	0.1799

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 12										
All										
PBO + 52 WK CS-T	77	0.6954	0.7168	0.0240	[0.0028, 0.0453]	0.0108				
UPA 7.5 + 26 WK CS-T	73	0.6628	0.6839	0.0164	[-0.0055, 0.0384]	0.0112	-0.0076	[-0.0377, 0.0225]	0.0153	0.6191
UPA 15 + 26 WK CS-T	161	0.6667	0.6913	0.0125	[-0.0028, 0.0277]	0.0077	-0.0116	[-0.0371, 0.0140]	0.0130	0.3735

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 12										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	47	0.6810	0.7067	0.0324	[0.0040, 0.0607]	0.0144				
UPA 7.5 + 26 WK CS-T	41	0.6455	0.6849	0.0270	[-0.0040, 0.0579]	0.0157	-0.0054	[-0.0474, 0.0366]	0.0213	0.7997
UPA 15 + 26 WK CS-T	89	0.6759	0.7051	0.0276	[0.0067, 0.0485]	0.0106	-0.0048	[-0.0400, 0.0304]	0.0178	0.7880

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	[95% CI]	SE	Between Groups Difference: Compared to Placebo: LS Mean	[95% CI]	SE	P-value
Utility Index Score										
Week 12										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	30	0.7180	0.7325	0.0155	[-0.0177, 0.0486]	0.0168				
UPA 7.5 + 26 WK CS-T	32	0.6850	0.6825	0.0013	[-0.0308, 0.0334]	0.0163	-0.0141	[-0.0574, 0.0291]	0.0219	0.5191
UPA 15 + 26 WK CS-T	72	0.6552	0.6743	-0.0039	[-0.0287, 0.0208]	0.0125	-0.0194	[-0.0571, 0.0183]	0.0191	0.3104

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 12										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	50	0.7038	0.7406	0.0447	[0.0197, 0.0697]	0.0127				
UPA 7.5 + 26 WK CS-T	49	0.6736	0.6968	0.0254	[0.0001, 0.0506]	0.0128	-0.0193	[-0.0549, 0.0162]	0.0180	0.2855
UPA 15 + 26 WK CS-T	114	0.6747	0.6912	0.0094	[-0.0073, 0.0262]	0.0085	-0.0353	[-0.0654, -0.0051]	0.0153	0.0222*

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 12										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	27	0.6799	0.6726	-0.0079	[-0.0478, 0.0320]	0.0201				
UPA 7.5 + 26 WK CS-T	24	0.6407	0.6575	0.0029	[-0.0400, 0.0458]	0.0216	0.0108	[-0.0460, 0.0676]	0.0286	0.7068
UPA 15 + 26 WK CS-T	47	0.6471	0.6917	0.0275	[-0.0043, 0.0593]	0.0160	0.0354	[-0.0128, 0.0836]	0.0243	0.1484

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 24										
All										
PBO + 52 WK CS-T	63	0.6820	0.7236	0.0279	[0.0040, 0.0518]	0.0121				
UPA 7.5 + 26 WK CS-T	57	0.6708	0.6720	-0.0051	[-0.0301, 0.0199]	0.0127	-0.0330	[-0.0672, 0.0012]	0.0174	0.0582
UPA 15 + 26 WK CS-T	143	0.6708	0.7024	0.0219	[0.0054, 0.0384]	0.0084	-0.0060	[-0.0345, 0.0225]	0.0145	0.6786

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 24										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	37	0.6656	0.7316	0.0487	[0.0183, 0.0791]	0.0154				
UPA 7.5 + 26 WK CS-T	31	0.6545	0.6702	-0.0010	[-0.0344, 0.0324]	0.0169	-0.0497	[-0.0949, -0.0045]	0.0229	0.0314*
UPA 15 + 26 WK CS-T	81	0.6804	0.7106	0.0317	[0.0105, 0.0529]	0.0107	-0.0170	[-0.0541, 0.0201]	0.0188	0.3666

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 24										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	26	0.7052	0.7122	-0.0000	[-0.0394, 0.0394]	0.0199				
UPA 7.5 + 26 WK CS-T	26	0.6902	0.6742	-0.0111	[-0.0500, 0.0278]	0.0197	-0.0111	[-0.0640, 0.0418]	0.0267	0.6793
UPA 15 + 26 WK CS-T	62	0.6582	0.6917	0.0119	[-0.0163, 0.0401]	0.0143	0.0119	[-0.0334, 0.0572]	0.0229	0.6041

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 24										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	41	0.6978	0.7454	0.0440	[0.0133, 0.0747]	0.0156				
UPA 7.5 + 26 WK CS-T	40	0.6781	0.6759	0.0005	[-0.0304, 0.0313]	0.0157	-0.0435	[-0.0870, 0.0000]	0.0221	0.0500*
UPA 15 + 26 WK CS-T	100	0.6771	0.7047	0.0217	[0.0018, 0.0417]	0.0101	-0.0223	[-0.0589, 0.0144]	0.0186	0.2321

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 24										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	22	0.6525	0.6830	0.0043	[-0.0335, 0.0420]	0.0190				
UPA 7.5 + 26 WK CS-T	17	0.6537	0.6630	-0.0079	[-0.0498, 0.0339]	0.0211	-0.0122	[-0.0666, 0.0422]	0.0273	0.6563
UPA 15 + 26 WK CS-T	43	0.6561	0.6969	0.0290	[0.0000, 0.0581]	0.0146	0.0248	[-0.0197, 0.0693]	0.0224	0.2712

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 52										
All										
PBO + 52 WK CS-T	44	0.6915	0.7279	0.0187	[-0.0093, 0.0467]	0.0142				
UPA 7.5 + 26 WK CS-T	49	0.6726	0.7076	0.0253	[-0.0019, 0.0525]	0.0138	0.0066	[-0.0321, 0.0452]	0.0196	0.7381
UPA 15 + 26 WK CS-T	123	0.6723	0.7161	0.0333	[0.0155, 0.0511]	0.0090	0.0146	[-0.0181, 0.0473]	0.0166	0.3793

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 52										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	26	0.6887	0.7232	0.0161	[-0.0192, 0.0513]	0.0178				
UPA 7.5 + 26 WK CS-T	29	0.6534	0.6893	0.0276	[-0.0071, 0.0622]	0.0175	0.0115	[-0.0380, 0.0610]	0.0250	0.6469
UPA 15 + 26 WK CS-T	70	0.6871	0.7326	0.0498	[0.0273, 0.0722]	0.0113	0.0337	[-0.0081, 0.0755]	0.0211	0.1129

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 52										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	18	0.6954	0.7346	0.0262	[-0.0213, 0.0737]	0.0240				
UPA 7.5 + 26 WK CS-T	20	0.7004	0.7341	0.0226	[-0.0229, 0.0681]	0.0230	-0.0036	[-0.0673, 0.0601]	0.0321	0.9108
UPA 15 + 26 WK CS-T	53	0.6526	0.6942	0.0129	[-0.0182, 0.0440]	0.0157	-0.0133	[-0.0674, 0.0409]	0.0273	0.6275

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 52										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	29	0.7026	0.7469	0.0399	[0.0052, 0.0745]	0.0176				
UPA 7.5 + 26 WK CS-T	34	0.6812	0.7226	0.0379	[0.0053, 0.0706]	0.0165	-0.0019	[-0.0495, 0.0457]	0.0241	0.9371
UPA 15 + 26 WK CS-T	87	0.6786	0.7195	0.0345	[0.0137, 0.0553]	0.0105	-0.0054	[-0.0458, 0.0351]	0.0205	0.7938

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__8.1

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1)

Parameter / Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Utility Index Score										
Week 52										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	15	0.6700	0.6911	-0.0143	[-0.0629, 0.0343]	0.0244				
UPA 7.5 + 26 WK CS-T	15	0.6531	0.6737	0.0103	[-0.0391, 0.0597]	0.0248	0.0246	[-0.0431, 0.0923]	0.0340	0.4714
UPA 15 + 26 WK CS-T	36	0.6568	0.7079	0.0352	[0.0015, 0.0690]	0.0170	0.0495	[-0.0073, 0.1063]	0.0285	0.0866

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

表 2.7.3.6-6

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

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Week 8										
All										
PBO + 52 WK CS-T	85	38.4	38.5	0.2	[-1.31, 1.75]	0.78				
UPA 7.5 + 26 WK CS-T	79	35.9	36.7	0.2	[-1.38, 1.83]	0.81	0.0	[-2.16, 2.18]	1.10	0.9955
UPA 15 + 26 WK CS-T	170	36.8	37.9	0.8	[-0.30, 1.94]	0.57	0.6	[-1.24, 2.44]	0.94	0.5206

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Week 8										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	51	37.2	37.4	0.0	[-1.99, 2.05]	1.02				
UPA 7.5 + 26 WK CS-T	43	34.1	37.3	2.0	[-0.23, 4.24]	1.13	2.0	[-1.04, 4.99]	1.53	0.1971
UPA 15 + 26 WK CS-T	93	37.9	39.5	2.0	[0.51, 3.52]	0.76	2.0	[-0.53, 4.50]	1.27	0.1214

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Week 8										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	34	40.1	40.2	0.3	[-2.08, 2.63]	1.19				
UPA 7.5 + 26 WK CS-T	36	38.2	35.9	-2.4	[-4.68, -0.04]	1.17	-2.6	[-5.66, 0.39]	1.53	0.0871
UPA 15 + 26 WK CS-T	77	35.5	36.0	-0.7	[-2.54, 1.16]	0.94	-1.0	[-3.60, 1.68]	1.34	0.4731

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Week 8										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	55	39.8	40.5	0.9	[-0.88, 2.61]	0.89				
UPA 7.5 + 26 WK CS-T	55	37.1	37.6	0.2	[-1.58, 1.94]	0.89	-0.7	[-3.17, 1.80]	1.26	0.5876
UPA 15 + 26 WK CS-T	120	38.3	38.8	0.5	[-0.69, 1.70]	0.61	-0.4	[-2.47, 1.76]	1.07	0.7390

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Week 8										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	30	35.7	34.9	-0.8	[-3.85, 2.24]	1.54				
UPA 7.5 + 26 WK CS-T	24	33.2	34.6	0.5	[-2.80, 3.88]	1.68	1.3	[-3.01, 5.69]	2.19	0.5421
UPA 15 + 26 WK CS-T	50	33.2	35.8	1.7	[-0.75, 4.20]	1.25	2.5	[-1.13, 6.19]	1.85	0.1737

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
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Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group ----- Change from Baseline ----- LS Mean	[95% CI]	SE	Between Groups Difference --------- Compared to Placebo --------- LS Mean	[95% CI]	SE	P-value
Week 12										
All										
PBO + 52 WK CS-T	77	38.4	37.3	-0.7	[-2.43, 1.07]	0.89				
UPA 7.5 + 26 WK CS-T	73	35.4	35.5	-0.4	[-2.22, 1.42]	0.93	0.3	[-2.21, 2.77]	1.27	0.8251
UPA 15 + 26 WK CS-T	161	36.7	37.8	0.7	[-0.60, 1.92]	0.64	1.3	[-0.77, 3.45]	1.07	0.2121

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Week 12										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	47	37.0	35.6	-1.0	[-3.32, 1.29]	1.17				
UPA 7.5 + 26 WK CS-T	41	33.5	36.1	1.2	[-1.35, 3.70]	1.28	2.2	[-1.23, 5.61]	1.73	0.2082
UPA 15 + 26 WK CS-T	89	37.7	38.4	1.1	[-0.63, 2.77]	0.86	2.1	[-0.78, 4.95]	1.45	0.1532

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group ----- Change from Baseline ----- LS Mean	[95% CI]	SE	Between Groups Difference --------- Compared to Placebo --------- LS Mean	[95% CI]	SE	P-value
Week 12										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	30	40.5	40.1	-0.6	[-3.31, 2.18]	1.39				
UPA 7.5 + 26 WK CS-T	32	37.7	34.8	-2.7	[-5.38, -0.03]	1.36	-2.1	[-5.73, 1.45]	1.82	0.2411
UPA 15 + 26 WK CS-T	72	35.4	36.9	0.1	[-1.96, 2.16]	1.04	0.7	[-2.45, 3.79]	1.58	0.6729

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Week 12										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	50	39.2	39.0	0.1	[-2.01, 2.23]	1.08				
UPA 7.5 + 26 WK CS-T	49	36.4	35.4	-1.4	[-3.54, 0.76]	1.09	-1.5	[-4.52, 1.52]	1.53	0.3287
UPA 15 + 26 WK CS-T	114	38.2	38.7	0.3	[-1.17, 1.69]	0.73	0.1	[-2.41, 2.71]	1.30	0.9096

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Week 12										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	27	36.9	34.3	-1.9	[-5.10, 1.20]	1.59				
UPA 7.5 + 26 WK CS-T	24	33.2	35.9	1.9	[-1.49, 5.23]	1.69	3.8	[-0.62, 8.26]	2.24	0.0907
UPA 15 + 26 WK CS-T	47	33.0	35.5	1.7	[-0.83, 4.24]	1.28	3.7	[-0.13, 7.44]	1.91	0.0583

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Week 24										
All										
PBO + 52 WK CS-T	63	38.0	39.2	0.6	[-1.31, 2.56]	0.98				
UPA 7.5 + 26 WK CS-T	57	36.2	35.2	-1.8	[-3.82, 0.23]	1.03	-2.4	[-5.19, 0.35]	1.41	0.0860
UPA 15 + 26 WK CS-T	143	37.3	38.3	0.8	[-0.57, 2.10]	0.68	0.1	[-2.16, 2.45]	1.17	0.9042

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Week 24										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	37	36.8	38.4	0.5	[-2.03, 2.94]	1.26				
UPA 7.5 + 26 WK CS-T	31	35.0	34.7	-1.7	[-4.43, 1.03]	1.38	-2.2	[-5.84, 1.54]	1.87	0.2508
UPA 15 + 26 WK CS-T	81	38.4	38.6	0.8	[-0.96, 2.50]	0.87	0.3	[-2.71, 3.34]	1.53	0.8362

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Week 24										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	26	39.8	40.5	0.7	[-2.47, 3.90]	1.61				
UPA 7.5 + 26 WK CS-T	26	37.7	35.9	-2.3	[-5.42, 0.87]	1.59	-3.0	[-7.26, 1.28]	2.15	0.1678
UPA 15 + 26 WK CS-T	62	36.0	38.0	0.7	[-1.60, 2.98]	1.16	-0.0	[-3.68, 3.62]	1.84	0.9882

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Week 24										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	41	39.5	41.2	1.5	[-0.91, 3.97]	1.24				
UPA 7.5 + 26 WK CS-T	40	36.4	35.8	-1.6	[-4.03, 0.89]	1.25	-3.1	[-6.57, 0.37]	1.76	0.0795
UPA 15 + 26 WK CS-T	100	38.9	39.3	0.3	[-1.27, 1.91]	0.81	-1.2	[-4.12, 1.70]	1.48	0.4136

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Week 24										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	22	35.3	35.5	-0.8	[-3.99, 2.40]	1.61				
UPA 7.5 + 26 WK CS-T	17	35.9	34.0	-2.2	[-5.72, 1.34]	1.78	-1.4	[-5.98, 3.19]	2.31	0.5462
UPA 15 + 26 WK CS-T	43	33.7	36.1	1.8	[-0.64, 4.28]	1.24	2.6	[-1.14, 6.37]	1.89	0.1701

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Week 52										
All										
PBO + 52 WK CS-T	45	38.0	36.5	-2.4	[-4.71, -0.07]	1.18				
UPA 7.5 + 26 WK CS-T	49	36.7	39.0	1.1	[-1.17, 3.37]	1.15	3.5	[0.27, 6.70]	1.63	0.0338*
UPA 15 + 26 WK CS-T	123	37.4	39.5	1.7	[0.18, 3.14]	0.75	4.0	[1.33, 6.76]	1.38	0.0036**

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Week 52										
Baseline CS Dose <= 30 mg										
PBO + 52 WK CS-T	27	37.1	34.3	-3.7	[-6.84, -0.64]	1.57				
UPA 7.5 + 26 WK CS-T	29	35.1	37.2	1.4	[-1.70, 4.44]	1.55	5.1	[0.75, 9.47]	2.20	0.0218*
UPA 15 + 26 WK CS-T	70	38.5	40.6	2.5	[0.47, 4.44]	1.00	6.2	[2.51, 9.87]	1.86	0.0011**

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Week 52										
Baseline CS Dose > 30 mg										
PBO + 52 WK CS-T	18	39.3	39.7	-0.8	[-4.42, 2.75]	1.81				
UPA 7.5 + 26 WK CS-T	20	38.9	41.6	0.2	[-3.20, 3.69]	1.74	1.1	[-3.70, 5.86]	2.41	0.6547
UPA 15 + 26 WK CS-T	53	35.9	38.1	0.6	[-1.79, 2.98]	1.20	1.4	[-2.63, 5.49]	2.05	0.4861

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE	Between Groups Difference: Compared to Placebo: P-value
Week 52										
New Onset Disease at Baseline										
PBO + 52 WK CS-T	30	39.5	38.5	-1.3	[-4.12, 1.61]	1.45				
UPA 7.5 + 26 WK CS-T	34	36.6	38.7	0.7	[-2.00, 3.46]	1.38	2.0	[-1.97, 5.94]	2.00	0.3234
UPA 15 + 26 WK CS-T	87	39.3	40.3	0.8	[-0.90, 2.57]	0.88	2.1	[-1.26, 5.43]	1.69	0.2192

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

TABLE 14.2__10.1

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1)

Time Point / Strata / Treatment	N	Baseline Mean	Visit Mean	Within Group ----- Change from Baseline ----- LS Mean	[95% CI]	SE	Between Groups Difference --------- Compared to Placebo --------- LS Mean	[95% CI]	SE	P-value
Week 52										
Relapsing Disease at Baseline										
PBO + 52 WK CS-T	15	35.0	32.5	-4.1	[-8.16, 0.02]	2.06				
UPA 7.5 + 26 WK CS-T	15	36.9	39.5	2.0	[-2.17, 6.08]	2.07	6.0	[0.36, 11.69]	2.84	0.0374*
UPA 15 + 26 WK CS-T	36	32.7	37.5	3.7	[0.88, 6.54]	1.42	7.8	[3.01, 12.55]	2.39	0.0018**

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction, stratification factors at randomization (Baseline CS dose (prednisone or prednisolone >30 mg, prednisone or prednisolone <= 30 mg) and Baseline disease status (new onset disease, relapsing disease)) included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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.
* P-value <=0.05; ** P-value <=0.01; *** P-value <=0.001.

Program Source Code: [redacted]

表 2.7.3.6-7

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ABT-494 (GIANT CELL ARTERITIS)
STUDY M16-852 (CUTOFF 06FEB2024)
R&D/23/2788 - CLINICAL/STATISTICAL

TABLE 14.1__4.1_J

Demographic Characteristics
(FAS1, Japanese Population)

	PBO + 52 WK CS-T (N=5)	UPA 7.5 + 26 WK CS-T (N=5)	UPA 15 + 26 WK CS-T (N=10)	Total (N=15)	Overall Total (N=20)
Sex - n (%)					
Female	4 (80.0)	4 (80.0)	8 (80.0)	12 (80.0)	16 (80.0)
Male	1 (20.0)	1 (20.0)	2 (20.0)	3 (20.0)	4 (20.0)
Race - n (%)					
White	0	0	0	0	0
Black or African American	0	0	0	0	0
Asian	5 (100)	5 (100)	10 (100)	15 (100)	20 (100)
American Indian or Alaska Native	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Multiple	0	0	0	0	0
Race Group - n (%)					
White	0	0	0	0	0
Non-White	5 (100)	5 (100)	10 (100)	15 (100)	20 (100)
Ethnicity - n (%)					
Hispanic or Latino	0	0	1 (10.0)	1 (6.7)	1 (5.0)
Not Hispanic or Latino	5 (100)	5 (100)	9 (90.0)	14 (93.3)	19 (95.0)
Age (year)					
n	5	5	10	15	20
Mean (SD)	76.6 (6.47)	73.4 (9.18)	72.3 (8.90)	72.7 (8.67)	73.7 (8.20)
Median	74.0	75.0	72.5	74.0	74.0
Min, Max	70, 87	60, 83	52, 83	52, 83	52, 87

Note: Percentages calculated on non-missing values.
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 14.1__4.1_J

Demographic Characteristics
(FAS1, Japanese Population)

	PBO + 52 WK CS-T (N=5)	UPA 7.5 + 26 WK CS-T (N=5)	UPA 15 + 26 WK CS-T (N=10)	UPA Total (N=15)	Overall Total (N=20)
Age Group 1 (year) - n (%)					
< 65	0	1 (20.0)	1 (10.0)	2 (13.3)	2 (10.0)
>= 65	5 (100)	4 (80.0)	9 (90.0)	13 (86.7)	18 (90.0)
Age Group 2 (year) - n (%)					
< 65	0	1 (20.0)	1 (10.0)	2 (13.3)	2 (10.0)
>= 65 and < 75	3 (60.0)	1 (20.0)	5 (50.0)	6 (40.0)	9 (45.0)
>= 75	2 (40.0)	3 (60.0)	4 (40.0)	7 (46.7)	9 (45.0)
Weight (kg)					
n	5	5	10	15	20
Mean (SD)	55.22 (14.354)	45.96 (10.956)	51.01 (9.493)	49.33 (9.914)	50.80 (11.075)
Median	53.20	42.30	49.15	48.20	50.90
Min, Max	37.6, 77.5	32.7, 60.2	39.9, 68.9	32.7, 68.9	32.7, 77.5
Height (cm)					
n	5	5	10	15	20
Mean (SD)	157.58 (11.662)	155.28 (7.040)	156.90 (7.992)	156.36 (7.473)	156.67 (8.371)
Median	152.30	150.80	155.90	155.60	153.95
Min, Max	149.4, 178.0	150.3, 166.5	148.2, 172.2	148.2, 172.2	148.2, 178.0
Body Mass Index (kg/m^2)					
n	5	5	10	15	20
Mean (SD)	21.9831 (3.3917)	18.8569 (2.9804)	20.5867 (2.4577)	20.0101 (2.6708)	20.5033 (2.9062)
Median	23.1627	18.6011	20.3122	19.9080	20.8660
Min, Max	16.210, 24.460	14.475, 21.715	17.665, 25.254	14.475, 25.254	14.475, 25.254

Note: Percentages calculated on non-missing values.
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 14.1__4.1_J

Demographic Characteristics
(FAS1, Japanese Population)

	PBO + 52 WK CS-T (N=5)	UPA 7.5 + 26 WK CS-T (N=5)	UPA 15 + 26 WK CS-T (N=10)	UPA Total (N=15)	Overall Total (N=20)
Body Mass Index (kg/m^2) - n (%)					
< 25	5 (100)	5 (100)	9 (90.0)	14 (93.3)	19 (95.0)
>= 25 and < 30	0	0	1 (10.0)	1 (6.7)	1 (5.0)
>= 30	0	0	0	0	0
Geographic Region - n (%)					
North America	0	0	0	0	0
Western Europe	0	0	0	0	0
Eastern Europe	0	0	0	0	0
Asia	5 (100)	5 (100)	10 (100)	15 (100)	20 (100)
Japan	5 (100)	5 (100)	10 (100)	15 (100)	20 (100)
Oceania	0	0	0	0	0
Nicotine User - n(%)					
Current	0	0	1 (10.0)	1 (6.7)	1 (5.0)
Former	1 (20.0)	1 (20.0)	3 (30.0)	4 (26.7)	5 (25.0)
Never	4 (80.0)	4 (80.0)	6 (60.0)	10 (66.7)	14 (70.0)
Unknown	0	0	0	0	0
Alcohol User - n(%)					
Current	2 (40.0)	2 (40.0)	3 (30.0)	5 (33.3)	7 (35.0)
Former	0	2 (40.0)	3 (30.0)	5 (33.3)	5 (25.0)
Never	3 (60.0)	1 (20.0)	4 (40.0)	5 (33.3)	8 (40.0)
Unknown	0	0	0	0	0

Note: Percentages calculated on non-missing values.
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 2.7.3.6-8

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ABT-494 (GIANT CELL ARTERITIS)
STUDY M16-852 (CUTOFF 06FEB2024)
R&D/23/2788 - CLINICAL/STATISTICAL

TABLE 14.2__17.1_J

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1, Japanese Population)

Visit / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Response Rate Diff Compared to Placebo [95% CI] #
Week 2						
PBO + 52 WK CS-T	5	5 (100)	[100.0, 100.0]	0		
UPA 7.5 + 26 WK CS-T	5	3 (60.0)	[17.1, 100.0]	0	-40.0	[-82.9, 2.9]
UPA 15 + 26 WK CS-T	10	9 (90.0)	[71.4, 100.0]	0	-10.0	[-28.6, 8.6]
Week 4						
PBO + 52 WK CS-T	5	5 (100)	[100.0, 100.0]	0		
UPA 7.5 + 26 WK CS-T	5	3 (60.0)	[17.1, 100.0]	0	-40.0	[-82.9, 2.9]
UPA 15 + 26 WK CS-T	10	10 (100)	[100.0, 100.0]	0		
Week 8						
PBO + 52 WK CS-T	5	5 (100)	[100.0, 100.0]	0		
UPA 7.5 + 26 WK CS-T	5	2 (40.0)	[0.0, 82.9]	0	-60.0	[-100.0, -17.1]
UPA 15 + 26 WK CS-T	10	9 (90.0)	[71.4, 100.0]	0	-10.0	[-28.6, 8.6]

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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 14.2__17.1_J

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1, Japanese Population)

Visit / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Response Rate Diff Compared to Placebo [95% CI] #
Week 12						
PBO + 52 WK CS-T	5	5 (100)	[100.0, 100.0]	0		
UPA 7.5 + 26 WK CS-T	5	2 (40.0)	[0.0, 82.9]	0	-60.0	[-100.0, -17.1]
UPA 15 + 26 WK CS-T	10	9 (90.0)	[71.4, 100.0]	0	-10.0	[-28.6, 8.6]
Week 16						
PBO + 52 WK CS-T	5	4 (80.0)	[44.9, 100.0]	0		
UPA 7.5 + 26 WK CS-T	5	2 (40.0)	[0.0, 82.9]	0	-40.0	[-95.4, 15.4]
UPA 15 + 26 WK CS-T	10	8 (80.0)	[55.2, 100.0]	0	0.0	[-42.9, 42.9]
Week 20						
PBO + 52 WK CS-T	5	4 (80.0)	[44.9, 100.0]	0		
UPA 7.5 + 26 WK CS-T	5	2 (40.0)	[0.0, 82.9]	0	-40.0	[-95.4, 15.4]
UPA 15 + 26 WK CS-T	10	7 (70.0)	[41.6, 98.4]	0	-10.0	[-55.1, 35.1]

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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 14.2__17.1_J

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1, Japanese Population)

Visit / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Response Rate Diff Compared to Placebo [95% CI] #
Week 24						
PBO + 52 WK CS-T	5	4 (80.0)	[44.9, 100.0]	0		
UPA 7.5 + 26 WK CS-T	5	2 (40.0)	[0.0, 82.9]	0	-40.0	[-95.4, 15.4]
UPA 15 + 26 WK CS-T	10	8 (80.0)	[55.2, 100.0]	0	0.0	[-42.9, 42.9]
Week 28						
PBO + 52 WK CS-T	5	4 (80.0)	[44.9, 100.0]	0		
UPA 7.5 + 26 WK CS-T	5	2 (40.0)	[0.0, 82.9]	0	-40.0	[-95.4, 15.4]
UPA 15 + 26 WK CS-T	10	8 (80.0)	[55.2, 100.0]	0	0.0	[-42.9, 42.9]
Week 36						
PBO + 52 WK CS-T	5	3 (60.0)	[17.1, 100.0]	0		
UPA 7.5 + 26 WK CS-T	5	1 (20.0)	[0.0, 55.1]	0	-40.0	[-95.4, 15.4]
UPA 15 + 26 WK CS-T	10	8 (80.0)	[55.2, 100.0]	0	20.0	[-29.6, 69.6]

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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 14.2__17.1_J

Proportion of Subjects in Remission by Visit through Week 52 (NRI-MI)
(FAS1, Japanese Population)

Visit / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Response Rate Diff Compared to Placebo [95% CI] #
Week 44						
PBO + 52 WK CS-T	5	3 (60.0)	[17.1, 100.0]	0		
UPA 7.5 + 26 WK CS-T	5	2 (40.0)	[0.0, 82.9]	0	-20.0	[-80.7, 40.7]
UPA 15 + 26 WK CS-T	10	8 (80.0)	[55.2, 100.0]	0	20.0	[-29.6, 69.6]
Week 52						
PBO + 52 WK CS-T	5	3 (60.0)	[17.1, 100.0]	0		
UPA 7.5 + 26 WK CS-T	5	2 (40.0)	[0.0, 82.9]	0	-20.0	[-80.7, 40.7]
UPA 15 + 26 WK CS-T	10	8 (80.0)	[55.2, 100.0]	0	20.0	[-29.6, 69.6]

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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 2.7.3.6-9

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ABT-494 (GIANT CELL ARTERITIS)

STUDY M16-852 (CUTOFF 06FEB2024)

R&D/23/2788 - CLINICAL/STATISTICAL

TABLE 14.2__7_J

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1, Japanese Population)

Visit / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Response Rate Diff Compared to Placebo [95% CI] #
Week 2						
PBO + 52 WK CS-T	5	4 (80.0)	[44.9, 100.0]	0		
UPA 7.5 + 26 WK CS-T	5	2 (40.0)	[0.0, 82.9]	0	-40.0	[-95.4, 15.4]
UPA 15 + 26 WK CS-T	10	9 (90.0)	[71.4, 100.0]	0	10.0	[-29.7, 49.7]
Week 4						
PBO + 52 WK CS-T	5	4 (80.0)	[44.9, 100.0]	0		
UPA 7.5 + 26 WK CS-T	5	3 (60.0)	[17.1, 100.0]	0	-20.0	[-75.4, 35.4]
UPA 15 + 26 WK CS-T	10	10 (100)	[100.0, 100.0]	0	20.0	[-15.1, 55.1]
Week 8						
PBO + 52 WK CS-T	5	4 (80.0)	[44.9, 100.0]	0		
UPA 7.5 + 26 WK CS-T	5	2 (40.0)	[0.0, 82.9]	0	-40.0	[-95.4, 15.4]
UPA 15 + 26 WK CS-T	10	9 (90.0)	[71.4, 100.0]	0	10.0	[-29.7, 49.7]

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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 14.2__7_J

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1, Japanese Population)

Visit Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Response Rate Diff Compared to Placebo [95% CI] #
Week 12						
PBO + 52 WK CS-T	5	3 (60.0)	[17.1, 100.0]	0		
UPA 7.5 + 26 WK CS-T	5	2 (40.0)	[0.0, 82.9]	0	-20.0	[-80.7, 40.7]
UPA 15 + 26 WK CS-T	10	8 (80.0)	[55.2, 100.0]	0	20.0	[-29.6, 69.6]
Week 16						
PBO + 52 WK CS-T	5	2 (40.0)	[0.0, 82.9]	0		
UPA 7.5 + 26 WK CS-T	5	1 (20.0)	[0.0, 55.1]	0	-20.0	[-75.4, 35.4]
UPA 15 + 26 WK CS-T	10	8 (80.0)	[55.2, 100.0]	0	40.0	[-9.6, 89.6]
Week 20						
PBO + 52 WK CS-T	5	3 (60.0)	[17.1, 100.0]	0		
UPA 7.5 + 26 WK CS-T	5	1 (20.0)	[0.0, 55.1]	0	-40.0	[-95.4, 15.4]
UPA 15 + 26 WK CS-T	10	7 (70.0)	[41.6, 98.4]	0	10.0	[-41.5, 61.5]

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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 14.2__7_J

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1, Japanese Population)

Visit / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Response Rate Diff Compared to Placebo [95% CI] #
Week 24						
PBO + 52 WK CS-T	5	2 (40.0)	[0.0, 82.9]	0		
UPA 7.5 + 26 WK CS-T	5	2 (40.0)	[0.0, 82.9]	0	0.0	[-60.7, 60.7]
UPA 15 + 26 WK CS-T	10	8 (80.0)	[55.2, 100.0]	0	40.0	[-9.6, 89.6]
Week 28						
PBO + 52 WK CS-T	5	2 (40.0)	[0.0, 82.9]	0		
UPA 7.5 + 26 WK CS-T	5	1 (20.0)	[0.0, 55.1]	0	-20.0	[-75.4, 35.4]
UPA 15 + 26 WK CS-T	10	8 (80.0)	[55.2, 100.0]	0	40.0	[-9.6, 89.6]
Week 36						
PBO + 52 WK CS-T	5	2 (40.0)	[0.0, 82.9]	0		
UPA 7.5 + 26 WK CS-T	5	0	[0.0, 0.0]	0	-40.0	[-82.9, 2.9]
UPA 15 + 26 WK CS-T	10	8 (80.0)	[55.2, 100.0]	0	40.0	[-9.6, 89.6]

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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 14.2__7_J

Proportion of Subjects in Complete Remission by Visit in Period 1 (NRI-MI)
(FAS1, Japanese Population)

Visit / Treatment	N	Responder n (%)	Responder [95% CI] &	Missing Due to COVID-19 n $	Response Rate Diff Compared to Placebo Diff(%)	Response Rate Diff Compared to Placebo [95% CI] #
Week 44						
PBO + 52 WK CS-T	5	1 (20.0)	[0.0, 55.1]	0		
UPA 7.5 + 26 WK CS-T	5	2 (40.0)	[0.0, 82.9]	0	20.0	[-35.4, 75.4]
UPA 15 + 26 WK CS-T	10	8 (80.0)	[55.2, 100.0]	0	60.0	[17.1, 100.0]
Week 52						
PBO + 52 WK CS-T	5	1 (20.0)	[0.0, 55.1]	0		
UPA 7.5 + 26 WK CS-T	5	2 (40.0)	[0.0, 82.9]	0	20.0	[-35.4, 75.4]
UPA 15 + 26 WK CS-T	10	8 (80.0)	[55.2, 100.0]	0	60.0	[17.1, 100.0]

Note: & 95% CI for response rate is the synthetic result based on Student's t-distribution from PROC MIANALYZE procedure if there are missing data due to COVID-19 logistic restriction or data after subject received more than 100 mg systemic CS (prednisone or equivalent) for a non-GCA indication. Otherwise, it is based on the normal approximation to the binomial distribution.
$ Only count assessment missing due to COVID-19 and imputed by MI.
# 95% CI for difference are calculated using normal approximation to the binomial distribution. The calculations are based on non-responder imputation incorporating multiple imputation or non-responder imputation only if there are no missing data due to COVID-19 logistic restrictions.
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 2.7.3.6-10

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ABT-494 (GIANT CELL ARTERITIS)
STUDY M16-852 (CUTOFF 06FEB2024)
R&D/23/2788 - CLINICAL/STATISTICAL

TABLE 14.2__8.1_J

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1, Japanese Population)

Parameter / Time Point / Treatment	N	Baseline Mean	Within Group: Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE
Bodily Pain Scale									
Week 8									
PBO + 52 WK CS-T	5	43.6117	51.2726	8.7686	[-2.6224, 20.1596]	5.2976			
UPA 7.5 + 26 WK CS-T	3	46.1385	43.5848	0.0083	[-14.8252, 14.8417]	6.9050	-8.7603	[-27.3359, 9.8152]	8.6376
UPA 15 + 26 WK CS-T	9	40.7175	46.5865	5.3108	[-3.1614, 13.7830]	3.9392	-3.4578	[-17.6903, 10.7748]	6.6204
Week 12									
PBO + 52 WK CS-T	5	43.6117	48.8534	6.3493	[-4.4272, 17.1259]	4.9566			
UPA 7.5 + 26 WK CS-T	2	48.0873	54.3370	8.0018	[-9.1390, 25.1426]	7.9601	1.6525	[-18.4315, 21.7365]	9.2962
UPA 15 + 26 WK CS-T	9	40.7175	46.1833	4.9076	[-3.1048, 12.9201]	3.6844	-1.4417	[-14.9102, 12.0267]	6.1960
Week 24									
PBO + 52 WK CS-T	4	43.8536	44.3576	2.5266	[-9.7861, 14.8393]	5.6936			
UPA 7.5 + 26 WK CS-T	2	48.0873	52.1194	5.8019	[-13.1473, 24.7512]	8.7383	3.2753	[-19.1811, 25.7318]	10.3562
UPA 15 + 26 WK CS-T	8	38.0575	42.3920	0.8425	[-8.1355, 9.8204]	4.1357	-1.6841	[-16.9521, 13.5839]	7.0581
Week 52									
PBO + 52 WK CS-T	3	47.0793	47.6169	1.8149	[-9.4943, 13.1240]	5.2098			
UPA 7.5 + 26 WK CS-T	1	34.1766	42.6440	5.0833	[-12.9726, 23.1393]	8.3763	3.2685	[-17.8539, 24.3908]	9.7995
UPA 15 + 26 WK CS-T	8	38.0575	42.6944	2.2953	[-5.2548, 9.8454]	3.4156	0.4804	[-13.1490, 14.1099]	6.2682

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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 14.2__8.1_J

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1, Japanese Population)

Parameter / Time Point / Treatment	N	Baseline Mean	Within Group: Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE
General Health Scale									
Week 8									
PBO + 52 WK CS-T	5	47.0996	42.8202	-4.2966	[-9.7727, 1.1795]	2.5045			
UPA 7.5 + 26 WK CS-T	3	52.0765	45.4196	-6.0584	[-13.2969, 1.1801]	3.3220	-1.7618	[-10.8459, 7.3222]	4.1644
UPA 15 + 26 WK CS-T	9	47.0045	45.5252	-1.5082	[-5.5904, 2.5739]	1.8671	2.7884	[-4.0413, 9.6181]	3.1236
Week 12									
PBO + 52 WK CS-T	5	47.0996	39.3015	-7.8153	[-14.1522, -1.4783]	2.8939			
UPA 7.5 + 26 WK CS-T	2	52.7105	46.7668	-6.7337	[-16.1581, 2.6908]	4.3991	1.0816	[-10.2703, 12.4334]	5.2689
UPA 15 + 26 WK CS-T	9	47.0045	42.1968	-4.8367	[-9.5604, -0.1129]	2.1573	2.9786	[-4.9249, 10.8820]	3.6093
Week 24									
PBO + 52 WK CS-T	4	43.7949	45.2214	-5.4097	[-18.3175, 7.4982]	5.6884			
UPA 7.5 + 26 WK CS-T	2	52.7105	51.5217	-3.3096	[-21.7941, 15.1749]	8.2209	2.1001	[-20.3559, 24.5560]	9.9626
UPA 15 + 26 WK CS-T	8	45.3403	40.1693	-4.9299	[-14.4209, 4.5611]	4.1534	0.4798	[-15.5145, 16.4740]	7.0334
Week 52									
PBO + 52 WK CS-T	3	48.9065	47.3215	-4.8709	[-14.3078, 4.5660]	4.1705			
UPA 7.5 + 26 WK CS-T	1	55.5634	45.1026	-7.5061	[-22.0274, 7.0152]	6.5974	-2.6351	[-19.8339, 14.5636]	7.7512
UPA 15 + 26 WK CS-T	8	45.3403	40.6448	-4.8061	[-11.4443, 1.8322]	2.8720	0.0649	[-11.4666, 11.5963]	5.0656

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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 14.2__8.1_J

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1, Japanese Population)

Parameter / Time Point / Treatment	N	Baseline Mean	Within Group: Change from Baseline: Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE
Mental Component Summary									
Week 8									
PBO + 52 WK CS-T	5	48.6676	47.2593	2.3420	[-5.1373, 9.8214]	3.4414			
UPA 7.5 + 26 WK CS-T	3	42.5909	49.5827	6.6841	[-2.4340, 15.8021]	4.1778	4.3420	[-7.4930, 16.1770]	5.4335
UPA 15 + 26 WK CS-T	9	42.4638	48.8444	5.9880	[0.7186, 11.2573]	2.4145	3.6459	[-5.5723, 12.8642]	4.2380
Week 12									
PBO + 52 WK CS-T	5	48.6676	51.1249	6.2077	[-3.0491, 15.4645]	4.2672			
UPA 7.5 + 26 WK CS-T	2	38.3297	52.9984	8.3825	[-5.2760, 22.0411]	6.3633	2.1749	[-14.4139, 18.7636]	7.7339
UPA 15 + 26 WK CS-T	9	42.4638	43.9501	1.0937	[-5.5750, 7.7623]	3.0605	-5.1140	[-16.5752, 6.3472]	5.2786
Week 24									
PBO + 52 WK CS-T	4	45.1419	51.8040	7.5166	[-2.4089, 17.4422]	4.4225			
UPA 7.5 + 26 WK CS-T	2	38.3297	48.3426	4.2685	[-9.4904, 18.0273]	6.2213	-3.2482	[-20.3443, 13.8480]	7.7211
UPA 15 + 26 WK CS-T	8	41.5635	44.8943	3.1956	[-3.7289, 10.1202]	3.0778	-4.3210	[-16.4919, 7.8500]	5.4259
Week 52									
PBO + 52 WK CS-T	3	45.7550	49.3442	2.5303	[-14.8348, 19.8954]	7.5265			
UPA 7.5 + 26 WK CS-T	1	25.0852	40.7482	-0.8196	[-30.9616, 29.3225]	13.4564	-3.3499	[-38.3737, 31.6739]	15.6172
UPA 15 + 26 WK CS-T	8	41.5635	47.2721	5.3157	[-5.0594, 15.6907]	4.3689	2.7853	[-17.4898, 23.0605]	8.7347

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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 14.2__8.1_J

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1, Japanese Population)

Parameter / Time Point / Treatment	N	Baseline Mean	Within Group: Change from Baseline: Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE
Mental Health Scale									
Week 8									
PBO + 52 WK CS-T	5	46.6820	46.1588	3.5031	[-6.0537, 13.0599]	4.4449			
UPA 7.5 + 26 WK CS-T	3	45.6356	48.2517	5.7071	[-6.4241, 17.8383]	5.6319	2.2040	[-13.0047, 17.4127]	7.0534
UPA 15 + 26 WK CS-T	9	40.1129	46.7983	4.8404	[-2.1680, 11.8489]	3.2539	1.3373	[-10.6944, 13.3690]	5.6013
Week 12									
PBO + 52 WK CS-T	5	46.6820	52.4373	9.7816	[0.9214, 18.6417]	4.0988			
UPA 7.5 + 26 WK CS-T	2	44.3276	53.4837	8.5088	[-4.0256, 21.0431]	5.8776	-1.2728	[-16.3963, 13.8507]	7.0633
UPA 15 + 26 WK CS-T	9	40.1129	42.7289	0.7711	[-5.7042, 7.2463]	2.9909	-9.0105	[-20.1865, 2.1655]	5.1745
Week 24									
PBO + 52 WK CS-T	4	42.3656	50.8677	8.1775	[-1.1880, 17.5431]	4.1764			
UPA 7.5 + 26 WK CS-T	2	44.3276	45.6356	1.4889	[-11.5259, 14.5036]	5.8652	-6.6887	[-22.6062, 9.2288]	7.1594
UPA 15 + 26 WK CS-T	8	40.4036	41.7116	0.6548	[-6.0235, 7.3330]	2.9745	-7.5228	[-19.1414, 4.0959]	5.1719
Week 52									
PBO + 52 WK CS-T	3	42.1476	49.9957	4.6823	[-10.4337, 19.7982]	6.8799			
UPA 7.5 + 26 WK CS-T	1	43.0196	43.0196	0.0090	[-24.3900, 24.4080]	11.3376	-4.6733	[-33.2082, 23.8617]	13.2051
UPA 15 + 26 WK CS-T	8	40.4036	44.9816	4.3145	[-5.6822, 14.3112]	4.4621	-0.3678	[-18.6109, 17.8754]	8.2603

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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 14.2__8.1_J

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1, Japanese Population)

Parameter / Time Point / Treatment	N	Baseline Mean	Within Group: Change from Baseline: Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE
Physical Component Summary									
Week 8									
PBO + 52 WK CS-T	5	42.6857	44.4026	1.5290	[-5.2022, 8.2601]	3.0612			
UPA 7.5 + 26 WK CS-T	3	44.0971	45.8052	2.0693	[-6.6247, 10.7633]	3.9542	0.5403	[-10.4610, 11.5416]	5.0039
UPA 15 + 26 WK CS-T	9	44.0774	46.2612	2.5374	[-2.4901, 7.5649]	2.2872	1.0084	[-7.4008, 9.4177]	3.8255
Week 12									
PBO + 52 WK CS-T	5	42.6857	42.0159	-0.8578	[-6.6730, 4.9574]	2.6719			
UPA 7.5 + 26 WK CS-T	2	41.3620	46.7964	3.4861	[-5.4022, 12.3743]	4.1392	4.3438	[-6.2645, 14.9522]	4.9239
UPA 15 + 26 WK CS-T	9	44.0774	45.7426	2.0188	[-2.3283, 6.3659]	1.9978	2.8766	[-4.3935, 10.1466]	3.3410
Week 24									
PBO + 52 WK CS-T	4	40.3452	45.7976	4.1668	[-3.2959, 11.6296]	3.4127			
UPA 7.5 + 26 WK CS-T	2	41.3620	53.1538	9.9921	[-0.5575, 20.5417]	4.8067	5.8253	[-7.0897, 18.7403]	5.8895
UPA 15 + 26 WK CS-T	8	42.6232	43.3806	0.5621	[-4.7191, 5.8433]	2.4031	-3.6047	[-12.7638, 5.5544]	4.1813
Week 52									
PBO + 52 WK CS-T	3	45.4107	50.2956	2.5634	[-7.5262, 12.6530]	4.5437			
UPA 7.5 + 26 WK CS-T	1	49.3761	47.0472	8.5049	[-7.9092, 24.9191]	7.5275	5.9415	[-13.2527, 25.1358]	8.7791
UPA 15 + 26 WK CS-T	8	42.6232	41.0966	-1.9861	[-8.8106, 4.8385]	2.9876	-4.5494	[-16.7637, 7.6648]	5.4497

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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 14.2__8.1_J

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1, Japanese Population)

Parameter / Time Point / Treatment	N	Baseline Mean	Within Group: Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE
Physical Functioning Scale									
Week 8									
PBO + 52 WK CS-T	5	42.6133	44.1446	1.1792	[-6.5671, 8.9256]	3.6051			
UPA 7.5 + 26 WK CS-T	3	42.2305	49.2475	6.5319	[-3.4700, 16.5337]	4.6549	5.3526	[-7.2856, 17.9909]	5.8810
UPA 15 + 26 WK CS-T	9	45.6341	45.2074	0.2713	[-5.5360, 6.0787]	2.7049	-0.9079	[-10.6129, 8.7972]	4.5195
Week 12									
PBO + 52 WK CS-T	5	42.6133	43.3791	0.4137	[-6.0053, 6.8328]	2.9485			
UPA 7.5 + 26 WK CS-T	2	35.5319	46.0576	5.2958	[-3.9563, 14.5479]	4.3440	4.8820	[-6.3268, 16.0909]	5.2268
UPA 15 + 26 WK CS-T	9	45.6341	45.8457	0.9097	[-3.9177, 5.7371]	2.2194	0.4959	[-7.5658, 8.5577]	3.7056
Week 24									
PBO + 52 WK CS-T	4	38.8814	49.8862	8.7672	[1.9622, 15.5723]	3.1142			
UPA 7.5 + 26 WK CS-T	2	35.5319	51.8010	12.0162	[2.4253, 21.6071]	4.4184	3.2490	[-8.3708, 14.8687]	5.3120
UPA 15 + 26 WK CS-T	8	45.3417	42.9485	-1.3207	[-6.1542, 3.5127]	2.1929	-10.0880	[-18.5071, -1.6689]	3.8523
Week 52									
PBO + 52 WK CS-T	3	43.5065	52.4377	11.4968	[0.4159, 22.5778]	4.9571			
UPA 7.5 + 26 WK CS-T	1	46.0576	49.8848	9.3472	[-9.6707, 28.3652]	8.6242	-2.1496	[-24.1083, 19.8091]	9.9407
UPA 15 + 26 WK CS-T	8	45.3417	40.0779	-4.9769	[-11.8162, 1.8623]	3.0079	-16.4738	[-29.5282, -3.4193]	5.8160

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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 14.2__8.1_J

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1, Japanese Population)

Parameter / Time Point / Treatment	N	Baseline Mean	Within Group: Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE
Role Emotional Scale									
Week 8									
PBO + 52 WK CS-T	5	46.4193	45.0266	0.4591	[-6.2827, 7.2009]	3.1142			
UPA 7.5 + 26 WK CS-T	3	42.2412	46.8835	4.3377	[-4.2602, 12.9357]	3.9675	3.8786	[-7.0641, 14.8213]	5.0522
UPA 15 + 26 WK CS-T	9	43.4018	47.6572	4.5499	[-0.4160, 9.5157]	2.2916	4.0908	[-4.2613, 12.4428]	3.8559
Week 12									
PBO + 52 WK CS-T	5	46.4193	42.9375	-1.6299	[-10.3333, 7.0734]	4.0119			
UPA 7.5 + 26 WK CS-T	2	35.2777	52.6864	12.6830	[-1.1113, 26.4772]	6.3925	14.3129	[-2.0761, 30.7019]	7.5997
UPA 15 + 26 WK CS-T	9	43.4018	43.7886	0.6813	[-5.7642, 7.1267]	2.9673	2.3112	[-8.5040, 13.1264]	4.9818
Week 24									
PBO + 52 WK CS-T	4	43.9821	47.4638	4.0132	[-4.9673, 12.9938]	4.0771			
UPA 7.5 + 26 WK CS-T	2	35.2777	50.9455	10.5327	[-2.3505, 23.4159]	5.8628	6.5195	[-9.2411, 22.2800]	7.1841
UPA 15 + 26 WK CS-T	8	41.8060	42.2412	0.4049	[-6.0252, 6.8349]	2.9015	-3.6084	[-14.6413, 7.4245]	5.0018
Week 52									
PBO + 52 WK CS-T	3	50.3652	49.2046	2.7052	[-9.3681, 14.7785]	5.4835			
UPA 7.5 + 26 WK CS-T	1	17.8691	38.7595	4.6601	[-17.7121, 27.0323]	10.1977	1.9549	[-23.6766, 27.5864]	11.7295
UPA 15 + 26 WK CS-T	8	41.8060	43.9821	2.0918	[-5.0069, 9.1904]	3.1371	-0.6134	[-14.6167, 13.3899]	6.3208

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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 14.2__8.1_J

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1, Japanese Population)

Parameter / Time Point / Treatment	N	Baseline Mean	Within Group: Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE
Role Physical Scale									
Week 8									
PBO + 52 WK CS-T	5	41.4372	39.6409	-0.3415	[-7.3843, 6.7013]	3.2603			
UPA 7.5 + 26 WK CS-T	3	37.6948	45.1796	6.8358	[-2.1828, 15.8544]	4.1736	7.1773	[-4.3008, 18.6554]	5.3131
UPA 15 + 26 WK CS-T	9	39.1918	47.9240	8.9248	[3.7221, 14.1274]	2.4076	9.2663	[0.5240, 18.0086]	4.0463
Week 12									
PBO + 52 WK CS-T	5	41.4372	41.4372	1.4548	[-7.2791, 10.1888]	4.0549			
UPA 7.5 + 26 WK CS-T	2	31.3328	47.0508	11.3631	[-1.4876, 24.2137]	6.0506	9.9082	[-5.6555, 25.4719]	7.3135
UPA 15 + 26 WK CS-T	9	39.1918	43.9321	4.9329	[-1.5430, 11.4088]	3.0042	3.4781	[-7.3848, 14.3410]	5.0412
Week 24									
PBO + 52 WK CS-T	4	37.5077	45.3667	6.5812	[-2.2365, 15.3988]	4.0453			
UPA 7.5 + 26 WK CS-T	2	31.3328	51.5416	15.8764	[3.6450, 28.1079]	5.6564	9.2953	[-5.8429, 24.4335]	6.9861
UPA 15 + 26 WK CS-T	8	38.3497	43.9633	5.9601	[-0.3454, 12.2656]	2.8842	-0.6211	[-11.4618, 10.2196]	4.9699
Week 52									
PBO + 52 WK CS-T	3	42.9342	51.1674	7.8618	[-1.4837, 17.2073]	4.3593			
UPA 7.5 + 26 WK CS-T	1	41.4372	41.4372	3.9185	[-11.0882, 18.9252]	7.0777	-3.9433	[-21.6460, 13.7594]	8.3350
UPA 15 + 26 WK CS-T	8	38.3497	43.6826	5.8902	[-0.5687, 12.3490]	2.9688	-1.9716	[-13.3203, 9.3771]	5.2710

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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 14.2__8.1_J

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1, Japanese Population)

Parameter / Time Point / Treatment	N	Baseline Mean	Within Group: Change from Baseline: Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE
Social Functioning Scale									
Week 8									
PBO + 52 WK CS-T	5	41.2971	43.3024	3.9586	[-5.6674, 13.5847]	4.4779			
UPA 7.5 + 26 WK CS-T	3	33.9443	50.6552	13.7218	[1.2607, 26.1828]	5.7982	9.7631	[-6.1040, 25.6303]	7.3875
UPA 15 + 26 WK CS-T	9	41.1857	47.3130	8.0058	[0.7988, 15.2127]	3.3540	4.0471	[-7.8775, 15.9717]	5.5437
Week 12									
PBO + 52 WK CS-T	5	41.2971	49.3183	9.9745	[-0.6995, 20.6486]	4.9366			
UPA 7.5 + 26 WK CS-T	2	27.2600	42.2997	5.4946	[-11.0122, 22.0014]	7.7409	-4.4800	[-24.2711, 15.3111]	9.2683
UPA 15 + 26 WK CS-T	9	41.1857	43.9708	4.6636	[-3.3201, 12.6473]	3.6943	-5.3109	[-18.5538, 7.9319]	6.1196
Week 24									
PBO + 52 WK CS-T	4	37.2865	49.8196	12.1171	[0.2863, 23.9478]	5.3912			
UPA 7.5 + 26 WK CS-T	2	27.2600	52.3262	17.0809	[-0.2498, 34.4116]	7.9320	4.9638	[-16.0402, 25.9678]	9.5923
UPA 15 + 26 WK CS-T	8	39.1665	46.0597	7.7323	[-0.5992, 16.0638]	3.7909	-4.3848	[-18.8666, 10.0970]	6.5983
Week 52									
PBO + 52 WK CS-T	3	35.6154	47.3130	9.2230	[-6.8266, 25.2725]	7.3249			
UPA 7.5 + 26 WK CS-T	1	17.2335	42.2997	8.1807	[-18.5440, 34.9053]	12.4311	-1.0423	[-32.2538, 30.1691]	14.4302
UPA 15 + 26 WK CS-T	8	39.1665	47.3130	8.9195	[-1.3346, 19.1736]	4.6080	-0.3035	[-19.3759, 18.7689]	8.6718

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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 14.2__8.1_J

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1, Japanese Population)

Parameter / Time Point / Treatment	N	Baseline Mean	Within Group: Change from Baseline: Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE
Vitality Scale									
Week 8									
PBO + 52 WK CS-T	5	53.1913	52.0031	3.1500	[-8.6794, 14.9795]	5.5223			
UPA 7.5 + 26 WK CS-T	3	44.6758	50.6168	3.8878	[-10.8081, 18.5836]	6.8339	0.7377	[-18.4249, 19.9004]	8.9389
UPA 15 + 26 WK CS-T	9	46.6562	51.6070	4.3840	[-4.0602, 12.8282]	3.9246	1.2340	[-13.4067, 15.8747]	6.8298
Week 12									
PBO + 52 WK CS-T	5	53.1913	51.4090	2.5559	[-7.9703, 13.0821]	4.8213			
UPA 7.5 + 26 WK CS-T	2	40.7151	55.5677	4.1143	[-10.1599, 18.3886]	6.6722	1.5584	[-16.6431, 19.7599]	8.4888
UPA 15 + 26 WK CS-T	9	46.6562	48.3064	1.0834	[-6.3128, 8.4797]	3.3726	-1.4725	[-14.4656, 11.5206]	5.9469
Week 24									
PBO + 52 WK CS-T	4	50.3693	55.5677	8.1295	[-1.4269, 17.6859]	4.3336			
UPA 7.5 + 26 WK CS-T	2	40.7151	51.1119	0.7862	[-11.9276, 13.5001]	5.8876	-7.3433	[-23.7986, 9.1120]	7.5835
UPA 15 + 26 WK CS-T	8	45.5422	50.3693	3.9749	[-2.6180, 10.5679]	2.9880	-4.1546	[-15.9502, 7.6411]	5.3546
Week 52									
PBO + 52 WK CS-T	3	52.5972	53.5873	2.8939	[-11.8614, 17.6492]	6.7615			
UPA 7.5 + 26 WK CS-T	1	40.7151	46.6562	-0.1556	[-22.6174, 22.3063]	10.4824	-3.0495	[-30.0712, 23.9723]	12.6005
UPA 15 + 26 WK CS-T	8	45.5422	46.2848	0.7196	[-9.0191, 10.4583]	4.3552	-2.1743	[-19.9143, 15.5658]	8.0911

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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 14.2__8.1_J

Change from Baseline in the SF-36 by Visit in Period 1 (MMRM)
(FAS1, Japanese Population)

Parameter / Time Point / Treatment	N	Baseline Mean	Within Group: Change from Baseline: Visit Mean	Within Group: Change from Baseline: LS Mean	Within Group: Change from Baseline: [95% CI]	Within Group: Change from Baseline: SE	Between Groups Difference: Compared to Placebo: LS Mean	Between Groups Difference: Compared to Placebo: [95% CI]	Between Groups Difference: Compared to Placebo: SE
Utility Index Score									
Week 8									
PBO + 52 WK CS-T	5	0.6858	0.6418	0.0113	[-0.1106, 0.1331]	0.0568			
UPA 7.5 + 26 WK CS-T	3	0.6657	0.6837	0.0581	[-0.0940, 0.2102]	0.0707	0.0468	[-0.1427, 0.2364]	0.0881
UPA 15 + 26 WK CS-T	9	0.5879	0.7084	0.1021	[0.0148, 0.1894]	0.0406	0.0908	[-0.0622, 0.2439]	0.0713
Week 12									
PBO + 52 WK CS-T	5	0.6858	0.7084	0.0779	[-0.0352, 0.1910]	0.0524			
UPA 7.5 + 26 WK CS-T	2	0.6495	0.7020	0.0639	[-0.0941, 0.2219]	0.0741	-0.0139	[-0.2032, 0.1753]	0.0884
UPA 15 + 26 WK CS-T	9	0.5879	0.6451	0.0387	[-0.0416, 0.1191]	0.0371	-0.0391	[-0.1813, 0.1031]	0.0659
Week 24									
PBO + 52 WK CS-T	4	0.6178	0.6943	0.0739	[-0.0791, 0.2269]	0.0693			
UPA 7.5 + 26 WK CS-T	2	0.6495	0.7360	0.0891	[-0.1103, 0.2886]	0.0918	0.0152	[-0.2312, 0.2617]	0.1128
UPA 15 + 26 WK CS-T	8	0.5764	0.6531	0.0776	[-0.0298, 0.1850]	0.0486	0.0037	[-0.1858, 0.1933]	0.0860
Week 52									
PBO + 52 WK CS-T	3	0.6187	0.7377	0.0545	[-0.1151, 0.2240]	0.0755			
UPA 7.5 + 26 WK CS-T	1	0.5490	0.6140	0.0489	[-0.2081, 0.3059]	0.1181	-0.0056	[-0.3110, 0.2999]	0.1397
UPA 15 + 26 WK CS-T	8	0.5764	0.6191	0.0353	[-0.0771, 0.1478]	0.0493	-0.0191	[-0.2250, 0.1867]	0.0915

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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 2.7.3.6-11

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ABT-494 (GIANT CELL ARTERITIS)
STUDY M16-852 (CUTOFF 06FEB2024)
R&D/23/2788 - CLINICAL/STATISTICAL

TABLE 14.2__10.1_J

Change from Baseline in FACIT-Fatigue by Visit in Period 1 (MMRM)
(FAS1, Japanese Population)

Time Point / Treatment	N	Baseline Mean	Within Group ----- Change from Baseline ----- Visit Mean	LS Mean	[95% CI]	SE	Between Groups Difference ------- Compared to Placebo ------- LS Mean	[95% CI]	SE
Week 8									
PBO + 52 WK CS-T	5	38.8	35.6	-2.8	[-8.83, 3.16]	2.78			
UPA 7.5 + 26 WK CS-T	3	42.0	39.3	-1.7	[-9.53, 6.18]	3.66	1.2	[-8.63, 10.95]	4.55
UPA 15 + 26 WK CS-T	9	35.3	37.1	1.5	[-3.01, 5.93]	2.08	4.3	[-3.22, 11.81]	3.49
Week 12									
PBO + 52 WK CS-T	5	38.8	38.4	-0.0	[-4.29, 4.22]	1.94			
UPA 7.5 + 26 WK CS-T	2	39.5	41.0	0.8	[-5.99, 7.50]	3.11	0.8	[-7.10, 8.69]	3.63
UPA 15 + 26 WK CS-T	9	35.3	35.1	-0.5	[-3.72, 2.64]	1.45	-0.5	[-5.88, 4.87]	2.45
Week 24									
PBO + 52 WK CS-T	4	37.8	39.0	1.2	[-5.50, 8.00]	2.93			
UPA 7.5 + 26 WK CS-T	2	39.5	37.5	-3.7	[-13.10, 5.70]	4.14	-4.9	[-16.48, 6.59]	5.06
UPA 15 + 26 WK CS-T	8	34.9	33.5	-1.1	[-5.94, 3.64]	2.07	-2.4	[-10.70, 5.91]	3.61
Week 52									
PBO + 52 WK CS-T	3	42.0	41.0	-0.8	[-10.78, 9.20]	4.49			
UPA 7.5 + 26 WK CS-T	1	37.0	31.0	-3.8	[-21.79, 14.20]	8.10	-3.0	[-23.51, 17.50]	9.22
UPA 15 + 26 WK CS-T	8	34.9	32.8	-2.5	[-8.39, 3.40]	2.61	-1.7	[-13.30, 9.90]	5.21

Note: MMRM is the Mixed-Effect Model Repeat Measurement with baseline value, categorical fixed effects of treatment, visit and treatment-by-visit interaction included in the model.
An unstructured variance covariance matrix is used.
Data after initiation of CS escape therapy are excluded from the model.
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]