表 2.7.4.7-26. 投与 24 週時データカットオフまでの重篤な有害事象（100 人年あたりの発現件数，安全性解析対象集団）：M15-554 試験

TABLE 14.3__2.1.2

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 290) (PYs = 292.8) Events (E/100 PYs)	UPA 30 mg QD (N = 308) (PYs = 296.2) Events (E/100 PYs)
Any adverse event	44 (15.0)	54 (18.2)
血液およびリンパ系障害	1 (0.3)	2 (0.7)
失血性貧血	1 (0.3)	1 (0.3)
汎血球減少症	0	1 (0.3)
心臓障害	5 (1.7)	6 (2.0)
急性心筋梗塞	1 (0.3)	0
狭心症	1 (0.3)	0
不安定狭心症	0	1 (0.3)
心房細動	0	2 (0.7)
徐脈	0	1 (0.3)
心肺停止	1 (0.3)	0
冠動脈狭窄	0	1 (0.3)
心筋梗塞	1 (0.3)	0
上室性頻脈	0	1 (0.3)
心室細動	1 (0.3)	0
内分泌障害	0	1 (0.3)
甲状腺腫	0	1 (0.3)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30mg QD group include those who started UPA 15 mg QD/30mg QD at the beginning of the study and those who switched to UPA 15 mg/30mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__2.1.2

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 290) (PYs = 292.8) Events (E/100 PYs)	UPA 30 mg QD (N = 308) (PYs = 296.2) Events (E/100 PYs)
胃腸障害	2 (0.7)	7 (2.4)
腹痛	0	1 (0.3)
下痢	0	1 (0.3)
十二指腸潰瘍	1 (0.3)	1 (0.3)
出血性十二指腸潰瘍	0	1 (0.3)
びらん性胃炎	1 (0.3)	0
吐血	0	1 (0.3)
鼠径ヘルニア	0	1 (0.3)
小腸潰瘍	0	1 (0.3)
一般・全身障害および投与部位の状態	0	2 (0.7)
発熱	0	1 (0.3)
全身性炎症反応症候群	0	1 (0.3)
肝胆道系障害	1 (0.3)	0
胆石症	1 (0.3)	0
感染症および寄生虫症	8 (2.7)	19 (6.4)
膿瘍	1 (0.3)	0
菌血症	0	1 (0.3)
細気管支炎	1 (0.3)	0
気管支炎	0	1 (0.3)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30mg QD group include those who started UPA 15 mg QD/30mg QD at the beginning of the study and those who switched to UPA 15 mg/30mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__2.1.2

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 290) (PYs = 292.8) Events (E/100 PYs)	UPA 30 mg QD (N = 308) (PYs = 296.2) Events (E/100 PYs)
感染症および寄生虫症 (Cont.)		
蜂巣炎	1 (0.3)	2 (0.7)
サイトメガロウイルス感染	0	1 (0.3)
憩室炎	0	1 (0.3)
硬膜外膿瘍	0	1 (0.3)
胃腸炎	0	1 (0.3)
ウイルス性胃腸炎	1 (0.3)	2 (0.7)
帯状疱疹	0	1 (0.3)
肺感染	1 (0.3)	0
ニューモシスチス・イロベチイ肺炎	0	1 (0.3)
肺炎	3 (1.0)	3 (1.0)
敗血症	0	1 (0.3)
上気道感染	0	1 (0.3)
尿路感染	0	1 (0.3)
ウイルス性上気道感染	0	1 (0.3)
傷害、中毒および処置合併症	8 (2.7)	1 (0.3)
頚椎骨折	1 (0.3)	0
転倒	1 (0.3)	0
大腿骨頚部骨折	0	1 (0.3)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30mg QD group include those who started UPA 15 mg QD/30mg QD at the beginning of the study and those who switched to UPA 15 mg/30mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__2.1.2

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 290) (PYs = 292.8) Events (E/100 PYs)	UPA 30 mg QD (N = 308) (PYs = 296.2) Events (E/100 PYs)
傷害、中毒および処置合併症 (Cont.)		
腰椎骨折	1 (0.3)	0
処置後胆汁漏出	1 (0.3)	0
交通事故	1 (0.3)	0
腱断裂	1 (0.3)	0
胸椎骨折	1 (0.3)	0
外傷性血胸	1 (0.3)	0
代謝および栄養障害	1 (0.3)	0
糖尿病	1 (0.3)	0
筋骨格系および結合組織障害	6 (2.0)	1 (0.3)
側腹部痛	1 (0.3)	0
変形性関節症	1 (0.3)	1 (0.3)
乾癬性関節症	2 (0.7)	0
急速進行性変形性関節症	1 (0.3)	0
全身性エリテマトーデス	1 (0.3)	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3 (1.0)	4 (1.4)
肛門性器疣贅	0	1 (0.3)
悪性黒色腫第3期	1 (0.3)	0
中咽頭扁平上皮癌	0	1 (0.3)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30mg QD group include those who started UPA 15 mg QD/30mg QD at the beginning of the study and those who switched to UPA 15 mg/30mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__2.1.2

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 290) (PYs = 292.8) Events (E/100 PYs)	UPA 30 mg QD (N = 308) (PYs = 296.2) Events (E/100 PYs)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)		
卵巣癌	0	1 (0.3)
前立腺癌	1 (0.3)	0
直腸腺癌	0	1 (0.3)
直腸癌	1 (0.3)	0
神経系障害	2 (0.7)	2 (0.7)
浮動性めまい	1 (0.3)	0
顔面麻痺	0	1 (0.3)
会話障害	1 (0.3)	0
一過性全健忘	0	1 (0.3)
妊娠、産褥および周産期の状態	0	1 (0.3)
異所性妊娠	0	1 (0.3)
精神障害	1 (0.3)	1 (0.3)
失見当識	1 (0.3)	0
精神状態変化	0	1 (0.3)
腎および尿路障害	3 (1.0)	2 (0.7)
急性腎障害	1 (0.3)	1 (0.3)
腎結石症	2 (0.7)	1 (0.3)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30mg QD group include those who started UPA 15 mg QD/30mg QD at the beginning of the study and those who switched to UPA 15 mg/30mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__2.1.2

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 290) (PYs = 292.8) Events (E/100 PYs)	UPA 30 mg QD (N = 308) (PYs = 296.2) Events (E/100 PYs)
生殖系および乳房障害	1 (0.3)	1 (0.3)
良性前立腺肥大症	0	1 (0.3)
子宮頚部上皮異形成	1 (0.3)	0
呼吸器、胸郭および縦隔障害	2 (0.7)	4 (1.4)
急性呼吸不全	1 (0.3)	1 (0.3)
慢性閉塞性肺疾患	0	1 (0.3)
間質性肺疾患	0	1 (0.3)
気胸	0	1 (0.3)
肺塞栓症	1 (0.3)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30mg QD group include those who started UPA 15 mg QD/30mg QD at the beginning of the study and those who switched to UPA 15 mg/30mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

表 2.7.4.7-27. 投与 24 週時までの重篤な有害事象の一覧表（安全性解析対象集団）：M15-554 試験

表中記載の説明

転帰：回復 ＝E 欄に日数が記載されており，S 欄に Death of subject の記載がない。継続中 ＝O 欄に YES と記載されているか，E 欄及び O 欄の記載がない。死亡 ＝S 欄に Death of subject と記載されている。

国内の実施医療機関の番号は，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted] 及び [redacted] である。

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:94.80 KG							
	PRE	TO -1						
	BLIND	1 TO 168	153	153	R: MODERATELY DIFFERENTIATED INVASIVE ADENOCARCINOMA (RECTUM) S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 直腸腺癌 L: Rectal adenocarcinoma	E: 491 L: 339 DAYS	T: Severe R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, ROBOTIC LOW ANTERIOR RESECTION OF THE RECTUM AND COVERING ILEOSTOMY - [redacted]/[redacted]/20[redacted])	S: YES, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY
	POST	169 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted] TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:89.81 KG							
	PRE	TO -1						
	BLIND	1 TO 396	165	165	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 178 L: 14 DAYS	T: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	OL	397 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 15 mg QD								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:66.30 KG							
	PRE	TO -1						
	BLIND	1 TO 392	20	20	R: ACUTE MYOCARDIAL INFARCTION S: Cardiac disorders P: 急性心筋梗塞 L: Acute myocardial infarction	E: 28 L: 9 DAYS	T: Moderate R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: CAN BE RELATED TO 23 YEARS OF SMOKING A: NO REASONABLE POSSIBILITY
	OL	393 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:86.50 KG							
	PRE	TO -1						
	BLIND	1 TO 392	17	17	R: RIGHT FEMORAL NECK FRACTURE S: Injury, poisoning and procedural complications P: 大腿骨頚部骨折 L: Femoral neck fracture	E: 345 L: 329 DAYS	T: Mild R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: STRESS FRACTURE A: NO REASONABLE POSSIBILITY
	OL	393 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:76.70 KG							
	PRE	TO -1						
	BLIND	1 TO 119	117	117	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 155 L: 39 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization O: INFECTION A: REASONABLE POSSIBILITY
	POST	120 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.84 KG							
		PRE	TO -1					
		BLIND	1 TO 161 88	88	R: TRANSIENT GLOBAL AMNESIA S: Nervous system disorders P: 一過性全健忘 L: Transient global amnesia	E: 91 L: 4 DAYS	T: Mild R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: URINARY TRACT INFECTION A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.84 KG							
	BLIND	1 TO 161	129	129	R: CORONARY STENOSIS S: Cardiac disorders P: 冠動脈狭窄 L: Coronary artery stenosis	O: YES	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CORONARY ARTERY BYPASS, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: SUBJECTS MEDICAL HISTORY OF HTN AND HYPERCHOLESTEREMIA AND FAMILY HISTORY OF CARDIAC ISSUES A: NO REASONABLE POSSIBILITY
	POST	162 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:64.00 KG							
	PRE	TO -1						
	BLIND	1 TO 152						
	POST	153 TO	4	156	R: ACUTE KIDNEY INJURY AND BACTERIEMIA S: Infections and infestations P: 菌血症 L: Bacteremia	E: 158 L: 3 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Persistent or significant disability, Important medical or surgical intervention O: INFECTION A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:64.00 KG							
	POST	153 TO	4	156	R: ACUTE KIDNEY INJURY AND BACTERIEMIA S: Renal and urinary disorders P: 急性腎障害 L: Acute kidney injury	E: 158 L: 3 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Persistent or significant disability, Important medical or surgical intervention O: INFECTION A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:64.00 KG							
		POST	153 TO 6	158	R: LOWER BACK EPIDURAL ABSCESS S: Infections and infestations P: 硬膜外膿瘍 L: Epidural abscess	E: 175 L: 18 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: LUMBAR PUNCTURE. A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:97.60 KG							
	PRE	TO -1						
	BLIND	1 TO 160	67	67	R: ACUTE HYPOXEMIC RESPIRATORY FAILURE S: Respiratory, thoracic and mediastinal disorders P: 急性呼吸不全 L: Acute respiratory failure	E: 68 L: 2 DAYS	T: Moderate R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CXR: NEGATIVE FOR INFILTRATE CTA NEGATIVE FOR PE)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY
	POST	161 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: Placebo to UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:132.20 KG							
	PRE	TO -1						
	BLIND	1 TO 14	5	5	R: LEFT FIBULAR FRACTURE S: Injury, poisoning and procedural complications P: 腓骨骨折 L: Fibula fracture	E: 16 L: 12 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: CAR CRASH A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: Placebo to UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:132.20 KG							
	BLIND	1 TO 14	5	5	R: MOTOR VEHICLE ACCIDENT S: Injury, poisoning and procedural complications P: 交通事故 L: Motor vehicle accident	E: 5 L: 1 DAY	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: NONE	S: YES, Hospitalization or prolonged hospitalization, Persistent or significant disability, Important medical or surgical intervention O: UNKNOWN A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: Placebo to UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:132.20 KG							
	BLIND	1 TO 14	5	5	R: RIGHT FRACTURED RIBS S: Injury, poisoning and procedural complications P: 肋骨骨折 L: Fractured ribs	E: 16 L: 12 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization O: CAR CRASH A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: Placebo to UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:132.20 KG							
	POST	15 TO	2	16	R: RIGHT HEMOTHORAX SECONDARY TO RIB FRACTURES S: Injury, poisoning and procedural complications P: 肋骨骨折 L: Rib fracture	E: 16 L: 1 DAY	T: Death R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: YES, Death of subject O: RIGHT HEMOTHORAX SECONDARY TO RIB FRACTURES A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: Placebo to UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:132.20 KG							
	POST	15 TO	2	16	R: RIGHT HEMOTHORAX SECONDARY TO RIB FRACTURES S: Injury, poisoning and procedural complications P: 外傷性血胸 L: Traumatic hemothorax	E: 16 L: 1 DAY	T: Death R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: YES, Death of subject O: RIGHT HEMOTHORAX SECONDARY TO RIB FRACTURES A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:84.00 KG							
	PRE	TO -1						
	BLIND	1 TO 56						
	POST	57 TO	1	57	R: ECTOPIC PREGNANCY S: Pregnancy, puerperium and perinatal conditions P: 異所性妊娠 L: Ectopic pregnancy	E: 90 L: 34 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: NONE	S: YES, Important medical or surgical intervention O: IUD A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:87.77 KG							
	PRE	TO -1						
	BLIND	1 TO 402	115	115	R: SYSTEMIC INFLAMMATORY RESPONSE SYNDROME S: General disorders and administration site conditions P: 全身性炎症反応症候群 L: Systemic inflammatory response syndrome	E: 121 L: 7 DAYS	T: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	OL	403 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:76.60 KG								
		PRE	TO -1						
		BLIND	1 TO 86	86	86	R: WORSENING PSORIATIC ARTHRITIS S: Musculoskeletal and connective tissue disorders P: 乾癬性関節症 L: Psoriatic arthritis aggravated	E: 90 L: 5 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: MULTIPLE (DRUG INTERRUPTED, DRUG WITHDRAWN) O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: PSORIATIC ARTHRITIS A: NO REASONABLE POSSIBILITY
		POST	87 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:127.46 KG								
		PRE	TO -1						
		BLIND	1 TO 222	60	60	R: SYMPTOMATIC BRADYCARDIA S: Cardiac disorders P: 徐脈 L: Bradycardia	E: 61 L: 2 DAYS	T: Mild R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: UNKNOWN ETIOLOGY A: NO REASONABLE POSSIBILITY
		POST	223 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:158.00 KG							
	PRE	TO -1						
	BLIND	1 TO 395	82	82	R: UNSTABLE ANGINA S: Cardiac disorders P: 不安定狭心症 L: Unstable angina	E: 86 L: 5 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CT, ULTRASOUND, CHEST X-RAY AND CATHETERIZATION)	S: YES, Hospitalization or prolonged hospitalization O: PAST HISTORY OF CARDIAC CATHETERIZATION ON [redacted]20[redacted] AND A HISTORY OF MILD HYPERCHOLESTEROLEMIA A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:158.00 KG							
	BLIND	1 TO 395	87	87	R: PSEUDOANEURYSM OF ARTERY OF LOWER EXTREMITY S: Injury, poisoning and procedural complications P: 血管偽動脈瘤 L: Pseudoaneurysm	E: 92 L: 6 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, ULTRASOUND)	S: YES, Hospitalization or prolonged hospitalization O: COMPLICATIONS FROM THE CARDIAC CATHETERIZATION A: NO REASONABLE POSSIBILITY
	OL	396 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:89.60 KG								
		PRE	TO -1						
		BLIND	1 TO 316	161	161	R: RIGHT KNEE OSTEOARTHRITIS S: Musculoskeletal and connective tissue disorders P: 変形性関節症 L: Knee osteoarthritis	E: 287 L: 127 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, RIGHT TOTAL KNEE JOINT REPLACEMENT)	S: YES, Hospitalization or prolonged hospitalization O: CAUSE OF EVENT IS OSTEOARTHRITIS A: NO REASONABLE POSSIBILITY
		POST	317 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: Placebo to UPA 15 mg QD								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:91.17 KG							
	PRE	TO -1						
	BLIND	1 TO 392	127	127	R: UTERINE FIBROIDS S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 子宮平滑筋腫 L: Uterine fibroids	E: 145 L: 19 DAYS	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: STUDY DRUG INTERRUPTED, SUBJECT DID NOT TAKE PILLS FOR 6 DAYS DUE TO HYSTERECTOMY	S: YES, Hospitalization or prolonged hospitalization O: HISTORY OF UTERINE FIBROIDS A: NO REASONABLE POSSIBILITY
	OL	393 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality

INV: [redacted]([redacted]
TRT: UPA 15 mg QD

[redacted] AGE:8[redacted] SEX:FEMALE RACE:WHITE WEIGHT:109.60 KG

PRE TO -1

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:8[redacted] SEX:FEMALE RACE:WHITE WEIGHT:109.60 KG							
	BLIND	1 TO 50	42	42	R: SYSTEMIC LUPUS ERYTHEMATOSUS S: Musculoskeletal and connective tissue disorders P: 全身性エリテマトーデス L: Systemic lupus erythematosus	O: YES	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization O: SUBJECTS WITH AUTOIMMUNE DISORDERS SUCH AS PLAQUE PSORIASIS, PSORIATIC ARTHRITIS, AND HYPOTHYROIDISM MAY BE MORE LIKELY TO DEVELOP SYSTEMIC LUPUS ERYTHEMATOSUS. A: NO REASONABLE POSSIBILITY
	POST	51 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:139.20 KG							
	PRE	TO -1						
	BLIND	1 TO	28	28	R: UNSTABLE ANGINA PECTORIS S: Cardiac disorders P: 不安定狭心症 L: Angina pectoris unstable	E: 32 L: 5 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CARDIAC CATHETERIZATION)	S: YES, Hospitalization or prolonged hospitalization O: FAMILY HISTORY OF CARDIAC EVENTS A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:78.90 KG							
	PRE	TO -1						
	BLIND	1 TO 99	83	83	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 113 L: 31 DAYS	T: Severe R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:78.90 KG							
		POST	100 TO 14	113	R: OVARY CANCER S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 卵巢癌 L: Ovarian cancer	O: YES	T: Severe R: NO REASONABLE POSSIBILITY A: STUDY DRUG PREVIOUSLY WITHDRAWN ON [redacted] DUE TO AE-URINARY TRACT INFECTION. O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization O: CAUSE UNKNOWN A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:79.50 KG							
	PRE	TO -1						
	BLIND	1 TO 83	71	71	R: ADENOCARCINOMA OF PROSTATE GLAND 7 (3 + 4) S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 前立腺癌 L: Adenocarcinoma of prostate		T: Severe R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Important medical or surgical intervention O: AGE AND PREVIOUS TREATMENT WITH BIOLOGIC THERAPY A: NO REASONABLE POSSIBILITY
	POST	84 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:64.00 KG								
		PRE	TO -1						
		BLIND	1 TO 148	82	82	R: RAPID DESTRUCTIVE OSTEOARTHRITIS OF THE HIP S: Musculoskeletal and connective tissue disorders P: 急速進行性変形性関節症 L: Rapidly progressive osteoarthritis	E: 163 L: 82 DAYS	T: Severe R: REASONABLE POSSIBILITY A: MULTIPLE (DRUG INTERRUPTED, DRUG WITHDRAWN) O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY
		POST	149 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:95.00 KG							
	PRE	TO -1						
	BLIND	1 TO 385	12	12	R: STONE IN RIGHT KIDNEY S: Renal and urinary disorders P: 腎結石症 L: Kidney stone	E: 16 L: 5 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, KIDNEY STONE REMOVED AND RENAL STENT INSERTED.)	S: YES, Hospitalization or prolonged hospitalization O: UNKNOWN AT THIS TIME A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:95.00 KG								
		BLIND	1 TO 385	47	47	R: RIGHT SIDE FLANK PAIN S: Musculoskeletal and connective tissue disorders P: 側腹部痛 L: Flank pain	E: 56 L: 10 DAYS	T: Moderate R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, RENAL STENT REMOVED IN HOSPITAL)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: PATIENT HAS TEMPORARY STENT IN RIGHT KIDNEY A: NO REASONABLE POSSIBILITY
		OL	386 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:97.52 KG							
	PRE	TO -1						
	BLIND	1 TO 392	97	97	R: WORSENING BENIGN PROSTATIC HYPERTROPHY S: Reproductive system and breast disorders P: 良性前立腺肥大症 L: BPH	E: 97 L: 1 DAY	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: SURGERY- TRANSURETHRAL RESECTION OF THE PROSTATE	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: HISTORY OF BENIGN PROSTATIC HYPERTROPHY A: NO REASONABLE POSSIBILITY
	OL	393 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:103.42 KG								
		PRE	TO -1						
		BLIND	1 TO 394	23	23	R: ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE S: Cardiac disorders P: 心房細動 L: Atrial fibrillation with rapid ventricular response	E: 51 L: 29 DAYS I: YES	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: UNKNOWN A: NO REASONABLE POSSIBILITY
		OL	395 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:130.82 KG							
		PRE	TO -1					
		BLIND	1 TO 94	64	64	R: SQUAMOUS CELL CARCINOMA, KERATINIZING, MODERATELY DIFFERENTIATED, RECTUM S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 直腸癌 L: Squamous cell carcinoma of rectum	O: YES	T: Severe R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: YES, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality

INV: [redacted]([redacted])
TRT: UPA 15 mg QD

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:130.82 KG

POST 95 TO

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

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INV: [redacted] ([redacted])
TRT: Placebo to UPA 30 mg QD

[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:66.22 KG

PRE TO -1

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

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(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:66.22 KG							
	BLIND	1 TO 80	79	79	R: ACUTE SEPTIC PREPATELLAR BURSITIS OF THE LEFT KNEE (MSSA) S: Infections and infestations P: ブドウ球菌感染性滑液包炎 L: Bursitis infective staphylococcal	E: 121 L: 43 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: SUBJECT RECENTLY HAD LEFT ANKLE REPAIR SURGERY. THIS AE MAY BE RELATED BUT LEFT ANKLE SURGERY SITE DID NOT SHOW SIGNS OF INFECTION. A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

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INV:[redacted]([redacted])								
TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:66.22 KG							
		POST	81 TO					

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:78.80 KG								
		PRE	TO -1						
		BLIND	1 TO 88	88	88	R: DIZZINESS, DIFFICULTY TO SPEAK, DISORIENTED, PATIENT FELL S: Injury, poisoning and procedural complications P: 転倒 L: Fall	O: YES I: YES	T: Mild R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITILIZED	S: YES, Hospitalization or prolonged hospitalization O: DATA IS UNKNOWN A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV:[redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:78.80 KG					
	BLIND	1 TO 88	88	88		R: DIZZINESS, DIFFICULTY TO SPEAK, DISORIENTED, PATIENT FELL S: Nervous system disorders P: 浮動性めまい L: Dizziness	O: YES I: YES	T: Mild R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITILIZED	S: YES, Hospitalization or prolonged hospitalization O: DATA IS UNKNOWN A: NO REASONABLE POSSIBILITY
			88	88		R: DIZZINESS, DIFFICULTY TO SPEAK, DISORIENTED, PATIENT FELL S: Nervous system disorders P: 会話障害 L: Speech impairment NOS	O: YES I: YES	T: Mild R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITILIZED	S: YES, Hospitalization or prolonged hospitalization O: DATA IS UNKNOWN A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 15 mg QD								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:78.80 KG							
	BLIND	1 TO 88	88	88	R: DIZZINESS, DIFFICULTY TO SPEAK, DISORIENTED, PATIENT FELL S: Psychiatric disorders P: 失見当識 L: Disorientated	O: YES I: YES	T: Mild R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITILIZED	S: YES, Hospitalization or prolonged hospitalization O: DATA IS UNKNOWN A: NO REASONABLE POSSIBILITY
	POST	89 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:6[redacted] SEX:MALE RACE:ASIAN WEIGHT:72.00 KG								
		PRE	TO -1						
		BLIND	1 TO 118	118	118	R: DRUG INDUCED PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 169 L: 52 DAYS I: YES	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY
		POST	119 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:104.20 KG								
		PRE	TO -1						
		BLIND	1 TO 249	4	4	R: ACUTE BRONCHITIS S: Infections and infestations P: 気管支炎 L: Acute bronchitis	E: 29 L: 26 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: VIRAL VS. BACTERIAL INFECTION A: REASONABLE POSSIBILITY
		POST	250 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:81.50 KG							
	PRE	TO -1						
	BLIND	1 TO 393	164	164	R: RENAL LITHIASIS ON THE RIGHT S: Renal and urinary disorders P: 腎結石症 L: Kidney stone	E: 168 L: 5 DAYS	T: Moderate R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: DIET AND LOW WATER INTAKE A: NO REASONABLE POSSIBILITY
	OL	394 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:92.20 KG							
	PRE	TO -1						
	BLIND	1 TO 35	31	31	R: SMALL INTESTINAL ULCER S: Gastrointestinal disorders P: 小腸潰瘍 L: Small intestinal ulcer NOS	E: 92 L: 62 DAYS I: YES	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY
	POST	36 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day	Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:104.90 KG								
		PRE	TO -1						
		BLIND	1 TO 28	23	23	R: EXACERBATION OF PSORIATIC ARTHRITIS S: Musculoskeletal and connective tissue disorders P: 乾癬性関節症 L: Psoriatic arthritis aggravated	O: YES I: YES	T: Moderate R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: HOSPITALIZATION	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
		POST	29 TO						

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:51.00 KG							
		PRE	TO -1					
		BLIND	1 TO 147					
		POST	148 TO 156	9	R: LEFT SIDE ABDOMINAL PAIN RADIATING TO LEFT FLANK UNKNOWN ETIOLOGY, DIARRHEA S: Gastrointestinal disorders P: 腹痛 L: Abdominal pain	E: 184 L: 29 DAYS	T: Moderate R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CLEAR LIQUID DIET)	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:51.00 KG								
		POST	148 TO	9	156	R: LEFT SIDE ABDOMINAL PAIN RADIATING TO LEFT FLANK UNKNOWN ETIOLOGY, DIARRHEA S: Gastrointestinal disorders P: 下痢 L: Diarrhea	E: 184 L: 29 DAYS	T: Moderate R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CLEAR LIQUID DIET)	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:103.40 KG							
		PRE	TO -1					
		BLIND	1 TO 160					
		POST	161 TO	1 161	R: ACUTE BLOOD LOSS ANEMIA S: Blood and lymphatic system disorders P: 失血性貧血 L: Acute blood loss anemia	E: 175 L: 15 DAYS	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (1 UNIT TRANSFUSED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:103.40 KG							
		POST	161 TO 1	161	R: ACUTE HYPOXIC RESPIRATORY FAILURE S: Respiratory, thoracic and mediastinal disorders P: 急性呼吸不全 L: Acute respiratory failure	E: 175 L: 15 DAYS	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:103.40 KG								
		POST	161 TO	1	161	R: BILATERAL PULMONARY EMBOLI S: Respiratory, thoracic and mediastinal disorders P: 肺塞栓症 L: Pulmonary embolism	E: 175 L: 15 DAYS	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:103.40 KG								
		POST	161 TO	1	161	R: CARDIOPULMONARY ARREST S: Cardiac disorders P: 心肺停止 L: Cardiopulmonary arrest	E: 175 L: 15 DAYS	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:103.40 KG							
		POST	161 TO 1	161	R: EROSIVE GASTRITIS S: Gastrointestinal disorders P: びらん性胃炎 L: Gastritis erosive	E: 175 L: 15 DAYS	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:103.40 KG								
		POST	161 TO	1	161	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 175 L: 15 DAYS	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - up to Week 24
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:103.40 KG									
	POST	161 TO	1	161	R: VENTRICULAR FIBRILLATION S: Cardiac disorders P: 心室細動 L: Ventricular fibrillation	E: 161 L: 1 DAY	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (SHOCK AND CPR, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

表 2.7.4.7-28. 投与 24 週時データカットオフまでの重篤な有害事象の一覧表（安全性解析対象集団）：M15-554 試験

表中記載の説明

転帰：回復 ＝E 欄に日数が記載されており，S 欄に Death of subject の記載がない。継続中 ＝O 欄に YES と記載されているか，E 欄及び O 欄の記載がない。死亡 ＝S 欄に Death of subject と記載されている。

国内の実施医療機関の番号は，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted]，[redacted] 及び [redacted] である。

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 15 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:76.20 KG							
	PRE	TO -1						
	BLIND	1 TO	277	277	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia		T: Moderate R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: NONE	S: YES, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality

INV: [redacted] ([redacted])
TRT: UPA 30 mg QD

[redacted] AGE:6[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:94.80 KG

PRE TO -1

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted] TRT: UPA 30 mg QD									
[redacted] AGE:6[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:94.80 KG									
	BLIND	1 TO 168	153	153		R: MODERATELY DIFFERENTIATED INVASIVE ADENOCARCINOMA (RECTUM) S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 直腸腺癌 L: Rectal adenocarcinoma	E: 491 L: 339 DAYS	T: Severe R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, ROBOTIC LOW ANTERIOR RESECTION OF THE RECTUM AND COVERING ILEOSTOMY - [redacted]/[redacted]/20[redacted])	S: YES, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY
	POST	169 TO							

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:106.14 KG							
		PRE	TO -1					
		BLIND	1 TO 394					
		OL	395 TO 419	25	R: ACUTE BLOOD LOSS ANEMIA S: Blood and lymphatic system disorders P: 失血性貧血 L: Acute blood loss anemia	E: 424 L: 6 DAYS	T: Moderate R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: SUBJECT REPORTED RECEIVING 6 UNITS OF BLOOD IN THE HOSPITAL	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:106.14 KG							
	OL	395 TO	25	419	R: DUODENAL ULCER BLEEDING S: Gastrointestinal disorders P: 出血性十二指腸潰瘍 L: Bleeding duodenal ulcer	E: 421 L: 3 DAYS	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: ULCER CLIPPED	S: YES, Hospitalization or prolonged hospitalization O: SUBJECT HAS CHRONIC GASTRITIS A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:101.40 KG							
	PRE	TO -1						
	BLIND	1 TO 392						
	OL	393 TO 553	58	450	R: UPPER RESPIRATORY INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory infection	E: 455 L: 6 DAYS	T: Severe R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CHEST X-RAY)	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	POST	554 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:82.80 KG							
		PRE	TO -1					
		BLIND	1 TO 400					
		OL	401 TO 653	449	R: CELLULITIS OF LEFT HAND S: Infections and infestations P: 蜂巢炎 L: Cellulitis of hand	E: 463 L: 15 DAYS	T: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY
		POST	654 TO					

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:97.30 KG							
	PRE	TO -1						
	BLIND	1 TO 348						
	POST	349 TO	16	364	R: CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION S: Respiratory, thoracic and mediastinal disorders P: 慢性閉塞性肺疾患 L: COPD exacerbation	E: 368 L: 5 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization O: PATIENT HAD PREVIOUS HISTORY OF BRONCHIAL ASTHMA A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted] TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:89.81 KG							
	PRE	TO -1						
	BLIND	1 TO 396	165	165	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 178 L: 14 DAYS	T: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	OL	397 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:98.50 KG							
	PRE	TO -1						
	BLIND	1 TO 393	225	225	R: LEFT INGUINOSCROTAL HERNIA S: Gastrointestinal disorders P: 鼠径ヘルニア L: Scrotal hernia	E: 325 L: 101 DAYS	T: Mild R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, LEFT INGUINOSCROTAL HERNIOPLASTY)	S: YES, Hospitalization or prolonged hospitalization O: LEFT INGUINOSCROTAL HERNIOPLASTY A: NO REASONABLE POSSIBILITY
	OL	394 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:66.30 KG							
	PRE	TO -1						
	BLIND	1 TO 392	20	20	R: ACUTE MYOCARDIAL INFARCTION S: Cardiac disorders P: 急性心筋梗塞 L: Acute myocardial infarction	E: 28 L: 9 DAYS	T: Moderate R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: CAN BE RELATED TO 23 YEARS OF SMOKING A: NO REASONABLE POSSIBILITY
	OL	393 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:86.50 KG							
	PRE	TO -1						
	BLIND	1 TO 392	17	17	R: RIGHT FEMORAL NECK FRACTURE S: Injury, poisoning and procedural complications P: 大腿骨頚部骨折 L: Femoral neck fracture	E: 345 L: 329 DAYS	T: Mild R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: STRESS FRACTURE A: NO REASONABLE POSSIBILITY
	OL	393 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:76.70 KG							
	PRE	TO -1						
	BLIND	1 TO 119	117	117	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 155 L: 39 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization O: INFECTION A: REASONABLE POSSIBILITY
	POST	120 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted] TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.84 KG							
	PRE	TO -1						
	BLIND	1 TO 161	88	88	R: TRANSIENT GLOBAL AMNESIA S: Nervous system disorders P: 一過性全健忘 L: Transient global amnesia	E: 91 L: 4 DAYS	T: Mild R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: URINARY TRACT INFECTION A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.84 KG							
	BLIND	1 TO 161	129	129	R: CORONARY STENOSIS S: Cardiac disorders P: 冠動脈狭窄 L: Coronary artery stenosis	O: YES	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CORONARY ARTERY BYPASS, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: SUBJECTS MEDICAL HISTORY OF HTN AND HYPERCHOLESTEREMIA AND FAMILY HISTORY OF CARDIAC ISSUES A: NO REASONABLE POSSIBILITY
	POST	162 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted] TRT: UPA 15 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:53.40 KG							
	PRE	TO -1						
	BLIND	1 TO 392	248	248	R: APICAL MYOCARDIAL INFARCTION S: Cardiac disorders P: 心筋梗塞 L: Apical myocardial infarction	E: 267 L: 20 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: HYPERTENSION A: NO REASONABLE POSSIBILITY
	OL	393 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:69.40 KG							
	PRE	TO -1						
	BLIND	1 TO 392	238	238	R: STRUMA NODOSA-ENLARGED THYROID GLAND S: Endocrine disorders P: 甲状腺腫 L: Struma nodosa	E: 287 L: 50 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: SURGERY - STRUMECTOMY	S: YES, Hospitalization or prolonged hospitalization O: UNKNOWN A: NO REASONABLE POSSIBILITY
	OL	393 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality

INV: [redacted]([redacted])
TRT: UPA 30 mg QD

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:64.00 KG

PRE TO -1

BLIND 1 TO 152

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:64.00 KG							
	POST	153 TO	4	156	R: ACUTE KIDNEY INJURY AND BACTERIEMIA S: Infections and infestations P: 菌血症 L: Bacteremia	E: 158 L: 3 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Persistent or significant disability, Important medical or surgical intervention O: INFECTION A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:64.00 KG							
	POST	153 TO 4	4	156	R: ACUTE KIDNEY INJURY AND BACTERIEMIA S: Renal and urinary disorders P: 急性腎障害 L: Acute kidney injury	E: 158 L: 3 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Persistent or significant disability, Important medical or surgical intervention O: INFECTION A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted] TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:64.00 KG							
	POST	153 TO	6	158	R: LOWER BACK EPIDURAL ABSCESS S: Infections and infestations P: 硬膜外膿瘍 L: Epidural abscess	E: 175 L: 18 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: LUMBAR PUNCTURE. A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:82.10 KG							
	PRE	TO -1						
	BLIND	1 TO 268	268	268	R: SKIN MELANOMA STAGE III LEFT SHOULDER S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 悪性黒色腫第3期 L: Malignant melanoma stage III	O: YES	T: Life threatening R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: YES, Important medical or surgical intervention O: UNKNOWN ETIOLOGY A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:82.10 KG							
		POST	269 TO					

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:97.60 KG							
	PRE	TO -1						
	BLIND	1 TO 160	67	67	R: ACUTE HYPOXEMIC RESPIRATORY FAILURE S: Respiratory, thoracic and mediastinal disorders P: 急性呼吸不全 L: Acute respiratory failure	E: 68 L: 2 DAYS	T: Moderate R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CXR: NEGATIVE FOR INFILTRATE CTA NEGATIVE FOR PE)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality

INV: [redacted]([redacted])
TRT: UPA 30 mg QD

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:97.60 KG

POST 161 TO

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:84.00 KG							
	PRE	TO -1						
	BLIND	1 TO 56						
	POST	57 TO	1	57	R: ECTOPIC PREGNANCY S: Pregnancy, puerperium and perinatal conditions P: 異所性妊娠 L: Ectopic pregnancy	E: 90 L: 34 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: NONE	S: YES, Important medical or surgical intervention O: IUD A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality

INV: [redacted]
TRT: UPA 30 mg QD

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:87.77 KG

PRE TO -1

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:87.77 KG							
	BLIND	1 TO 402	115	115	R: SYSTEMIC INFLAMMATORY RESPONSE SYNDROME S: General disorders and administration site conditions P: 全身性炎症反応症候群 L: Systemic inflammatory response syndrome	E: 121 L: 7 DAYS	T: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	OL	403 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] TRT: Placebo to UPA 15 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:43.00 KG							
	PRE	TO -1						
	BLIND	1 TO 365	191	191	R: INFECTIOUS BRONCHIOLITIS S: Infections and infestations P: 細気管支炎 L: Bronchiolitis	E: 203 L: 13 DAYS	T: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: NONE	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: Placebo to UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:43.00 KG								
		BLIND	1 TO 365	345	345	R: PULMONARY INFECTION S: Infections and infestations P: 肺感染 L: Lung infection	E: 373 L: 29 DAYS I: YES	T: Severe R: REASONABLE POSSIBILITY A: MULTIPLE (DRUG INTERRUPTED, DRUG WITHDRAWN) O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
		POST	366 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted])								
TRT: UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:76.60 KG							
	PRE	TO -1						
	BLIND	1 TO 86	86	86	R: WORSENING PSORIATIC ARTHRITIS S: Musculoskeletal and connective tissue disorders P: 乾癬性関節症 L: Psoriatic arthritis aggravated	E: 90 L: 5 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: MULTIPLE (DRUG INTERRUPTED, DRUG WITHDRAWN) O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: PSORIATIC ARTHRITIS A: NO REASONABLE POSSIBILITY
	POST	87 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:116.80 KG							
	PRE	TO -1						
	BLIND	1 TO 385						
	OL	386 TO	43	428	R: LEFT FACIAL NERVE PALSY S: Nervous system disorders P: 顔面麻痺 L: Facial nerve paralysis	E: 457 L: 30 DAYS	T: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:116.80 KG							
	OL	386 TO	212	597	R: VIRAL ENTERITIS S: Infections and infestations P: ウイルス性胃腸炎 L: Viral gastroenteritis	E: 615 L: 19 DAYS	T: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality

INV: [redacted]([redacted]
TRT: UPA 15 mg QD

[redacted]AGE:6[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:94.80 KG

PRE TO -1

BLIND 1 TO 384

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:94.80 KG							
	OL	385 TO	57	441	R: ANGINA S: Cardiac disorders P: 狭心症 L: Angina pectoris	E: 442 L: 2 DAYS I: YES	T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening O: NEW DEVELOPMENT OF CORONARY ARTERY DISEASE A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] [redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:127.46 KG							
	PRE	TO -1						
	BLIND	1 TO 222	60	60	R: SYMPTOMATIC BRADYCARDIA S: Cardiac disorders P: 徐脈 L: Bradycardia	E: 61 L: 2 DAYS	T: Mild R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: UNKNOWN ETIOLOGY A: NO REASONABLE POSSIBILITY
	POST	223 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality

INV:[redacted]([redacted])
TRT: Placebo to UPA 15 mg QD

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:78.90 KG

PRE	TO -1
BLIND	1 TO 391

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: Placebo to UPA 15 mg QD									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:78.90 KG								
		OL	392 TO 437	42	433	R: LEFT AXIAL ABSCESS S: Infections and infestations P: 膿瘍 L: Abscess	E: 450 L: 18 DAYS	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, REFER THE PATIENT TO HOSPITAL EMERGENCY, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: REASONABLE POSSIBILITY
		POST	438 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 15 mg QD								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:130.18 KG							
	PRE	TO -1						
	BLIND	1 TO 392						
	OL	393 TO	118	510	R: CELLULITIS LEFT LEG, ACUTE RENAL FAILURE S: Infections and infestations P: 蜂巢炎 L: Cellulitis of leg		T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: TRAUMA TO THE LEG A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:130.18 KG							
	OL	393 TO	118	510	R: CELLULITIS LEFT LEG, ACUTE RENAL FAILURE S: Renal and urinary disorders P: 急性腎障害 L: Acute renal failure		T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: TRAUMA TO THE LEG A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted])								
TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:90.70 KG							
	PRE	TO -1						
	BLIND	1 TO 392	294	294	R: KELLGREN LAWRENCE GRADE 4 OSTEOARTHRITIS RIGHT HIP S: Musculoskeletal and connective tissue disorders P: 変形性関節症 L: Hips osteoarthritis	E: 316 L: 23 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: RIGHT HIP REPLACEMENT	S: YES, Hospitalization or prolonged hospitalization O: GRADE 4 HIP OSTEOARTHRITIS A: NO REASONABLE POSSIBILITY
	OL	393 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:91.90 KG							
	PRE	TO -1						
	BLIND	1 TO 392	288	288	R: BILATERAL NEPHROLITHIASIS S: Renal and urinary disorders P: 腎結石症 L: Nephrolithiasis	E: 293 L: 6 DAYS	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: UNKNOWN AT THIS TIME-WAITING FOR MEDICAL RECORDS A: NO REASONABLE POSSIBILITY
	POST	393 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:69.00 KG							
	PRE	TO -1						
	BLIND	1 TO 392						
	OL	393 TO	49	441	R: GASTROENTERITIS S: Infections and infestations P: 胃腸炎 L: Gastroenteritis	E: 450 L: 10 DAYS	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: STOMACH VIRUS A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:69.00 KG							
	OL	393 TO	49	441	R: HEMATEMESIS S: Gastrointestinal disorders P: 吐血 L: Hematemesis	E: 450 L: 10 DAYS	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, PENDING HOSPITAL RECORDS)	S: YES, Hospitalization or prolonged hospitalization O: SUBJECT EXPERIENCED GASTROENTERITIS AND HEMATEMESIS RELATED TO FAMILY MEMBERS EXPERIENCING THE SAME A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 15 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:89.60 KG							
		PRE	TO -1					
		BLIND	1 TO 316	161	R: RIGHT KNEE OSTEOARTHRITIS S: Musculoskeletal and connective tissue disorders P: 変形性関節症 L: Knee osteoarthritis	E: 287 L: 127 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, RIGHT TOTAL KNEE JOINT REPLACEMENT)	S: YES, Hospitalization or prolonged hospitalization O: CAUSE OF EVENT IS OSTEOARTHRITIS A: NO REASONABLE POSSIBILITY
		POST	317 TO					

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER WEIGHT:110.00 KG							
	PRE	TO -1						
	BLIND	1 TO 255	227	227	R: VIRAL GASTROENTERITIS S: Infections and infestations P: ウイルス性胃腸炎 L: Viral gastroenteritis	E: 245 L: 19 DAYS I: YES	T: Moderate R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:6[redacted] SEX:FEMALE RACE:NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER WEIGHT:110.00 KG								
	POST	256 TO	27	282	R: SEPSIS SECONDARY TO RIGHT LOWER LEG CELLULITIS O: YES S: Infections and infestations P: 蜂巢炎 L: Cellulitis of leg		T: Severe R: NO REASONABLE POSSIBILITY A: STUDY DRUG ALREADY WHTHELD SINCE [redacted]20[redacted] O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization O: HAD A FALL ON [redacted]20[redacted] AFTER SYMPTOMS OF POSTURAL SYNCOPE. SUSTAINED ABRASION ON RIGHT LOWER LEG. SWELLING AND FEVER FOLLOWING 72 HOURS. A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:6[redacted] SEX:FEMALE RACE:NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER WEIGHT:110.00 KG								
	POST	256 TO	27	282	R: SEPSIS SECONDARY TO RIGHT LOWER LEG CELLULITIS O: YES S: Infections and infestations P: 敗血症 L: Sepsis secondary		T: Severe R: NO REASONABLE POSSIBILITY A: STUDY DRUG ALREADY WHTHELD SINCE [redacted]20[redacted] O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization O: HAD A FALL ON [redacted]20[redacted] AFTER SYMPTOMS OF POSTURAL SYNCOPE. SUSTAINED ABRASION ON RIGHT LOWER LEG. SWELLING AND FEVER FOLLOWING 72 HOURS. A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: Placebo to UPA 15 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:96.10 KG							
	PRE	TO -1						
	BLIND	1 TO 392						
	OL	393 TO	70	462	R: CHOLELITHIASIS S: Hepatobiliary disorders P: 胆石症 L: Cholelithiasis	E: 466 L: 5 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CHOLECYSTECTOMY	S: YES, Hospitalization or prolonged hospitalization O: OBESITY A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: Placebo to UPA 15 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:96.10 KG							
	OL	393 TO	83	475	R: BILIARY DUCT LEAK (PROCEDURAL INJURY) S: Injury, poisoning and procedural complications P: 処置後胆汁漏出 L: Post procedural bile leak	E: 476 L: 2 DAYS	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, STENT PLACED IN LIVER)	S: YES, Hospitalization or prolonged hospitalization O: CHOLECYSTECTOMY A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality

INV: [redacted]([redacted])
TRT: UPA 15 mg QD

[redacted] AGE:8[redacted] SEX:FEMALE RACE:WHITE WEIGHT:109.60 KG

PRE TO -1

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:8[redacted] SEX:FEMALE RACE:WHITE WEIGHT:109.60 KG							
	BLIND	1 TO 50	42	42	R: SYSTEMIC LUPUS ERYTHEMATOSUS S: Musculoskeletal and connective tissue disorders P: 全身性エリテマトーデス L: Systemic lupus erythematosus	O: YES	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization O: SUBJECTS WITH AUTOIMMUNE DISORDERS SUCH AS PLAQUE PSORIASIS, PSORIATIC ARTHRITIS, AND HYPOTHYROIDISM MAY BE MORE LIKELY TO DEVELOP SYSTEMIC LUPUS ERYTHEMATOSUS. A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality

INV: [redacted]([redacted])
TRT: UPA 15 mg QD

[redacted] AGE:8[redacted] SEX:FEMALE RACE:WHITE WEIGHT:109.60 KG

POST 51 TO

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:139.20 KG							
	PRE	TO -1						
	BLIND	1 TO	28	28	R: UNSTABLE ANGINA PECTORIS S: Cardiac disorders P: 不安定狭心症 L: Angina pectoris unstable	E: 32 L: 5 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CARDIAC CATHETERIZATION)	S: YES, Hospitalization or prolonged hospitalization O: FAMILY HISTORY OF CARDIAC EVENTS A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:82.40 KG								
		PRE	TO -1						
		BLIND	1 TO 391	365	365	R: CONDYLOMA S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 肛門性器疣贅 L: Condyloma	E: 392 L: 28 DAYS	T: Mild R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, RESECTION)	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
		OL	392 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:70.00 KG							
	PRE	TO -1						
	BLIND	1 TO 392						
	OL	393 TO	64	456	R: HERPES ZOSTER S: Infections and infestations P: 帶状疱疹 L: Herpes zoster		T: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted] TRT: UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:55.50 KG							
	PRE	TO -1						
	BLIND	1 TO 391	281	281	R: TENDON RUPTURE (RIGHT HAND EXTENSOR TENDON) S: Injury, poisoning and procedural complications P: 腱断裂 L: Tendon rupture	E: 432 L: 152 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: SURGERY	S: YES, Hospitalization or prolonged hospitalization O: PSORIATIC ARTHRITIS A: NO REASONABLE POSSIBILITY
	OL	392 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:78.90 KG							
	PRE	TO -1						
	BLIND	1 TO 99	83	83	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 113 L: 31 DAYS	T: Severe R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:78.90 KG								
	POST	100 TO	14	113	R: OVARY CANCER S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 卵巢癌 L: Ovarian cancer	O: YES	T: Severe R: NO REASONABLE POSSIBILITY A: STUDY DRUG PREVIOUSLY WITHDRAWN ON [redacted] DUE TO AE-URINARY TRACT INFECTION. O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization O: CAUSE UNKNOWN A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:79.50 KG							
	PRE	TO -1						
	BLIND	1 TO 83	71	71	R: ADENOCARCINOMA OF PROSTATE GLAND 7 (3 + 4) S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 前立腺癌 L: Adenocarcinoma of prostate		T: Severe R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Important medical or surgical intervention O: AGE AND PREVIOUS TREATMENT WITH BIOLOGIC THERAPY A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality

INV: [redacted]([redacted])
TRT: UPA 15 mg QD

[redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:79.50 KG

POST 84 TO

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:64.00 KG							
	PRE	TO -1						
	BLIND	1 TO 148	82	82	R: RAPID DESTRUCTIVE OSTEOARTHRITIS OF THE HIP S: Musculoskeletal and connective tissue disorders P: 急速進行性変形性関節症 L: Rapidly progressive osteoarthritis	E: 163 L: 82 DAYS	T: Severe R: REASONABLE POSSIBILITY A: MULTIPLE (DRUG INTERRUPTED, DRUG WITHDRAWN) O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality

INV: [redacted] ([redacted])
TRT: UPA 15 mg QD

[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:64.00 KG

POST 149 TO

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:95.00 KG							
	PRE	TO -1						
	BLIND	1 TO 385	12	12	R: STONE IN RIGHT KIDNEY S: Renal and urinary disorders P: 腎結石症 L: Kidney stone	E: 16 L: 5 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, KIDNEY STONE REMOVED AND RENAL STENT INSERTED.)	S: YES, Hospitalization or prolonged hospitalization O: UNKNOWN AT THIS TIME A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:95.00 KG							
	BLIND	1 TO 385	47	47	R: RIGHT SIDE FLANK PAIN S: Musculoskeletal and connective tissue disorders P: 側腹部痛 L: Flank pain	E: 56 L: 10 DAYS	T: Moderate R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, RENAL STENT REMOVED IN HOSPITAL)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: PATIENT HAS TEMPORARY STENT IN RIGHT KIDNEY A: NO REASONABLE POSSIBILITY
	OL	386 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:96.16 KG							
	PRE	TO -1						
	BLIND	1 TO 307	306	306	R: ALTERED MENTAL STATUS S: Psychiatric disorders P: 精神状態変化 L: Mental status changes	E: 309 L: 4 DAYS	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: HOSPITALIZED	S: YES, Hospitalization or prolonged hospitalization O: PRESUMED INFECTION A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:96.16 KG							
	BLIND	1 TO 307	306	306	R: FEVER S: General disorders and administration site conditions P: 発熱 L: Fever	E: 309 L: 4 DAYS	T: Severe R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, HOSPITALIZATION, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY
	POST	308 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:97.52 KG							
	PRE	TO -1						
	BLIND	1 TO 392	97	97	R: WORSENING BENIGN PROSTATIC HYPERTROPHY S: Reproductive system and breast disorders P: 良性前立腺肥大症 L: BPH	E: 97 L: 1 DAY	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: SURGERY- TRANSURETHRAL RESECTION OF THE PROSTATE	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: HISTORY OF BENIGN PROSTATIC HYPERTROPHY A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:97.52 KG							
		OL	393	TO				

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:103.42 KG							
	PRE	TO -1						
	BLIND	1 TO 394	23	23	R: ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE S: Cardiac disorders P: 心房細動 L: Atrial fibrillation with rapid ventricular response	E: 51 L: 29 DAYS I: YES	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: UNKNOWN A: NO REASONABLE POSSIBILITY
	OL	395 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:86.18 KG							
	PRE	TO -1						
	BLIND	1 TO 390						
	OL	391 TO	70	460	R: LARGE HEMOPNEUMOTHORAX S: Injury, poisoning and procedural complications P: 外傷性血胸 L: Hemopneumothorax	E: 470 L: 11 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: MOTOR VEHICLE ACCIDENT A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:86.18 KG								
		OL	391 TO	70	460	R: MOTOR VEHICLE ACCIDENT, CERVICAL SPINE FRACTURE, THORACIC SPINE FRACTURE S: Injury, poisoning and procedural complications P: 頚椎骨折 L: Fractured cervical spine	E: 470 L: 11 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: MOTOR VEHICLE ACCIDENT A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:86.18 KG								
		OL	391 TO	70	460	R: MOTOR VEHICLE ACCIDENT, CERVICAL SPINE FRACTURE, THORACIC SPINE FRACTURE S: Injury, poisoning and procedural complications P: 交通事故 L: Motor vehicle accident	E: 470 L: 11 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: MOTOR VEHICLE ACCIDENT A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:86.18 KG								
		OL	391 TO	70	460	R: MOTOR VEHICLE ACCIDENT, CERVICAL SPINE FRACTURE, THORACIC SPINE FRACTURE S: Injury, poisoning and procedural complications P: 胸椎骨折 L: Thoracic vertebral fracture	E: 470 L: 11 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: MOTOR VEHICLE ACCIDENT A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:86.18 KG								
		OL	391 TO	70	460	R: NON DISPLACED FRACTURE OF BILATERAL PEDICLES OF L3 S: Injury, poisoning and procedural complications P: 腰椎骨折 L: Lumbar vertebral fracture	E: 470 L: 11 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: MOTOR VEHICLE ACCIDENT A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:81.92 KG							
	PRE	TO -1						
	BLIND	1 TO 298						
	POST	299 TO	1	299	R: DIVERTICULITS S: Infections and infestations P: 憩室炎 L: Diverticulitis	O: YES	T: Severe R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted] TRT: UPA 15 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:90.90 KG							
	PRE	TO -1						
	BLIND	1 TO	177	177	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 192 L: 16 DAYS	T: Mild R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CHEST XRAY 1 VIEW, CT ABDOMEN/PELVIS W/O CONTRAST, CT CHEST W/O CONTRAST, NECLEAR GALLIUM SCAN	S: YES, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 15 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:130.82 KG							
		PRE	TO -1					

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted] TRT: UPA 15 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:130.82 KG							
	BLIND	1 TO 94	64	64	R: SQUAMOUS CELL CARCINOMA, KERATINIZING, MODERATELY DIFFERENTIATED, RECTUM S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 直腸癌 L: Squamous cell carcinoma of rectum	O: YES	T: Severe R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: YES, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY
	POST	95 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted] TRT: UPA 15 mg QD								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:78.80 KG							
	PRE	TO -1						
	BLIND	1 TO 88	88	88	R: DIZZINESS, DIFFICULTY TO SPEAK, DISORIENTED, PATIENT FELL S: Injury, poisoning and procedural complications P: 転倒 L: Fall	O: YES I: YES	T: Mild R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITILIZED	S: YES, Hospitalization or prolonged hospitalization O: DATA IS UNKNOWN A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 15 mg QD								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:78.80 KG							
	BLIND	1 TO 88	88	88	R: DIZZINESS, DIFFICULTY TO SPEAK, DISORIENTED, PATIENT FELL S: Nervous system disorders P: 浮動性めまい L: Dizziness	O: YES I: YES	T: Mild R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITILIZED	S: YES, Hospitalization or prolonged hospitalization O: DATA IS UNKNOWN A: NO REASONABLE POSSIBILITY
				88	R: DIZZINESS, DIFFICULTY TO SPEAK, DISORIENTED, PATIENT FELL S: Nervous system disorders P: 会話障害 L: Speech impairment NOS	O: YES I: YES	T: Mild R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITILIZED	S: YES, Hospitalization or prolonged hospitalization O: DATA IS UNKNOWN A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] [redacted] TRT: UPA 15 mg QD								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:78.80 KG							
	BLIND	1 TO 88	88	88	R: DIZZINESS, DIFFICULTY TO SPEAK, DISORIENTED, PATIENT FELL S: Psychiatric disorders P: 失見当識 L: Disorientated	O: YES I: YES	T: Mild R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITILIZED	S: YES, Hospitalization or prolonged hospitalization O: DATA IS UNKNOWN A: NO REASONABLE POSSIBILITY
	POST	89 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality

INV: [redacted]
TRT: UPA 30 mg QD

[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:53.00 KG

PRE TO -1

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:53.00 KG							
	BLIND	1 TO 330	323	323	R: RIGHT SIDE TONGUE SQUAMOUS CELL CARCINOMA, MODERATELY DIFFERENTIATED, INVASIVE IN SITU HYBRIDIZATION OF HPV IN PROGRESS. S: Neoplasms benign, malignant and unspecified (incl cysts and polyps) P: 中咽頭扁平上皮癌 L: HPV positive oropharyngeal squamous cell carcinoma	O: YES	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN, DERMATOLOGIST CONSULT FOR BIOPSY O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: INVASIVE IN SITU HYBRIDIZATION OF HPV IN PROGRESS. A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:53.00 KG							
		POST	331 TO					

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 15 mg QD								
[redacted]	AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:106.70 KG							
	PRE	TO -1						
	BLIND	1 TO 392	366	366	R: VIRAL GASTROENTEROCOLITIS S: Infections and infestations P: ウイルス性胃腸炎 L: Viral gastroenteritis	E: 374 L: 9 DAYS I: YES	T: Mild R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	OL	393 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:MALE RACE:ASIAN WEIGHT:72.00 KG							
	PRE	TO -1						
	BLIND	1 TO 118	118	118	R: DRUG INDUCED PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 169 L: 52 DAYS I: YES	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY
	POST	119 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:77.60 KG							
	PRE	TO -1						
	BLIND	1 TO 392	230	230	R: HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESIONS (CIN2) S: Reproductive system and breast disorders P: 子宮頚部上皮異形成 L: High grade squamous intraepithelial lesion	E: 253 L: 24 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: YES, Important medical or surgical intervention O: FEMALE SUBJECT A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 15 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:77.60 KG							
	OL	393 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:104.20 KG							
	PRE	TO -1						
	BLIND	1 TO 249	4	4	R: ACUTE BRONCHITIS S: Infections and infestations P: 気管支炎 L: Acute bronchitis	E: 29 L: 26 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: VIRAL VS. BACTERIAL INFECTION A: REASONABLE POSSIBILITY
	POST	250 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:85.20 KG							
	PRE	TO -1						
	BLIND	1 TO 391	278	278	R: UPPER RESPIRATORY VIRAL ILLNESS S: Infections and infestations P: ウイルス性上気道感染 L: Viral upper respiratory tract infection	E: 305 L: 28 DAYS	T: Mild R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, LUMBAR SPINE MRI, BLOOD AND URINE CULTURE)	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	OL	392 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] [redacted] TRT: UPA 15 mg QD								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:82.60 KG							
	PRE	TO -1						
	BLIND	1 TO	327	327	R: DUODENAL ULCERS S: Gastrointestinal disorders P: 十二指腸潰瘍 L: Duodenal ulcer		T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: CONCOMITANT MEDICATIONS

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:8[redacted] SEX:MALE RACE:WHITE WEIGHT:77.29 KG							
	PRE	TO -1						
	BLIND	1 TO 203	193	193	R: ATRIAL FIBRILLATION S: Cardiac disorders P: 心房細動 L: Atrial fibrillation	E: 197 L: 5 DAYS	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: THE SUBJECT'S AGE, HISTORY OF CORONARY ARTERY DISEASE AND DIABETES ARE ALL LIKELY CAUSES. A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality

INV: [redacted]([redacted])
TRT: Placebo to UPA 30 mg QD

[redacted] AGE:8[redacted] SEX:MALE RACE:WHITE WEIGHT:77.29 KG

POST 204 TO

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 15 mg QD								
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:81.50 KG							
	PRE	TO -1						
	BLIND	1 TO 393	164	164	R: RENAL LITHIASIS ON THE RIGHT S: Renal and urinary disorders P: 腎結石症 L: Kidney stone	E: 168 L: 5 DAYS	T: Moderate R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: DIET AND LOW WATER INTAKE A: NO REASONABLE POSSIBILITY
	OL	394 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted] TRT: Placebo to UPA 15 mg QD								
[redacted]	AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:52.70 KG							
	PRE	TO -1						
	BLIND	1 TO	281	281	R: WORSENING OF DIABETES MELLITUS S: Metabolism and nutrition disorders P: 糖尿病 L: Diabetes mellitus aggravated		T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: THERE IS NO CAUSAL RELATIONSHIP BECAUSE IT IS AGGRAVATED BY POOR CONTROL OF BLOOD GLUCOSE. A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:60.10 KG							
	PRE	TO -1						
	BLIND	1 TO 392						
	OL	393 TO 632						
	POST	633 TO	1	633	R: INTERSTITIAL PNEUMONIA S: Respiratory, thoracic and mediastinal disorders P: 間質性肺疾患 L: Interstitial pneumonia	E: 662 L: 30 DAYS I: YES	T: Life threatening R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:60.10 KG							
	POST	633 TO	1	633	R: RIGHT PNEUMOTHORAX S: Respiratory, thoracic and mediastinal disorders P: 気胸 L: Pneumothorax	E: 662 L: 30 DAYS	T: Life threatening R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, EMERGENCY SURGERY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening O: A CYST ON THE SURFACE OF THE LUNGS (PRIMARY SIDE) = PRIMARY SPONTANEOUS PNEUMOTHORAX IN WHICH BRA BREV RUPTURES. A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:60.10 KG							
	POST	633 TO	5	637	R: PANCYTOPENIA S: Blood and lymphatic system disorders P: 汎血球減少症 L: Pancytopenia	E: 662 L: 26 DAYS	T: Death R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Life threatening, Death of subject A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted] TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:60.10 KG							
	POST	633 TO	5	637	R: PNEUMOCYSTIS PNEUMONIA S: Infections and infestations P: ニューモシスチス・イロベチイ肺炎 L: Pneumocystis pneumonia	E: 662 L: 26 DAYS I: YES	T: Life threatening R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted] TRT: Placebo to UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:60.10 KG							
	POST	633 TO	8	640	R: CYTOMEGALOVIRUS INFECTION S: Infections and infestations P: サイトメガロウイルス感染 L: Cytomegalovirus infection	E: 662 L: 23 DAYS	T: Life threatening R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted] TRT: Placebo to UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:60.10 KG								
		POST	633 TO	16	648	R: DUODENAL ULCER S: Gastrointestinal disorders P: 十二指腸潰瘍 L: Duodenal ulcer	E: 662 L: 15 DAYS	T: Life threatening R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:92.20 KG							
		PRE	TO -1					

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:92.20 KG								
		BLIND	1 TO 35	31	31	R: SMALL INTESTINAL ULCER S: Gastrointestinal disorders P: 小腸潰瘍 L: Small intestinal ulcer NOS	E: 92 L: 62 DAYS I: YES	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY
		POST	36 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 15 mg QD								
[redacted]	AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:104.90 KG							
	PRE	TO -1						
	BLIND	1 TO 28	23	23	R: EXACERBATION OF PSORIATIC ARTHRITIS S: Musculoskeletal and connective tissue disorders P: 乾癬性関節症 L: Psoriatic arthritis aggravated	O: YES I: YES	T: Moderate R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: HOSPITALIZATION	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	POST	29 TO						

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
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# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:51.00 KG							
	PRE	TO -1						
	BLIND	1 TO 147						
	POST	148 TO	9	156	R: LEFT SIDE ABDOMINAL PAIN RADIATING TO LEFT FLANK UNKNOWN ETIOLOGY, DIARRHEA S: Gastrointestinal disorders P: 腹痛 L: Abdominal pain	E: 184 L: 29 DAYS	T: Moderate R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CLEAR LIQUID DIET)	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:51.00 KG									
		POST	148 TO	9	156	R: LEFT SIDE ABDOMINAL PAIN RADIATING TO LEFT FLANK UNKNOWN ETIOLOGY, DIARRHEA S: Gastrointestinal disorders P: 下痢 L: Diarrhea	E: 184 L: 29 DAYS	T: Moderate R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CLEAR LIQUID DIET)	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:57.50 KG							
	PRE	TO -1						
	BLIND	1 TO 393						
	OL	394 TO	100	493	R: PAROXYSMAL SUPRAVENTRICULAR TACHYCARDIA S: Cardiac disorders P: 上室性頻脈 L: Paroxysmal supraventricular tachycardia	E: 493 L: 1 DAY I: YES	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: HISTORY OF PALPITATIONS; PREEXISTING CONDUCTION ISSUE A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	RX Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:103.40 KG							
	PRE	TO -1						
	BLIND	1 TO 160						
	POST	161 TO	1	161	R: ACUTE BLOOD LOSS ANEMIA S: Blood and lymphatic system disorders P: 失血性貧血 L: Acute blood loss anemia	E: 175 L: 15 DAYS	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (1 UNIT TRANSFUSED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

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Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:103.40 KG								
		POST	161 TO	1	161	R: ACUTE HYPOXIC RESPIRATORY FAILURE S: Respiratory, thoracic and mediastinal disorders P: 急性呼吸不全 L: Acute respiratory failure	E: 175 L: 15 DAYS	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:103.40 KG							
	POST	161 TO	1	161	R: BILATERAL PULMONARY EMBOLI S: Respiratory, thoracic and mediastinal disorders P: 肺塞栓症 L: Pulmonary embolism	E: 175 L: 15 DAYS	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
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Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted] TRT: UPA 15 mg QD								
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:103.40 KG							
	POST	161 TO	1	161	R: CARDIOPULMONARY ARREST S: Cardiac disorders P: 心肺停止 L: Cardiopulmonary arrest	E: 175 L: 15 DAYS	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:7[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:103.40 KG					
	POST	161 TO	1		161	R: EROSIVE GASTRITIS S: Gastrointestinal disorders P: びらん性胃炎 L: Gastritis erosive	E: 175 L: 15 DAYS	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:103.40 KG								
		POST	161 TO	1	161	R: PNEUMONIA S: Infections and infestations P: 肺炎 L: Pneumonia	E: 175 L: 15 DAYS	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1.2

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
(Safety Analysis Set)

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:103.40 KG								
	POST	161 TO	1	161	R: VENTRICULAR FIBRILLATION S: Cardiac disorders P: 心室細動 L: Ventricular fibrillation	E: 161 L: 1 DAY	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (SHOCK AND CPR, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent AE (TEAE) is defined an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

表 2.7.4.7-29.　　重篤な有害事象の一覧表（安全性解析対象集団）：M20-017 試験

表中記載の説明

転帰：回復 ＝E 欄に日数が記載されており，S 欄に Death of subject の記載がない。継続中 ＝O 欄に YES と記載されている。死亡 ＝S 欄に Death of subject と記載されている。

TABLE 14.3__2.1.1
Listing of Treatment-Emergent SAE - Part 1
(Safety Analysis Set)

Subject Number	------ Name	Epoch Interval	---- Day	RX Day/ Time of Onset@	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day/Time Ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity T: Toxicity Grade Relationship To R1: Upadacitinib ER17Y R2: Upadacitinib ER17 A: Action Taken with Study Treatment O: Other Actions Taken C: Concomitant Medication or Therapy Started?	S: Serous AE? O: Other Cause of Event
INV: [redacted] ([redacted]) SEQ: REGIMEN C IN PERIOD 1, REGIMEN A IN PERIOD 2, REGIMEN D IN PERIOD 3, REGIMEN B IN PERIOD 4 (SEQUENCE GROUP 3: CADB) [redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:87.70 KG								
	OFF	10 TO	1	10 19:00 [129:33]	R: CHOLELITHIASIS S: 肝胆道系障害 P: 胆石症 L: CHOLELITHIASIS	E: 12 / 13:00 L: 3 DAYS I: SINGLE EVENT	S: SEVERE T: GRADE 4 R1: NO REASONABLE POSSIBILITY R2: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: HOSPITAL ADMISSION AND CHOLECYSTECTOMY C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION

Regimen A: Single 15 mg dose of Upadacitinib phase 3 formulation (ER17Y) administered under fasting conditions (Reference for B).
Regimen B: Single 15 mg dose of Upadacitinib market-image formulation (ER17) administered under fasting conditions (Test for A).
Regimen C: Single 15 mg dose of Upadacitinib phase 3 formulation (ER17Y) administered after high-fat/high-calorie meal (Reference for D).
Regimen D: Single 15 mg dose of Upadacitinib market-image formulation (ER17) administered after high-fat/high-calorie meal (Test for C).
@ Time relative to most recent dose in [].
# Subject Prematurely Discontinued.

Program Source Code: [redacted]

表 2.7.4.7-30. プラセボ対照併合解析集団（投与 24 週時）の治験薬の投与中止に至った有害事象

TABLE 2.4__1.1.3.5

Number and Percentage of Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
Any adverse event	24 (3.8) [3.8]	28 (4.4) [4.4]	41 (6.4) [6.4]
血液およびリンパ系障害	0	2 (0.3) [0.3]	4 (0.6) [0.6]
貧血	0	0	1 (0.2) [0.2]
失血性貧血	0	1 (0.2) [0.2]	0
白血球減少症	0	0	1 (0.2) [0.2]
リンパ組織過形成	0	0	1 (0.2) [0.2]
リンパ球減少症	0	1 (0.2) [0.2]	2 (0.3) [0.3]
正色素性貧血	0	0	1 (0.2) [0.2]
心臓障害	0	1 (0.2) [0.2]	1 (0.2) [0.2]
心肺停止	0	1 (0.2) [0.2]	0
冠動脈狭窄	0	0	1 (0.2) [0.2]
心室細動	0	1 (0.2) [0.2]	0
先天性、家族性および遺伝性障害	1 (0.2) [0.2]	0	0
ミトコンドリアミオパチー	1 (0.2) [0.2]	0	0
胃腸障害	2 (0.3) [0.3]	1 (0.2) [0.2]	6 (0.9) [0.9]
腹痛	0	0	1 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.3.5

Number and Percentage of Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
胃腸障害 (Cont.)			
下痢	2 (0.3) [0.3]	0	3 (0.5) [0.5]
胃出血	0	0	1 (0.2) [0.2]
びらん性胃炎	0	1 (0.2) [0.2]	0
悪心	0	0	1 (0.2) [0.2]
小腸出血	0	0	1 (0.2) [0.2]
小腸潰瘍	0	0	1 (0.2) [0.2]
嘔吐	0	0	1 (0.2) [0.2]
一般・全身障害および投与部位の状態	4 (0.6) [0.6]	2 (0.3) [0.3]	3 (0.5) [0.5]
胸痛	1 (0.2) [0.2]	0	0
疲労	1 (0.2) [0.2]	0	0
インフルエンザ様疾患	0	0	1 (0.2) [0.2]
倦怠感	0	1 (0.2) [0.2]	0
疼痛	1 (0.2) [0.2]	0	0
発熱	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.3) [0.3]
肝胆道系障害	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.3) [0.3]
胆道仙痛	1 (0.2) [0.2]	0	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.3.5

Number and Percentage of Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
肝胆道系障害 (Cont.)			
肝機能異常	0	0	1 (0.2) [0.2]
肝毒性	0	1 (0.2) [0.2]	1 (0.2) [0.2]
感染症および寄生虫症	6 (0.9) [0.9]	8 (1.3) [1.3]	16 (2.5) [2.5]
四肢膿瘍	0	0	1 (0.2) [0.2]
異型肺炎	0	0	1 (0.2) [0.2]
菌血症	0	0	1 (0.2) [0.2]
乳房蜂巣炎	1 (0.2) [0.2]	0	0
細菌性気管支炎	0	0	1 (0.2) [0.2]
ブドウ球菌感染性滑液包炎	1 (0.2) [0.2]	0	0
毛包炎	0	0	1 (0.2) [0.2]
陰部ヘルペス	0	1 (0.2) [0.2]	0
C型肝炎	1 (0.2) [0.2]	0	0
帯状疱疹	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.3) [0.3]
インフルエンザ	0	1 (0.2) [0.2]	0
下気道感染	0	1 (0.2) [0.2]	0
肺感染	0	0	1 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.3.5

Number and Percentage of Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
感染症および寄生虫症 (Cont.)			
レンサ球菌性咽頭炎	0	1 (0.2) [0.2]	0
肺炎	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.3) [0.3]
気道感染	1 (0.2) [0.2]	0	0
ウイルス性気道感染	0	0	1 (0.2) [0.2]
敗血症	0	2 (0.3) [0.3]	0
気管炎	0	0	1 (0.2) [0.2]
上気道感染	0	0	1 (0.2) [0.2]
尿路感染	0	0	2 (0.3) [0.3]
尿路性敗血症	0	0	1 (0.2) [0.2]
ウイルス性上気道感染	0	1 (0.2) [0.2]	0
傷害、中毒および処置合併症	3 (0.5) [0.5]	0	0
腓骨骨折	1 (0.2) [0.2]	0	0
肋骨骨折	1 (0.2) [0.2]	0	0
交通事故	1 (0.2) [0.2]	0	0
各種物質毒性	2 (0.3) [0.3]	0	0
外傷性血胸	1 (0.2) [0.2]	0	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.3.5

Number and Percentage of Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
臨床検査	2 (0.3) [0.3]	5 (0.8) [0.8]	8 (1.2) [1.2]
アラニンアミノトランスフェラーゼ増加	0	0	3 (0.5) [0.5]
アスパラギン酸アミノトランスフェラーゼ増加	0	0	1 (0.2) [0.2]
血中クレアチンホスホキナーゼ増加	1 (0.2) [0.2]	0	2 (0.3) [0.3]
血中クレアチニン増加	0	1 (0.2) [0.2]	0
ヘマトクリット減少	0	1 (0.2) [0.2]	0
ヘモグロビン減少	0	1 (0.2) [0.2]	1 (0.2) [0.2]
肝酵素上昇	1 (0.2) [0.2]	0	2 (0.3) [0.3]
リンパ球数減少	0	1 (0.2) [0.2]	0
赤血球数減少	0	1 (0.2) [0.2]	0
トランスアミナーゼ上昇	0	1 (0.2) [0.2]	0
白血球数減少	0	2 (0.3) [0.3]	0
代謝および栄養障害	0	1 (0.2) [0.2]	0
高血糖	0	1 (0.2) [0.2]	0
低カリウム血症	0	1 (0.2) [0.2]	0
低ナトリウム血症	0	1 (0.2) [0.2]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.3.5

Number and Percentage of Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
筋骨格系および結合組織障害	5 (0.8) [0.8]	7 (1.1) [1.1]	0
背部痛	1 (0.2) [0.2]	0	0
筋痙縮	2 (0.3) [0.3]	0	0
乾癬性関節症	2 (0.3) [0.3]	5 (0.8) [0.8]	0
急速進行性変形性関節症	0	1 (0.2) [0.2]	0
全身性エリテマトーデス	0	1 (0.2) [0.2]	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	3 (0.5) [0.5]	3 (0.5) [0.5]
基底細胞癌	0	0	1 (0.2) [0.2]
肺腺癌	0	0	1 (0.2) [0.2]
神経内分泌癌	0	1 (0.2) [0.2]	0
前立腺癌	0	1 (0.2) [0.2]	0
直腸腺癌	0	0	1 (0.2) [0.2]
直腸癌	0	1 (0.2) [0.2]	0
神経系障害	2 (0.3) [0.3]	1 (0.2) [0.2]	1 (0.2) [0.2]
浮動性めまい	1 (0.2) [0.2]	1 (0.2) [0.2]	0
頭痛	1 (0.2) [0.2]	0	1 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.3.5

Number and Percentage of Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
妊娠、産褥および周産期の状態	0	0	1 (0.2) [0.2]
異所性妊娠	0	0	1 (0.2) [0.2]
精神障害	0	1 (0.2) [0.2]	1 (0.2) [0.2]
うつ病	0	0	1 (0.2) [0.2]
不眠症	0	1 (0.2) [0.2]	0
パニック発作	0	0	1 (0.2) [0.2]
呼吸器、胸郭および縦隔障害	1 (0.2) [0.2]	1 (0.2) [0.2]	3 (0.5) [0.5]
急性呼吸不全	0	1 (0.2) [0.2]	0
咳嗽	0	0	1 (0.2) [0.2]
閉塞性気道障害	1 (0.2) [0.2]	0	0
肺塞栓症	0	1 (0.2) [0.2]	1 (0.2) [0.2]
肺線維症	0	0	1 (0.2) [0.2]
皮膚および皮下組織障害	2 (0.3) [0.3]	3 (0.5) [0.5]	0
ざ瘡	0	1 (0.2) [0.2]	0
湿疹	0	1 (0.2) [0.2]	0
乾癬	2 (0.3) [0.3]	0	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.3.5

Number and Percentage of Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
皮膚および皮下組織障害 (Cont.)			
皮膚病変	0	1 (0.2) [0.2]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-31. 全ウパダシチニブ併合解析集団（長期）の治験薬の投与中止に至った有害事象（100 人年あたりの発現件数）

TABLE 2.4__1.2.3.6

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
Any Adverse Event	59 (9.1) [9.0]	70 (10.8) [10.8]	69 (8.4) [8.5]	78 (9.5) [9.5]
血液およびリンパ系障害	2 (0.3) [0.3]	7 (1.1) [1.1]	3 (0.4) [0.4]	8 (1.0) [1.0]
貧血	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
失血性貧血	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
白血球減少症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
リンパ組織過形成	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
リンパ球減少症	1 (0.2) [0.2]	3 (0.5) [0.5]	1 (0.1) [0.1]	3 (0.4) [0.4]
正色素性貧血	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
汎血球減少症	0	0	0	1 (0.1) [0.1]
血小板減少症	0	0	1 (0.1) [0.1]	0
心臓障害	2 (0.3) [0.3]	1 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.1) [0.1]
心肺停止	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
冠動脈狭窄	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
心室細動	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
胃腸障害	2 (0.3) [0.3]	10 (1.5) [1.5]	2 (0.2) [0.2]	11 (1.3) [1.3]
腹痛	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.6

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
胃腸障害 (Cont.)				
上腹部痛	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
腹水	0	0	0	1 (0.1) [0.1]
下痢	0	3 (0.5) [0.5]	0	3 (0.4) [0.4]
胃出血	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
穿孔性胃潰瘍	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
びらん性胃炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
悪心	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
小腸出血	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
小腸潰瘍	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
嘔吐	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
一般・全身障害および投与部位の状態	2 (0.3) [0.3]	4 (0.6) [0.6]	2 (0.2) [0.2]	5 (0.6) [0.6]
インフルエンザ様疾患	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
倦怠感	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
発熱	1 (0.2) [0.2]	3 (0.5) [0.5]	1 (0.1) [0.1]	4 (0.5) [0.5]
肝胆道系障害	1 (0.2) [0.2]	2 (0.3) [0.3]	1 (0.1) [0.1]	3 (0.4) [0.4]
肝硬変	0	0	0	1 (0.1) [0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.6

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
肝胆道系障害 (Cont.)				
肝機能異常	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
肝毒性	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
感染症および寄生虫症	14 (2.1) [2.1]	23 (3.6) [3.6]	19 (2.3) [2.3]	24 (2.9) [2.9]
膿瘍	0	0	1 (0.1) [0.1]	0
四肢膿瘍	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
肛門膿瘍	0	0	1 (0.1) [0.1]	0
細菌性関節炎	0	0	1 (0.1) [0.1]	0
異型肺炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
菌血症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
体部白癬	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
気管支炎	0	2 (0.3) [0.3]	1 (0.1) [0.1]	2 (0.2) [0.2]
細菌性気管支炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
蜂巣炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
コクシジオイデス症	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
憩室炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
毛包炎	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.6

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

	Upadacitinib			
System Organ Class MedDRA 22.0 Preferred Term	15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
陰部ヘルペス	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
H1N1インフルエンザ	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
帯状疱疹	2 (0.3) [0.3]	2 (0.3) [0.3]	2 (0.2) [0.2]	2 (0.2) [0.2]
インフルエンザ	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
下気道感染	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
肺感染	0	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
上咽頭炎	0	0	0	1 (0.1) [0.1]
レンサ球菌性咽頭炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
肺炎	1 (0.2) [0.2]	2 (0.3) [0.3]	1 (0.1) [0.1]	2 (0.2) [0.2]
ウイルス性気道感染	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
敗血症	2 (0.3) [0.3]	0	2 (0.2) [0.2]	0
ブドウ球菌性菌血症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
ブドウ球菌性敗血症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
気管炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
上気道感染	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
尿路感染	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.6

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

	Upadacitinib			
System Organ Class MedDRA 22.0 Preferred Term	15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
細菌性尿路感染	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
尿路性敗血症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
ウイルス性上気道感染	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
臨床検査	8 (1.2) [1.2]	9 (1.4) [1.4]	9 (1.1) [1.1]	10 (1.2) [1.2]
アラニンアミノトランスフェラーゼ増加	0	3 (0.5) [0.5]	0	3 (0.4) [0.4]
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
血中クレアチンホスホキナーゼ増加	0	2 (0.3) [0.3]	1 (0.1) [0.1]	2 (0.2) [0.2]
血中クレアチニン増加	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
ヘマトクリット減少	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
ヘモグロビン減少	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
肝酵素上昇	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
肝機能検査値上昇	0	0	0	1 (0.1) [0.1]
リンパ球数減少	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
赤血球数減少	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
トランスアミナーゼ上昇	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
白血球数減少	2 (0.3) [0.3]	0	2 (0.2) [0.2]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.6

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
代謝および栄養障害	3 (0.5) [0.5]	0	3 (0.4) [0.4]	0
高血糖	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
低カリウム血症	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
低ナトリウム血症	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
筋骨格系および結合組織障害	8 (1.2) [1.2]	1 (0.2) [0.2]	8 (1.0) [1.0]	1 (0.1) [0.1]
腰部脊柱管狭窄症	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
骨壊死	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
乾癬性関節症	5 (0.8) [0.8]	0	5 (0.6) [0.6]	0
急速進行性変形性関節症	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
全身性エリテマトーデス	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	5 (0.8) [0.8]	4 (0.6) [0.6]	7 (0.9) [0.9]	4 (0.5) [0.5]
基底細胞癌	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
肺腺癌	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
遠隔転移を伴う肺癌	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
悪性黒色腫	0	0	1 (0.1) [0.1]	0
悪性黒色腫第3期	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.6

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
神経内分泌癌	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
中咽頭扁平上皮癌	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
前立腺癌	1 (0.2) [0.2]	0	2 (0.2) [0.2]	0
直腸腺癌	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
直腸癌	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
神経系障害	2 (0.3) [0.3]	1 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.1) [0.1]
浮動性めまい	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
頭痛	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
ラクナ脳卒中	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
妊娠、産褥および周産期の状態	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
異所性妊娠	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
精神障害	1 (0.2) [0.2]	2 (0.3) [0.3]	1 (0.1) [0.1]	2 (0.2) [0.2]
うつ病	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
不眠症	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
パニック発作	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
呼吸器、胸郭および縦隔障害	3 (0.5) [0.5]	5 (0.8) [0.8]	3 (0.4) [0.4]	7 (0.9) [0.9]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.6

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
呼吸器、胸郭および縦隔障害 (Cont.)				
急性呼吸不全	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
慢性閉塞性肺疾患	0	1 (0.2) [0.2]	0	2 (0.2) [0.2]
咳嗽	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
気胸	0	0	0	1 (0.1) [0.1]
肺塞栓症	2 (0.3) [0.3]	2 (0.3) [0.3]	2 (0.2) [0.2]	2 (0.2) [0.2]
肺線維症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
皮膚および皮下組織障害	5 (0.8) [0.8]	0	6 (0.7) [0.7]	0
ざ瘡	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
湿疹	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
乾癬	1 (0.2) [0.2]	0	2 (0.2) [0.2]	0
発疹	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
皮膚病変	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
血管障害	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
深部静脈血栓症	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-32. 投与 24 週時までの治験薬の投与中止に至った有害事象（安全性解析対象集団）：M15-572 試験

TABLE 14.3__2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by Primary MedDRA System Organ Class and Preferred Term - up to Week 24
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 423) n (%)	ADA 40 mg EOW (N = 429) n (%)	UPA 15 mg QD (N = 429) n (%)	UPA 30 mg QD (N = 423) n (%)
Any adverse event	13 (3.1)	22 (5.1)	13 (3.0)	21 (5.0)
血液およびリンパ系障害	0	0	1 (0.2)	3 (0.7)
白血球減少症	0	0	0	1 (0.2)
リンパ組織過形成	0	0	0	1 (0.2)
リンパ球減少症	0	0	1 (0.2)	2 (0.5)
正色素性貧血	0	0	0	1 (0.2)
胃腸障害	1 (0.2)	3 (0.7)	0	2 (0.5)
上腹部痛	0	1 (0.2)	0	0
便秘	0	1 (0.2)	0	0
下痢	1 (0.2)	0	0	1 (0.2)
血便排泄	0	1 (0.2)	0	0
口腔内白斑症	0	1 (0.2)	0	0
悪心	0	0	0	1 (0.2)
一般・全身障害および投与部位の状態	2 (0.5)	3 (0.7)	2 (0.5)	3 (0.7)
医薬品副作用	0	1 (0.2)	0	0
胸痛	1 (0.2)	0	0	0
疲労	0	1 (0.2)	0	0
インフルエンザ様疾患	0	0	0	1 (0.2)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA and up to 70 days for adalimumab, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

TABLE 14.3__2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by Primary MedDRA System Organ Class and Preferred Term - up to Week 24
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 423) n (%)	ADA 40 mg EOW (N = 429) n (%)	UPA 15 mg QD (N = 429) n (%)	UPA 30 mg QD (N = 423) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
注射部位過敏反応	0	1 (0.2)	0	0
注射部位蕁麻疹	0	1 (0.2)	0	0
倦怠感	0	1 (0.2)	1 (0.2)	0
発熱	1 (0.2)	0	1 (0.2)	2 (0.5)
肝胆道系障害	1 (0.2)	3 (0.7)	1 (0.2)	2 (0.5)
胆道仙痛	1 (0.2)	0	0	0
肝機能異常	0	1 (0.2)	0	1 (0.2)
脂肪肝	0	1 (0.2)	0	0
肝毒性	0	0	1 (0.2)	1 (0.2)
門脈血栓症	0	1 (0.2)	0	0
感染症および寄生虫症	4 (0.9)	2 (0.5)	5 (1.2)	9 (2.1)
異型肺炎	0	0	0	1 (0.2)
菌血症	0	0	0	1 (0.2)
乳房蜂巣炎	1 (0.2)	0	0	0
細菌性気管支炎	0	0	0	1 (0.2)
毛包炎	0	0	0	1 (0.2)
陰部ヘルペス	0	0	1 (0.2)	0
C型肝炎	1 (0.2)	0	0	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA and up to 70 days for adalimumab, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

TABLE 14.3__2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by Primary MedDRA System Organ Class and Preferred Term - up to Week 24
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 423) n (%)	ADA 40 mg EOW (N = 429) n (%)	UPA 15 mg QD (N = 429) n (%)	UPA 30 mg QD (N = 423) n (%)
感染症および寄生虫症 (Cont.)				
帯状疱疹	1 (0.2)	0	1 (0.2)	0
インフルエンザ	0	0	1 (0.2)	0
下気道感染	0	0	1 (0.2)	0
肺感染	0	0	0	1 (0.2)
肺炎	1 (0.2)	1 (0.2)	0	0
ウイルス性気道感染	0	0	0	1 (0.2)
サルモネラ症	0	1 (0.2)	0	0
敗血症	0	0	2 (0.5)	0
気管炎	0	0	0	1 (0.2)
上気道感染	0	0	0	1 (0.2)
尿路性敗血症	0	0	0	1 (0.2)
傷害、中毒および処置合併症	1 (0.2)	0	0	0
各種物質毒性	1 (0.2)	0	0	0
臨床検査	1 (0.2)	4 (0.9)	1 (0.2)	2 (0.5)
アラニンアミノトランスフェラーゼ増加	0	2 (0.5)	0	1 (0.2)
アスパラギン酸アミノトランスフェラーゼ増加	0	2 (0.5)	0	0
血中クレアチンホスホキナーゼ増加	0	0	0	1 (0.2)
血中クレアチニン増加	0	0	1 (0.2)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA and up to 70 days for adalimumab, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

TABLE 14.3__2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by Primary MedDRA System Organ Class and Preferred Term - up to Week 24
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 423) n (%)	ADA 40 mg EOW (N = 429) n (%)	UPA 15 mg QD (N = 429) n (%)	UPA 30 mg QD (N = 423) n (%)
臨床検査 (Cont.)				
肝酵素上昇	1 (0.2)	0	0	0
トランスアミナーゼ上昇	0	1 (0.2)	0	0
体重増加	0	1 (0.2)	0	0
筋骨格系および結合組織障害	3 (0.7)	1 (0.2)	1 (0.2)	0
背部痛	1 (0.2)	1 (0.2)	0	0
筋痙縮	2 (0.5)	0	0	0
乾癬性関節症	0	0	1 (0.2)	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	3 (0.7)	1 (0.2)	2 (0.5)
基底細胞癌	0	0	0	1 (0.2)
遠隔転移を伴う結腸癌	0	1 (0.2)	0	0
肺腺癌	0	0	0	1 (0.2)
神経内分泌癌	0	0	1 (0.2)	0
卵巣癌	0	1 (0.2)	0	0
子宮癌	0	1 (0.2)	0	0
神経系障害	0	2 (0.5)	1 (0.2)	0
筋萎縮性側索硬化症	0	1 (0.2)	0	0
浮動性めまい	0	0	1 (0.2)	0
肝性脳症	0	1 (0.2)	0	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA and up to 70 days for adalimumab, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

TABLE 14.3__2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by Primary MedDRA System Organ Class and Preferred Term - up to Week 24
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 423) n (%)	ADA 40 mg EOW (N = 429) n (%)	UPA 15 mg QD (N = 429) n (%)	UPA 30 mg QD (N = 423) n (%)
精神障害	0	0	1 (0.2)	0
不眠症	0	0	1 (0.2)	0
生殖系および乳房障害	0	1 (0.2)	0	0
無月経	0	1 (0.2)	0	0
呼吸器、胸郭および縦隔障害	1 (0.2)	0	0	2 (0.5)
閉塞性気道障害	1 (0.2)	0	0	0
肺塞栓症	0	0	0	1 (0.2)
肺線維症	0	0	0	1 (0.2)
皮膚および皮下組織障害	0	3 (0.7)	2 (0.5)	0
脱毛症	0	2 (0.5)	0	0
皮膚炎	0	1 (0.2)	0	0
湿疹	0	0	1 (0.2)	0
乾癬	0	1 (0.2)	0	0
皮膚病変	0	0	1 (0.2)	0
血管障害	0	1 (0.2)	0	0
血管炎	0	1 (0.2)	0	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA and up to 70 days for adalimumab, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

表 2.7.4.7-33. 投与 24 週時までの治験薬の投与中止に至った有害事象（安全性解析対象集団）：M15-554 試験

TABLE 14.3__2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by Primary MedDRA System Organ Class and Preferred Term - up to Week 24
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 212) n (%)	UPA 15 mg QD (N = 211) n (%)	UPA 30 mg QD (N = 218) n (%)
Any adverse event	11 (5.2)	15 (7.1)	20 (9.2)
血液およびリンパ系障害	0	1 (0.5)	1 (0.5)
貧血	0	0	1 (0.5)
失血性貧血	0	1 (0.5)	0
心臓障害	0	1 (0.5)	1 (0.5)
心肺停止	0	1 (0.5)	0
冠動脈狭窄	0	0	1 (0.5)
心室細動	0	1 (0.5)	0
先天性、家族性および遺伝性障害	1 (0.5)	0	0
ミトコンドリアミオパチー	1 (0.5)	0	0
胃腸障害	1 (0.5)	1 (0.5)	4 (1.8)
腹痛	0	0	1 (0.5)
下痢	1 (0.5)	0	2 (0.9)
胃出血	0	0	1 (0.5)
びらん性胃炎	0	1 (0.5)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

TABLE 14.3__2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by Primary MedDRA System Organ Class and Preferred Term - up to Week 24
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 212) n (%)	UPA 15 mg QD (N = 211) n (%)	UPA 30 mg QD (N = 218) n (%)
胃腸障害 (Cont.)			
小腸出血	0	0	1 (0.5)
小腸潰瘍	0	0	1 (0.5)
嘔吐	0	0	1 (0.5)
一般・全身障害および投与部位の状態	2 (0.9)	0	0
疲労	1 (0.5)	0	0
疼痛	1 (0.5)	0	0
感染症および寄生虫症	2 (0.9)	3 (1.4)	7 (3.2)
四肢膿瘍	0	0	1 (0.5)
ブドウ球菌感染性滑液包炎	1 (0.5)	0	0
帯状疱疹	0	0	2 (0.9)
レンサ球菌性咽頭炎	0	1 (0.5)	0
肺炎	0	1 (0.5)	2 (0.9)
気道感染	1 (0.5)	0	0
尿路感染	0	0	2 (0.9)
ウイルス性上気道感染	0	1 (0.5)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

TABLE 14.3__2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by Primary MedDRA System Organ Class and Preferred Term - up to Week 24
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 212) n (%)	UPA 15 mg QD (N = 211) n (%)	UPA 30 mg QD (N = 218) n (%)
傷害、中毒および処置合併症	2 (0.9)	0	0
腓骨骨折	1 (0.5)	0	0
肋骨骨折	1 (0.5)	0	0
交通事故	1 (0.5)	0	0
各種物質毒性	1 (0.5)	0	0
外傷性血胸	1 (0.5)	0	0
臨床検査	1 (0.5)	4 (1.9)	6 (2.8)
アラニンアミノトランスフェラーゼ増加	0	0	2 (0.9)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	1 (0.5)
血中クレアチンホスホキナーゼ増加	1 (0.5)	0	1 (0.5)
ヘマトクリット減少	0	1 (0.5)	0
ヘモグロビン減少	0	1 (0.5)	1 (0.5)
肝酵素上昇	0	0	2 (0.9)
リンパ球数減少	0	1 (0.5)	0
赤血球数減少	0	1 (0.5)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

TABLE 14.3__2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by Primary MedDRA System Organ Class and Preferred Term - up to Week 24
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 212) n (%)	UPA 15 mg QD (N = 211) n (%)	UPA 30 mg QD (N = 218) n (%)
臨床検査 (Cont.)			
トランスアミナーゼ上昇	0	1 (0.5)	0
白血球数減少	0	2 (0.9)	0
代謝および栄養障害	0	1 (0.5)	0
高血糖	0	1 (0.5)	0
低カリウム血症	0	1 (0.5)	0
低ナトリウム血症	0	1 (0.5)	0
筋骨格系および結合組織障害	2 (0.9)	6 (2.8)	0
乾癬性関節症	2 (0.9)	4 (1.9)	0
急速進行性変形性関節症	0	1 (0.5)	0
全身性エリテマトーデス	0	1 (0.5)	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	2 (0.9)	1 (0.5)
前立腺癌	0	1 (0.5)	0
直腸腺癌	0	0	1 (0.5)
直腸癌	0	1 (0.5)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

[redacted]
ABT-494 (PSA)
STUDY M15-554 - WEEK 24 (DATA CUTOFF - [redacted]20[redacted])
R&D/19/0848 - CLINICAL/STATISTICAL

TABLE 14.3__2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by Primary MedDRA System Organ Class and Preferred Term - up to Week 24
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 212) n (%)	UPA 15 mg QD (N = 211) n (%)	UPA 30 mg QD (N = 218) n (%)
神経系障害	2 (0.9)	0	1 (0.5)
浮動性めまい	1 (0.5)	0	0
頭痛	1 (0.5)	0	1 (0.5)
妊娠、産褥および周産期の状態	0	0	1 (0.5)
異所性妊娠	0	0	1 (0.5)
精神障害	0	0	1 (0.5)
うつ病	0	0	1 (0.5)
パニック発作	0	0	1 (0.5)
呼吸器、胸郭および縦隔障害	0	1 (0.5)	1 (0.5)
急性呼吸不全	0	1 (0.5)	0
咳嗽	0	0	1 (0.5)
肺塞栓症	0	1 (0.5)	0
皮膚および皮下組織障害	2 (0.9)	1 (0.5)	0
ざ瘡	0	1 (0.5)	0
乾癬	2 (0.9)	0	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

表 2.7.4.7-34.　全ウパダシチニブ併合解析集団（長期）の特に注目すべき有害事象の概要（100人年あたりの発現被験者数）

TABLE 2.4__1.2.2.2.2

Overview of Treatment-Emergent Adverse Events
of Special Interest in Exposure-Adjusted Incidence Rate per 100 Patient Years
(Any Upadacitinib Analysis Set)

	Upadacitinib					Treatment Comparison (95% CI) [A]	
	15 mg QD (No Cross-Over from Placebo) (N = 640) n/PYs (n/100 PYs) [SSA n/100 PYs]	30 mg QD (No Cross-Over from Placebo) (N = 641) n/PYs (n/100 PYs) [SSA n/100 PYs]	Any 15 mg QD (N = 907) n/PYs (n/100 PYs) [SSA n/100 PYs]	Any 30 mg QD (N = 920) n/PYs (n/100 PYs) [SSA n/100 PYs]	Adalimumab 40 mg EOW (N = 429) n/PYs (n/100 PYs)	30 mg QD - 15 mg QD (No Cross-Over from Placebo)	Any 30 mg QD - Any 15 mg QD
Any infections	335/401.9 (83.4) [83.4]	385/356.7 (107.9) [108.1]	433/514.0 (84.2) [84.2]	485/472.6 (102.6) [102.6]	198/270.1 (73.3)	24.7 (10.6, 38.7)	18.4 (6.3, 30.5)
Any serious infections	15/645.3 (2.3) [2.3]	35/638.6 (5.5) [5.5]	18/809.9 (2.2) [2.2]	44/809.4 (5.4) [5.4]	5/392.7 (1.3)	3.2 (1.0, 5.3)	3.2 (1.3, 5.1)
Any opportunistic infection excluding tuberculosis and herpes zoster	3/650.6 (0.5) [0.5]	6/646.2 (0.9) [0.9]	4/814.7 (0.5) [0.5]	7/821.4 (0.9) [0.9]	0/394.5	0.5 (-0.4, 1.4)	0.4 (-0.4, 1.2)
Any herpes zoster	21/641.2 (3.3) [3.3]	39/628.5 (6.2) [6.2]	26/805.0 (3.2) [3.2]	54/793.6 (6.8) [6.8]	2/392.9 (0.5)	2.9 (0.5, 5.3)	3.6 (1.4, 5.8)
Any active tuberculosis	0/651.8	0/647.1	0/816.9	0/822.3	0/394.5	0.0	0.0
Any possible malignancy	10/647.6 (1.5) [1.5]	12/642.9 (1.9) [1.9]	13/812.4 (1.6) [1.6]	13/817.9 (1.6) [1.6]	7/392.7 (1.8)	0.3 (-1.1, 1.8)	-0.0 (-1.2, 1.2)
Any malignancy	8/649.2 (1.2) [1.2]	11/643.8 (1.7) [1.7]	11/814.0 (1.4) [1.4]	12/818.8 (1.5) [1.5]	6/393.7 (1.5)	0.5 (-0.8, 1.8)	0.1 (-1.0, 1.3)
Any non-melanoma skin cancer (NMSC)	3/649.4 (0.5) [0.5]	5/644.5 (0.8) [0.8]	5/814.3 (0.6) [0.6]	5/819.6 (0.6) [0.6]	2/394.2 (0.5)	0.3 (-0.5, 1.2)	-0.0 (-0.8, 0.8)

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo, and no more than 70 days after the last dose of adalimumab.
Patients could be included in more than one treatment group.
SSA = Study size adjusted.
n/100 PYs = Number of subjects with at least one event per 100 patient-years.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

TABLE 2.4__1.2.2.2.2

Overview of Treatment-Emergent Adverse Events
of Special Interest in Exposure-Adjusted Incidence Rate per 100 Patient Years
(Any Upadacitinib Analysis Set)

	Upadacitinib					Treatment Comparison (95% CI) [A]	
	15 mg QD (No Cross-Over from Placebo) (N = 640) n/PYs (n/100 PYs) [SSA n/100 PYs]	30 mg QD (No Cross-Over from Placebo) (N = 641) n/PYs (n/100 PYs) [SSA n/100 PYs]	Any 15 mg QD (N = 907) n/PYs (n/100 PYs) [SSA n/100 PYs]	Any 30 mg QD (N = 920) n/PYs (n/100 PYs) [SSA n/100 PYs]	Adalimumab 40 mg EOW (N = 429) n/PYs (n/100 PYs)	30 mg QD - 15 mg QD (No Cross-Over from Placebo)	Any 30 mg QD - Any 15 mg QD
Any malignancy other than NMSC	5/651.6 (0.8) [0.8]	6/646.5 (0.9) [0.9]	7/816.6 (0.9) [0.9]	7/821.4 (0.9) [0.9]	4/394.0 (1.0)	0.2 (-0.8, 1.2)	-0.0 (-0.9, 0.9)
Any lymphoma	1/650.0 (0.2) [0.2]	0/647.1	2/815.0 (0.2) [0.2]	0/822.3	0/394.5	-0.2 (-0.5, 0.1)	-0.2 (-0.6, 0.1)
Any hepatic disorder	64/611.6 (10.5) [10.5]	89/581.9 (15.3) [15.3]	82/764.1 (10.7) [10.7]	107/745.7 (14.3) [14.3]	78/346.0 (22.5)	4.8 (0.7, 8.8)	3.6 (0.0, 7.2)
Any adjudicated gastrointestinal perforation	1/651.7 (0.2) [0.2]	0/647.1	1/816.8 (0.1) [0.1]	0/822.3	0/394.5	-0.2 (-0.5, 0.1)	-0.1 (-0.4, 0.1)
Any anemia	16/643.3 (2.5) [2.5]	43/622.6 (6.9) [6.9]	18/808.1 (2.2) [2.2]	49/795.0 (6.2) [6.2]	5/390.1 (1.3)	4.4 (2.0, 6.8)	3.9 (1.9, 5.9)
Any neutropenia	13/642.5 (2.0) [2.0]	34/626.5 (5.4) [5.4]	16/806.0 (2.0) [2.0]	41/799.5 (5.1) [5.1]	17/383.7 (4.4)	3.4 (1.3, 5.5)	3.1 (1.3, 5.0)
Any lymphopenia	13/645.2 (2.0) [2.0]	22/628.9 (3.5) [3.5]	14/809.6 (1.7) [1.7]	24/802.8 (3.0) [3.0]	1/394.4 (0.3)	1.5 (-0.3, 3.3)	1.3 (-0.2, 2.8)
Any creatine phosphokinase (CPK) elevation	62/606.9 (10.2) [10.2]	83/580.4 (14.3) [14.3]	75/765.6 (9.8) [9.8]	99/745.1 (13.3) [13.3]	30/374.5 (8.0)	4.1 (0.1, 8.1)	3.5 (0.1, 7.0)

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo, and no more than 70 days after the last dose of adalimumab.
Patients could be included in more than one treatment group.
SSA = Study size adjusted.
n/100 PYs = Number of subjects with at least one event per 100 patient-years.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

TABLE 2.4__1.2.2.2.2

Overview of Treatment-Emergent Adverse Events
of Special Interest in Exposure-Adjusted Incidence Rate per 100 Patient Years
(Any Upadacitinib Analysis Set)

	Upadacitinib					Treatment Comparison (95% CI) [A]	
	15 mg QD (No Cross-Over from Placebo) (N = 640) n/PYs (n/100 PYs) [SSA n/100 PYs]	30 mg QD (No Cross-Over from Placebo) (N = 641) n/PYs (n/100 PYs) [SSA n/100 PYs]	Any 15 mg QD (N = 907) n/PYs (n/100 PYs) [SSA n/100 PYs]	Any 30 mg QD (N = 920) n/PYs (n/100 PYs) [SSA n/100 PYs]	Adalimumab 40 mg EOW (N = 429) n/PYs (n/100 PYs)	30 mg QD - 15 mg QD (No Cross-Over from Placebo)	Any 30 mg QD - Any 15 mg QD
Any renal dysfunction	2/651.1 (0.3) [0.3]	1/647.1 (0.2) [0.2]	2/816.1 (0.2) [0.2]	1/822.3 (0.1) [0.1]	0/394.5	-0.2 (-0.7, 0.4)	-0.1 (-0.5, 0.3)
Any adjudicated MACE*	4/649.1 (0.6) [0.6]	1/646.0 (0.2) [0.2]	4/814.2 (0.5) [0.5]	2/821.2 (0.2) [0.2]	3/394.2 (0.8)	-0.5 (-1.1, 0.2)	-0.2 (-0.8, 0.3)
Any adjudicated VTE**	4/651.1 (0.6) [0.6]	2/647.1 (0.3) [0.3]	4/816.2 (0.5) [0.5]	2/822.3 (0.2) [0.2]	2/392.8 (0.5)	-0.3 (-1.0, 0.4)	-0.2 (-0.8, 0.3)

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo, and no more than 70 days after the last dose of adalimumab.
Patients could be included in more than one treatment group.
SSA = Study size adjusted.
n/100 PYs = Number of subjects with at least one event per 100 patient-years.
[A] Study size adjusted risk difference between treatment groups.
* MACE: Major Adverse Cardiovascular Events, defined as cardiovascular death, non-fatal myocardial infarction and non-fatal stroke.
** VTE: Venous thromboembolic events, defined as deep vein thrombosis (DVT) And pulmonary embolism (PE) (fatal and non-fatal).

Program Source Code: [redacted]

表 2.7.4.7-35.　全ウパダシチニブ併合解析集団（長期）の日本人部分集団の特に注目すべき有害事象の概要（100 人年あたりの発現被験者数）

[redacted]

TABLE 2.4__1.2.2.2.2_J

Overview of Treatment-Emergent Adverse Events
of Special Interest in Exposure-Adjusted Incidence Rate per 100 Patient Years
(Any Upadacitinib Analysis Set, Japanese Population)

	Upadacitinib					Treatment Comparison (95% CI) [A]	
	15 mg QD (No Cross-Over from Placebo) (N = 17) n/PYs (n/100 PYs) [SSA n/100 PYs]	30 mg QD (No Cross-Over from Placebo) (N = 18) n/PYs (n/100 PYs) [SSA n/100 PYs]	Any 15 mg QD (N = 23) n/PYs (n/100 PYs) [SSA n/100 PYs]	Any 30 mg QD (N = 26) n/PYs (n/100 PYs) [SSA n/100 PYs]	Adalimumab 40 mg EOW (N = 4) n/PYs (n/100 PYs)	30 mg QD - 15 mg QD (No Cross-Over from Placebo)	Any 30 mg QD - Any 15 mg QD
Any infections	12/7.9 (151.9) [147.8]	17/8.8 (193.2) [199.1]	14/12.2 (114.8) [111.8]	24/10.8 (222.2) [228.5]	1/4.7 (21.3)	51.3 (-75.6, 178.1)	116.7 (7.3, 226.1)
Any serious infections	1/17.3 (5.8) [5.3]	5/19.8 (25.3) [26.0]	1/22.1 (4.5) [4.1]	7/27.0 (25.9) [27.2]	0/5.2	20.7 (-4.5, 45.9)	23.0 (1.3, 44.8)
Any opportunistic infection excluding tuberculosis and herpes zoster	0/18.2	0/20.9	0/23.0	1/28.1 (3.6) [3.9]	0/5.2	0.0	3.9 (-3.7, 11.5)
Any herpes zoster	2/16.3 (12.3) [11.3]	5/20.2 (24.8) [25.4]	2/21.1 (9.5) [8.6]	5/27.4 (18.2) [18.7]	0/5.2	14.2 (-13.1, 41.5)	10.1 (-10.3, 30.5)
Any active tuberculosis	0/18.2	0/20.9	0/23.0	0/28.1	0/5.2	0.0	0.0
Any possible malignancy	0/18.2	1/20.9 (4.8) [5.2]	0/23.0	1/28.2 (3.5) [3.9]	1/4.8 (20.8)	5.2 (-5.0, 15.4)	3.9 (-3.7, 11.4)
Any malignancy	0/18.2	1/20.9 (4.8) [5.2]	0/23.0	1/28.2 (3.5) [3.9]	1/4.8 (20.8)	5.2 (-5.0, 15.4)	3.9 (-3.7, 11.4)
Any non-melanoma skin cancer (NMSC)	0/18.2	0/20.9	0/23.0	0/28.1	0/5.2	0.0	0.0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo, and no more than 70 days after the last dose of adalimumab.
Patients could be included in more than one treatment group.
SSA = Study size adjusted.
n/100 PYs = Number of subjects with at least one event per 100 patient-years.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

TABLE 2.4__1.2.2.2.2_J

Overview of Treatment-Emergent Adverse Events
of Special Interest in Exposure-Adjusted Incidence Rate per 100 Patient Years
(Any Upadacitinib Analysis Set, Japanese Population)

	Upadacitinib					Treatment Comparison (95% CI) [A]	
	15 mg QD (No Cross-Over from Placebo) (N = 17) n/PYs (n/100 PYs) [SSA n/100 PYs]	30 mg QD (No Cross-Over from Placebo) (N = 18) n/PYs (n/100 PYs) [SSA n/100 PYs]	Any 15 mg QD (N = 23) n/PYs (n/100 PYs) [SSA n/100 PYs]	Any 30 mg QD (N = 26) n/PYs (n/100 PYs) [SSA n/100 PYs]	Adalimumab 40 mg EOW (N = 4) n/PYs (n/100 PYs)	30 mg QD - 15 mg QD (No Cross-Over from Placebo)	Any 30 mg QD - Any 15 mg QD
Any malignancy other than NMSC	0/18.2	1/20.9 (4.8) [5.2]	0/23.0	1/28.2 (3.5) [3.9]	1/4.8 (20.8)	5.2 (-5.0, 15.4)	3.9 (-3.7, 11.4)
Any lymphoma	1/16.4 (6.1) [5.6]	0/20.9	2/21.1 (9.5) [8.7]	0/28.1	0/5.2	-5.6 (-16.6, 5.4)	-8.7 (-20.7, 3.3)
Any hepatic disorder	4/15.5 (25.8) [34.8]	2/19.4 (10.3) [11.6]	5/19.2 (26.0) [32.6]	3/25.4 (11.8) [13.2]	1/4.7 (21.3)	-23.1 (-62.7, 16.4)	-19.4 (-53.4, 14.6)
Any adjudicated gastrointestinal perforation	0/18.2	0/20.9	0/23.0	0/28.1	0/5.2	0.0	0.0
Any anemia	1/17.4 (5.7) [5.1]	2/18.0 (11.1) [12.6]	1/22.2 (4.5) [4.0]	2/25.2 (7.9) [8.8]	0/5.2	7.4 (-12.7, 27.6)	4.8 (-9.8, 19.4)
Any neutropenia	1/16.4 (6.1) [5.8]	1/19.4 (5.2) [4.6]	1/21.3 (4.7) [4.4]	1/26.6 (3.8) [3.2]	0/5.2	-1.3 (-15.8, 13.2)	-1.2 (-11.9, 9.4)
Any lymphopenia	1/16.9 (5.9) [5.6]	2/18.9 (10.6) [10.1]	1/21.7 (4.6) [4.3]	3/25.7 (11.7) [10.6]	0/5.2	4.5 (-13.3, 22.3)	6.3 (-8.5, 21.0)
Any creatine phosphokinase (CPK) elevation	2/15.7 (12.7) [15.1]	5/15.3 (32.7) [30.9]	4/19.3 (20.7) [22.2]	5/22.5 (22.2) [21.1]	1/4.0 (25.0)	15.9 (-18.9, 50.6)	-1.1 (-30.2, 28.1)

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo, and no more than 70 days after the last dose of adalimumab.
Patients could be included in more than one treatment group.
SSA = Study size adjusted.
n/100 PYs = Number of subjects with at least one event per 100 patient-years.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

TABLE 2.4__1.2.2.2.2_J

Overview of Treatment-Emergent Adverse Events
of Special Interest in Exposure-Adjusted Incidence Rate per 100 Patient Years
(Any Upadacitinib Analysis Set, Japanese Population)

	Upadacitinib					---Treatment Comparison (95% CI) [A]---	
	15 mg QD (No Cross-Over from Placebo) (N = 17) n/PYs (n/100 PYs) [SSA n/100 PYs]	30 mg QD (No Cross-Over from Placebo) (N = 18) n/PYs (n/100 PYs) [SSA n/100 PYs]	Any 15 mg QD (N = 23) n/PYs (n/100 PYs) [SSA n/100 PYs]	Any 30 mg QD (N = 26) n/PYs (n/100 PYs) [SSA n/100 PYs]	Adalimumab 40 mg EOW (N = 4) n/PYs (n/100 PYs)	30 mg QD - 15 mg QD (No Cross-Over from Placebo)	Any 30 mg QD - Any 15 mg QD
Any renal dysfunction	0/18.2	0/20.9	0/23.0	0/28.1	0/5.2	0.0	0.0
Any adjudicated MACE*	0/18.2	0/20.9	0/23.0	1/28.1 (3.6) [3.9]	0/5.2	0.0	3.9 (-3.7, 11.5)
Any adjudicated VTE**	0/18.2	0/20.9	0/23.0	0/28.1	0/5.2	0.0	0.0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo, and no more than 70 days after the last dose of adalimumab.
Patients could be included in more than one treatment group.
SSA = Study size adjusted.
n/100 PYs = Number of subjects with at least one event per 100 patient-years.
[A] Study size adjusted risk difference between treatment groups.
* MACE: Major Adverse Cardiovascular Events, defined as cardiovascular death, non-fatal myocardial infarction and non-fatal stroke.
** VTE: Venous thromboembolic events, defined as deep vein thrombosis (DVT) And pulmonary embolism (PE) (fatal and non-fatal).

Program Source Code: [redacted]

表 2.7.4.7-36.　　プラセボ対照併合解析集団（投与 24 週時）の重篤な感染症の発現状況

TABLE 2.4__1.1.4.1.2

Number and Percentage of Subjects with Treatment-Emergent Serious Infections
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
Any adverse event	5 (0.8) [0.8]	6 (0.9) [0.9]	17 (2.7) [2.7]
感染症および寄生虫症	5 (0.8) [0.8]	6 (0.9) [0.9]	17 (2.7) [2.7]
肛門膿瘍	0	0	1 (0.2) [0.2]
虫垂炎	1 (0.2) [0.2]	0	1 (0.2) [0.2]
異型肺炎	0	0	2 (0.3) [0.3]
菌血症	0	0	2 (0.3) [0.3]
乳房蜂巣炎	1 (0.2) [0.2]	0	0
気管支炎	0	0	1 (0.2) [0.2]
ブドウ球菌感染性滑液包炎	1 (0.2) [0.2]	0	0
丹毒	0	1 (0.2) [0.2]	0
硬膜外膿瘍	0	0	1 (0.2) [0.2]
喉頭炎	0	1 (0.2) [0.2]	0
肺感染	0	0	1 (0.2) [0.2]
ニューモシスチス・イロベチイ肺炎	0	0	1 (0.2) [0.2]
肺炎	2 (0.3) [0.3]	2 (0.3) [0.3]	6 (0.9) [0.9]
敗血症	0	2 (0.3) [0.3]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.4.1.2

Number and Percentage of Subjects with Treatment-Emergent Serious Infections
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
感染症および寄生虫症 (Cont.)			
尿路感染	0	0	1 (0.2) [0.2]
尿路性敗血症	0	0	1 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-37.　全ウパダシチニブ併合解析集団（長期）の重篤な感染症の発現状況（100 人年あたりの発現件数）

TABLE 2.4__1.2.4.1.2

Treatment-Emergent Serious Infections in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
Any Adverse Event	15 (2.3) [2.3]	39 (6.0) [6.0]	19 (2.3) [2.3]	49 (6.0) [6.0]
感染症および寄生虫症	15 (2.3) [2.3]	38 (5.9) [5.9]	19 (2.3) [2.3]	48 (5.8) [5.8]
膿瘍	0	0	1 (0.1) [0.1]	0
四肢膿瘍	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
肛門膿瘍	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
虫垂炎	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]
細菌性関節炎	0	0	1 (0.1) [0.1]	0
異型肺炎	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
菌血症	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
細気管支炎	0	0	1 (0.1) [0.1]	0
気管支炎	1 (0.2) [0.2]	3 (0.5) [0.5]	1 (0.1) [0.1]	3 (0.4) [0.4]
蜂巣炎	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]
サイトメガロウイルス感染	0	0	0	1 (0.1) [0.1]
憩室炎	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
丹毒	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
硬膜外膿瘍	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.2.4.1.2

Treatment-Emergent Serious Infections in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
胃腸炎	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
ウイルス性胃腸炎	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]
H1N1インフルエンザ	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
帯状疱疹	1 (0.2) [0.2]	4 (0.6) [0.6]	1 (0.1) [0.1]	5 (0.6) [0.6]
喉頭炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
肺感染	0	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
ニューモシスチス・イロベチイ肺炎	0	1 (0.2) [0.2]	0	2 (0.2) [0.2]
肺炎	4 (0.6) [0.6]	6 (0.9) [0.9]	4 (0.5) [0.5]	8 (1.0) [1.0]
レンサ球菌性肺炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
腎盂腎炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
卵管炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
敗血症	2 (0.3) [0.3]	1 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.1) [0.1]
ブドウ球菌性菌血症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
ブドウ球菌性敗血症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
上気道感染	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
尿路感染	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.2.4.1.2

Treatment-Emergent Serious Infections in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
尿路性敗血症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
ウイルス感染	0	0	0	1 (0.1) [0.1]
ウイルス性上気道感染	0	0	0	1 (0.1) [0.1]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
肛門性器疣贅	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-38.　プラセボ対照併合解析集団（投与 24 週時）の日和見感染（結核及び帯状疱疹を除く）の発現状況

TABLE 2.4__1.1.4.1.3

Number and Percentage of Subjects with Treatment-Emergent Opportunistic Infections Excluding Tuberculosis and Herpes Zoster by Primary MedDRA System Organ Class and Preferred Term (PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
Any adverse event	0	1 (0.2) [0.2]	4 (0.6) [0.6]
感染症および寄生虫症	0	1 (0.2) [0.2]	4 (0.6) [0.6]
カンジダ性尿道炎	0	1 (0.2) [0.2]	0
気管カンジダ症	0	0	1 (0.2) [0.2]
サイトメガロウイルス感染	0	0	1 (0.2) [0.2]
中咽頭カンジダ症	0	0	1 (0.2) [0.2]
ニューモシスチス・イロベチイ肺炎	0	0	1 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-39.　全ウパダシチニブ併合解析集団（長期）の日和見感染（結核及び帯状疱疹を除く）の発現状況（100 人年あたりの発現件数）

[redacted]

ABT-494 (PSA)
INTEGRATED SUMMARY OF SAFETY
R&D/19/1133 - CLINICAL/STATISTICAL

TABLE 2.4__1.2.4.1.3

Treatment-Emergent Opportunistic Infections Excluding Tuberculosis and Herpes Zoster
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
Any Adverse Event	3 (0.5) [0.5]	7 (1.1) [1.1]	4 (0.5) [0.5]	9 (1.1) [1.1]
感染症および寄生虫症	3 (0.5) [0.5]	7 (1.1) [1.1]	4 (0.5) [0.5]	9 (1.1) [1.1]
気管支肺アスペルギルス症	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
カンジダ性尿道炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
気管カンジダ症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
コクシジオイデス症	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
サイトメガロウイルス感染	0	1 (0.2) [0.2]	0	2 (0.2) [0.2]
食道カンジダ症	0	0	1 (0.1) [0.1]	0
口腔真菌感染	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
中咽頭カンジダ症	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
ニューモシスチス・イロベチイ肺炎	0	1 (0.2) [0.2]	0	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-40.　　プラセボ対照併合解析集団（投与 24 週時）の帯状疱疹の発現状況

TABLE 2.4__1.1.4.1.14

Number and Percentage of Subjects with Treatment-Emergent Herpes Zoster
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
Any adverse event	5 (0.8) [0.8]	7 (1.1) [1.1]	13 (2.0) [2.0]
感染症および寄生虫症	5 (0.8) [0.8]	7 (1.1) [1.1]	13 (2.0) [2.0]
帯状疱疹	5 (0.8) [0.8]	7 (1.1) [1.1]	13 (2.0) [2.0]
神経系障害	1 (0.2) [0.2]	0	3 (0.5) [0.5]
ヘルペス後神経痛	1 (0.2) [0.2]	0	3 (0.5) [0.5]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-41.　全ウパダシチニブ併合解析集団（長期）の帯状疱疹の発現状況（100 人年あたりの発現件数）

TABLE 2.4__1.2.4.1.14

Treatment-Emergent Herpes Zoster in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
Any Adverse Event	23 (3.5) [3.5]	48 (7.4) [7.4]	29 (3.6) [3.6]	65 (7.9) [7.9]
感染症および寄生虫症	22 (3.4) [3.4]	41 (6.3) [6.3]	27 (3.3) [3.3]	57 (6.9) [6.9]
陰部帯状疱疹	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
帯状疱疹	21 (3.2) [3.2]	41 (6.3) [6.3]	26 (3.2) [3.2]	57 (6.9) [6.9]
神経系障害	1 (0.2) [0.2]	7 (1.1) [1.1]	2 (0.2) [0.2]	8 (1.0) [1.0]
ヘルペス後神経痛	1 (0.2) [0.2]	7 (1.1) [1.1]	2 (0.2) [0.2]	8 (1.0) [1.0]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-42.　全ウパダシチニブ併合解析集団（長期）の活動性結核の発現状況（100 人年あたりの発現件数）

TABLE 2.4__1.2.4.1.17

Treatment-Emergent Active Tuberculosis in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

	Upadacitinib			
	15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8)	30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1)	Any 15 mg QD (N = 907) (PYs = 816.9)	Any 30 mg QD (N = 920) (PYs = 822.3)
System Organ Class MedDRA 22.0 Preferred Term	Events (E/100 PYs) [SSA E/100 PYs]	Events (E/100 PYs) [SSA E/100 PYs]	Events (E/100 PYs) [SSA E/100 PYs]	Events (E/100 PYs) [SSA E/100 PYs]
Any Adverse Event	0	0	0	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-43.　　プラセボ対照併合解析集団（投与 24 週時）の悪性腫瘍の発現状況

TABLE 2.4__1.1.4.1.5

Number and Percentage of Subjects with Treatment-Emergent Malignancy
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
Any adverse event	1 (0.2) [0.2]	4 (0.6) [0.6]	6 (0.9) [0.9]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1 (0.2) [0.2]	4 (0.6) [0.6]	6 (0.9) [0.9]
基底細胞癌	1 (0.2) [0.2]	1 (0.2) [0.2]	3 (0.5) [0.5]
子宮内膜癌	0	0	1 (0.2) [0.2]
肺腺癌	0	0	1 (0.2) [0.2]
神経内分泌癌	0	1 (0.2) [0.2]	0
卵巣癌	0	0	1 (0.2) [0.2]
前立腺癌	0	1 (0.2) [0.2]	0
直腸腺癌	0	0	1 (0.2) [0.2]
直腸癌	0	1 (0.2) [0.2]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-44.　全ウパダシチニブ併合解析集団（長期）の悪性腫瘍の発現状況（100 人年あたりの発現被験者数）

TABLE 2.4__1.2.4.1.5

Treatment-Emergent Malignancy in Exposure-Adjusted Incidence Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) n/PYs (n/100 PYs) [SSA n/100 PYs]
Any Adverse Event	8/649.2 (1.2) [1.2]	11/643.8 (1.7) [1.7]	11/814.0 (1.4) [1.4]	12/818.8 (1.5) [1.5]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	8/649.2 (1.2) [1.2]	11/643.8 (1.7) [1.7]	11/814.0 (1.4) [1.4]	12/818.8 (1.5) [1.5]
基底細胞癌	2/649.9 (0.3) [0.3]	3/645.6 (0.5) [0.5]	4/814.8 (0.5) [0.5]	3/820.8 (0.4) [0.4]
基底扁平上皮癌	0/651.8	1/647.0 (0.2) [0.2]	0/816.9	1/822.1 (0.1) [0.1]
ボーエン病	0/651.8	1/646.6 (0.2) [0.2]	0/816.9	1/821.7 (0.1) [0.1]
子宮内膜癌	0/651.8	1/647.1 (0.2) [0.2]	0/816.9	1/822.3 (0.1) [0.1]
肺腺癌	0/651.8	1/647.1 (0.2) [0.2]	0/816.9	1/822.3 (0.1) [0.1]
遠隔転移を伴う肺癌	1/651.8 (0.2) [0.2]	0/647.1	1/816.9 (0.1) [0.1]	0/822.3
悪性黒色腫	0/651.8	1/646.6 (0.2) [0.2]	1/816.9 (0.1) [0.1]	1/821.7 (0.1) [0.1]
悪性黒色腫第3期	1/651.8 (0.2) [0.2]	0/647.1	1/816.9 (0.1) [0.1]	0/822.3
神経内分泌癌	1/651.8 (0.2) [0.2]	0/647.1	1/816.8 (0.1) [0.1]	0/822.3
中咽頭扁平上皮癌	0/651.8	1/647.1 (0.2) [0.2]	0/816.9	1/822.2 (0.1) [0.1]
卵巣癌	0/651.8	1/647.1 (0.2) [0.2]	0/816.9	1/822.3 (0.1) [0.1]
前立腺癌	1/651.8 (0.2) [0.2]	0/647.1	2/816.8 (0.2) [0.2]	0/822.3
直腸腺癌	0/651.8	1/647.0 (0.2) [0.2]	0/816.9	1/822.2 (0.1) [0.1]
直腸癌	1/651.7 (0.2) [0.2]	0/647.1	1/816.8 (0.1) [0.1]	0/822.3
扁平上皮癌	0/651.8	1/647.0 (0.2) [0.2]	0/816.9	2/822.0 (0.2) [0.2]
皮膚有棘細胞癌	1/651.3 (0.2) [0.2]	1/646.4 (0.2) [0.2]	1/816.4 (0.1) [0.1]	1/821.6 (0.1) [0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
n/100 PYs = Number of subjects with at least one event per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-45. プラセボ対照併合解析集団（投与 24 週時）の悪性腫瘍（NMSC を除く）の発現状況

[redacted]

TABLE 2.4__1.1.4.1.7

Number and Percentage of Subjects with Treatment-Emergent Malignancy Other than NMSC
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
Any adverse event	0	3 (0.5) [0.5]	3 (0.5) [0.5]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	3 (0.5) [0.5]	3 (0.5) [0.5]
子宮内膜癌	0	0	1 (0.2) [0.2]
肺腺癌	0	0	1 (0.2) [0.2]
神経内分泌癌	0	1 (0.2) [0.2]	0
卵巣癌	0	0	1 (0.2) [0.2]
前立腺癌	0	1 (0.2) [0.2]	0
直腸腺癌	0	0	1 (0.2) [0.2]
直腸癌	0	1 (0.2) [0.2]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-46.　全ウパダシチニブ併合解析集団（長期）の悪性腫瘍（NMSC を除く）の発現状況（100 人年あたりの発現被験者数）

TABLE 2.4__1.2.4.1.7

Treatment-Emergent Malignancy other than NMSC in Exposure-Adjusted Incidence Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) n/PYs (n/100 PYs) [SSA n/100 PYs]
Any Adverse Event	5/651.6 (0.8) [0.8]	6/646.5 (0.9) [0.9]	7/816.6 (0.9) [0.9]	7/821.4 (0.9) [0.9]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	5/651.6 (0.8) [0.8]	6/646.5 (0.9) [0.9]	7/816.6 (0.9) [0.9]	7/821.4 (0.9) [0.9]
基底扁平上皮癌	0/651.8	1/647.0 (0.2) [0.2]	0/816.9	1/822.1 (0.1) [0.1]
子宮内膜癌	0/651.8	1/647.1 (0.2) [0.2]	0/816.9	1/822.3 (0.1) [0.1]
肺腺癌	0/651.8	1/647.1 (0.2) [0.2]	0/816.9	1/822.3 (0.1) [0.1]
遠隔転移を伴う肺癌	1/651.8 (0.2) [0.2]	0/647.1	1/816.9 (0.1) [0.1]	0/822.3
悪性黒色腫	0/651.8	1/646.6 (0.2) [0.2]	1/816.9 (0.1) [0.1]	1/821.7 (0.1) [0.1]
悪性黒色腫第3期	1/651.8 (0.2) [0.2]	0/647.1	1/816.9 (0.1) [0.1]	0/822.3
神経内分泌癌	1/651.8 (0.2) [0.2]	0/647.1	1/816.8 (0.1) [0.1]	0/822.3
中咽頭扁平上皮癌	0/651.8	1/647.1 (0.2) [0.2]	0/816.9	1/822.2 (0.1) [0.1]
卵巣癌	0/651.8	1/647.1 (0.2) [0.2]	0/816.9	1/822.3 (0.1) [0.1]
前立腺癌	1/651.8 (0.2) [0.2]	0/647.1	2/816.8 (0.2) [0.2]	0/822.3
直腸腺癌	0/651.8	1/647.0 (0.2) [0.2]	0/816.9	1/822.2 (0.1) [0.1]
直腸癌	1/651.7 (0.2) [0.2]	0/647.1	1/816.8 (0.1) [0.1]	0/822.3
扁平上皮癌	0/651.8	1/647.0 (0.2) [0.2]	0/816.9	2/822.0 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
n/100 PYs = Number of subjects with at least one event per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-47.　　プラセボ対照併合解析集団（投与 24 週時）の NMSC の発現状況

[redacted]

TABLE 2.4__1.1.4.1.6

Number and Percentage of Subjects with Treatment-Emergent Non-Melanoma Skin Cancer (NMSC)
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
Any adverse event	1 (0.2) [0.2]	1 (0.2) [0.2]	3 (0.5) [0.5]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1 (0.2) [0.2]	1 (0.2) [0.2]	3 (0.5) [0.5]
基底細胞癌	1 (0.2) [0.2]	1 (0.2) [0.2]	3 (0.5) [0.5]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-48. 全ウパダシチニブ併合解析集団（長期）の NMSC の発現状況（100 人年あたりの発現被験者数）

[redacted]
ABT-494 (PSA)
INTEGRATED SUMMARY OF SAFETY
R&D/19/1133 - CLINICAL/STATISTICAL

TABLE 2.4__1.2.4.1.6

Treatment-Emergent Non-Melanoma Skin Cancer (NMSC) in Exposure-Adjusted Incidence Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) n/PYs (n/100 PYs) [SSA n/100 PYs]
Any Adverse Event	3/649.4 (0.5) [0.5]	5/644.5 (0.8) [0.8]	5/814.3 (0.6) [0.6]	5/819.6 (0.6) [0.6]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	3/649.4 (0.5) [0.5]	5/644.5 (0.8) [0.8]	5/814.3 (0.6) [0.6]	5/819.6 (0.6) [0.6]
基底細胞癌	2/649.9 (0.3) [0.3]	3/645.6 (0.5) [0.5]	4/814.8 (0.5) [0.5]	3/820.8 (0.4) [0.4]
ボーエン病	0/651.8	1/646.6 (0.2) [0.2]	0/816.9	1/821.7 (0.1) [0.1]
皮膚有棘細胞癌	1/651.3 (0.2) [0.2]	1/646.4 (0.2) [0.2]	1/816.4 (0.1) [0.1]	1/821.6 (0.1) [0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
n/100 PYs = Number of subjects with at least one event per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-49.　　プラセボ対照併合解析集団（投与 24 週時）のリンパ腫の発現状況

[redacted]

TABLE 2.4__1.1.4.1.8

Number and Percentage of Subjects with Treatment-Emergent Lymphoma
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
Any adverse event	0	1 (0.2) [0.2]	0
臨床検査	0	1 (0.2) [0.2]	0
リンパ球形態異常	0	1 (0.2) [0.2]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-50.　全ウパダシチニブ併合解析集団（長期）のリンパ腫の発現状況（100 人年あたりの発現被験者数）

[redacted]
ABT-494 (PSA)
INTEGRATED SUMMARY OF SAFETY
R&D/19/1133 - CLINICAL/STATISTICAL

TABLE 2.4__1.2.4.1.8

Treatment-Emergent Lymphoma in Exposure-Adjusted Incidence Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) n/PYs (n/100 PYs) [SSA n/100 PYs]
Any Adverse Event	1/650.0 (0.2) [0.2]	0/647.1	2/815.0 (0.2) [0.2]	0/822.3
臨床検査	1/650.0 (0.2) [0.2]	0/647.1	2/815.0 (0.2) [0.2]	0/822.3
リンパ球形態異常	1/650.0 (0.2) [0.2]	0/647.1	2/815.0 (0.2) [0.2]	0/822.3

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
n/100 PYs = Number of subjects with at least one event per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-51.　　プラセボ対照併合解析集団（投与 24 週時）の薬物性肝障害の発現状況

TABLE 2.4__1.1.4.1.9

Number and Percentage of Subjects with Treatment-Emergent Hepatic Disorder
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
Any adverse event	19 (3.0) [3.0]	43 (6.7) [6.7]	70 (10.9) [10.9]
肝胆道系障害	3 (0.5) [0.5]	11 (1.7) [1.7]	15 (2.3) [2.4]
肝嚢胞	0	0	1 (0.2) [0.2]
肝機能異常	0	4 (0.6) [0.6]	4 (0.6) [0.6]
脂肪肝	1 (0.2) [0.2]	2 (0.3) [0.3]	4 (0.6) [0.6]
肝毒性	0	1 (0.2) [0.2]	1 (0.2) [0.2]
高ビリルビン血症	0	2 (0.3) [0.3]	1 (0.2) [0.2]
高トランスアミナーゼ血症	0	0	1 (0.2) [0.2]
肝障害	0	0	2 (0.3) [0.3]
肝損傷	0	0	1 (0.2) [0.2]
非アルコール性脂肪性肝炎	1 (0.2) [0.2]	0	0
非アルコール性脂肪性肝疾患	1 (0.2) [0.2]	0	0
脂肪性肝炎	0	2 (0.3) [0.3]	0
臨床検査	17 (2.7) [2.7]	34 (5.3) [5.3]	57 (8.9) [8.9]
アラニンアミノトランスフェラーゼ増加	13 (2.0) [2.0]	21 (3.3) [3.3]	35 (5.5) [5.5]
アスパラギン酸アミノトランスフェラーゼ増加	9 (1.4) [1.4]	14 (2.2) [2.2]	22 (3.4) [3.4]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.1.4.1.9

Number and Percentage of Subjects with Treatment-Emergent Hepatic Disorder
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
臨床検査 (Cont.)			
血中ビリルビン増加	1 (0.2) [0.2]	2 (0.3) [0.3]	1 (0.2) [0.2]
γ－グルタミルトランスフェラーゼ増加	0	0	1 (0.2) [0.2]
肝酵素上昇	4 (0.6) [0.6]	2 (0.3) [0.3]	8 (1.2) [1.2]
肝機能検査値上昇	0	5 (0.8) [0.8]	2 (0.3) [0.3]
トランスアミナーゼ上昇	0	3 (0.5) [0.5]	8 (1.2) [1.3]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-52.　全ウパダシチニブ併合解析集団（長期）の薬物性肝障害の発現状況（100 人年あたりの発現件数）

TABLE 2.4__1.2.4.1.9

Treatment-Emergent Hepatic Disorder in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
Any Adverse Event	110 (16.9) [16.9]	154 (23.8) [23.8]	133 (16.3) [16.3]	183 (22.3) [22.3]
胃腸障害	0	0	0	1 (0.1) [0.1]
腹水	0	0	0	1 (0.1) [0.1]
肝胆道系障害	21 (3.2) [3.2]	35 (5.4) [5.4]	29 (3.6) [3.5]	42 (5.1) [5.1]
薬物性肝障害	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
肝硬変	0	0	0	1 (0.1) [0.1]
肝嚢胞	0	4 (0.6) [0.6]	0	4 (0.5) [0.5]
肝機能異常	9 (1.4) [1.4]	9 (1.4) [1.4]	13 (1.6) [1.6]	12 (1.5) [1.5]
肝腫瘤	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
脂肪肝	4 (0.6) [0.6]	12 (1.9) [1.9]	5 (0.6) [0.6]	14 (1.7) [1.7]
肝炎	0	0	1 (0.1) [0.1]	0
肝腫大	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
肝毒性	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
高ビリルビン血症	2 (0.3) [0.3]	1 (0.2) [0.2]	4 (0.5) [0.5]	1 (0.1) [0.1]
高トランスアミナーゼ血症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
肝障害	0	2 (0.3) [0.3]	0	3 (0.4) [0.4]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.2.4.1.9

Treatment-Emergent Hepatic Disorder in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
肝胆道系障害 (Cont.)				
肝損傷	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
非アルコール性脂肪性肝炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
非アルコール性脂肪性肝疾患	2 (0.3) [0.3]	1 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.1) [0.1]
脂肪性肝炎	2 (0.3) [0.3]	0	2 (0.2) [0.2]	0
臨床検査	89 (13.7) [13.7]	119 (18.4) [18.4]	104 (12.7) [12.7]	140 (17.0) [17.0]
アラニンアミノトランスフェラーゼ増加	43 (6.6) [6.6]	55 (8.5) [8.5]	50 (6.1) [6.1]	63 (7.7) [7.7]
アスパラギン酸アミノトランスフェラーゼ増加	29 (4.4) [4.5]	36 (5.6) [5.6]	33 (4.0) [4.0]	43 (5.2) [5.2]
血中ビリルビン増加	2 (0.3) [0.3]	1 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.1) [0.1]
γ−グルタミルトランスフェラーゼ増加	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
肝酵素上昇	3 (0.5) [0.5]	8 (1.2) [1.2]	5 (0.6) [0.6]	10 (1.2) [1.2]
肝機能検査値上昇	7 (1.1) [1.1]	7 (1.1) [1.1]	7 (0.9) [0.9]	9 (1.1) [1.1]
トランスアミナーゼ上昇	5 (0.8) [0.8]	11 (1.7) [1.7]	7 (0.9) [0.9]	13 (1.6) [1.6]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-53.　　プラセボ対照併合解析集団（投与 24 週時）の消化管穿孔の発現状況

TABLE 2.4__1.1.4.1.10

Number and Percentage of Subjects with Treatment-Emergent Adjudicated Gastrointestinal Perforation
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
Any adverse event	0	0	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-54.　全ウパダシチニブ併合解析集団（長期）の消化管穿孔の発現状況（100 人年あたりの発現件数）

TABLE 2.4__1.2.4.1.10

Treatment-Emergent Adjudicated Gastrointestinal Perforation in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
Any Adverse Event	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
胃腸障害	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
穿孔性胃潰瘍	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-55.　　プラセボ対照併合解析集団（投与 24 週時）の貧血の発現状況

TABLE 2.4__1.1.4.1.11

Number and Percentage of Subjects with Treatment-Emergent Anemia
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
Any adverse event	6 (0.9) [0.9]	7 (1.1) [1.1]	34 (5.3) [5.3]
血液およびリンパ系障害	4 (0.6) [0.6]	6 (0.9) [0.9]	25 (3.9) [3.9]
貧血	4 (0.6) [0.6]	4 (0.6) [0.6]	20 (3.1) [3.1]
大球性貧血	0	0	1 (0.2) [0.2]
失血性貧血	0	1 (0.2) [0.2]	1 (0.2) [0.2]
鉄欠乏性貧血	0	1 (0.2) [0.2]	2 (0.3) [0.3]
正色素性貧血	0	0	1 (0.2) [0.2]
臨床検査	2 (0.3) [0.3]	1 (0.2) [0.2]	11 (1.7) [1.7]
ヘマトクリット減少	0	1 (0.2) [0.2]	0
ヘモグロビン減少	2 (0.3) [0.3]	1 (0.2) [0.2]	8 (1.2) [1.2]
平均赤血球容積増加	0	0	4 (0.6) [0.6]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-56. 全ウパダシチニブ併合解析集団（長期）の貧血の発現状況（100 人年あたりの発現件数）

TABLE 2.4__1.2.4.1.11

Treatment-Emergent Anemia in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
Any Adverse Event	21 (3.2) [3.2]	50 (7.7) [7.7]	23 (2.8) [2.8]	57 (6.9) [6.9]
血液およびリンパ系障害	16 (2.5) [2.5]	36 (5.6) [5.6]	18 (2.2) [2.2]	42 (5.1) [5.1]
貧血	11 (1.7) [1.7]	30 (4.6) [4.6]	13 (1.6) [1.6]	35 (4.3) [4.3]
大球性貧血	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
失血性貧血	1 (0.2) [0.2]	2 (0.3) [0.3]	1 (0.1) [0.1]	2 (0.2) [0.2]
鉄欠乏性貧血	3 (0.5) [0.5]	2 (0.3) [0.3]	3 (0.4) [0.4]	3 (0.4) [0.4]
正色素性貧血	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
臨床検査	5 (0.8) [0.8]	14 (2.2) [2.2]	5 (0.6) [0.6]	15 (1.8) [1.8]
ヘマトクリット減少	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
ヘモグロビン減少	2 (0.3) [0.3]	8 (1.2) [1.2]	2 (0.2) [0.2]	8 (1.0) [1.0]
平均赤血球容積増加	2 (0.3) [0.3]	5 (0.8) [0.8]	2 (0.2) [0.2]	6 (0.7) [0.7]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-57.　　プラセボ対照併合解析集団（投与 24 週時）の好中球減少症の発現状況

TABLE 2.4__1.1.4.1.12

Number and Percentage of Subjects with Treatment-Emergent Neutropenia
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
Any adverse event	2 (0.3) [0.3]	6 (0.9) [0.9]	27 (4.2) [4.2]
血液およびリンパ系障害	2 (0.3) [0.3]	6 (0.9) [0.9]	19 (3.0) [3.0]
顆粒球減少症	0	0	1 (0.2) [0.2]
好中球減少症	2 (0.3) [0.3]	6 (0.9) [0.9]	18 (2.8) [2.8]
臨床検査	0	0	9 (1.4) [1.4]
好中球数減少	0	0	9 (1.4) [1.4]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-58.　全ウパダシチニブ併合解析集団（長期）の好中球減少症の発現状況（100 人年あたりの発現件数）

TABLE 2.4__1.2.4.1.12

Treatment-Emergent Neutropenia in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
Any Adverse Event	15 (2.3) [2.3]	42 (6.5) [6.5]	18 (2.2) [2.2]	51 (6.2) [6.2]
血液およびリンパ系障害	13 (2.0) [2.0]	31 (4.8) [4.8]	16 (2.0) [2.0]	38 (4.6) [4.6]
顆粒球減少症	0	1 (0.2) [0.2]	0	3 (0.4) [0.4]
好中球減少症	13 (2.0) [2.0]	30 (4.6) [4.6]	16 (2.0) [2.0]	35 (4.3) [4.3]
臨床検査	2 (0.3) [0.3]	11 (1.7) [1.7]	2 (0.2) [0.2]	13 (1.6) [1.6]
好中球数減少	2 (0.3) [0.3]	11 (1.7) [1.7]	2 (0.2) [0.2]	13 (1.6) [1.6]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-59.　　プラセボ対照併合解析集団（投与 24 週時）のリンパ球減少症の発現状況

TABLE 2.4__1.1.4.1.13

Number and Percentage of Subjects with Treatment-Emergent Lymphopenia
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
Any adverse event	5 (0.8) [0.8]	8 (1.3) [1.2]	17 (2.7) [2.7]
血液およびリンパ系障害	5 (0.8) [0.8]	5 (0.8) [0.8]	15 (2.3) [2.4]
リンパ球減少症	5 (0.8) [0.8]	5 (0.8) [0.8]	15 (2.3) [2.4]
臨床検査	0	3 (0.5) [0.5]	2 (0.3) [0.3]
リンパ球数減少	0	3 (0.5) [0.5]	2 (0.3) [0.3]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-60.　全ウパダシチニブ併合解析集団（長期）のリンパ球減少症の発現状況（100 人年あたりの発現件数）

TABLE 2.4__1.2.4.1.13

Treatment-Emergent Lymphopenia in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
Any Adverse Event	19 (2.9) [2.9]	26 (4.0) [4.0]	20 (2.4) [2.4]	29 (3.5) [3.5]
血液およびリンパ系障害	15 (2.3) [2.3]	23 (3.6) [3.6]	16 (2.0) [2.0]	25 (3.0) [3.0]
リンパ球減少症	15 (2.3) [2.3]	23 (3.6) [3.6]	16 (2.0) [2.0]	25 (3.0) [3.0]
臨床検査	4 (0.6) [0.6]	3 (0.5) [0.5]	4 (0.5) [0.5]	4 (0.5) [0.5]
リンパ球数減少	4 (0.6) [0.6]	3 (0.5) [0.5]	4 (0.5) [0.5]	4 (0.5) [0.5]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-61.　　プラセボ対照併合解析集団（投与 24 週時）の CPK 増加の発現状況

[redacted]

TABLE 2.4__1.1.4.1.15

Number and Percentage of Subjects with Treatment-Emergent Creatinine Phosphokinase (CPK) Elevation
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
Any adverse event	10 (1.6) [1.6]	42 (6.6) [6.5]	53 (8.3) [8.3]
臨床検査	10 (1.6) [1.6]	42 (6.6) [6.5]	53 (8.3) [8.3]
血中クレアチンホスホキナーゼ増加	10 (1.6) [1.6]	42 (6.6) [6.5]	53 (8.3) [8.3]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-62. 全ウパダシチニブ併合解析集団（長期）の CPK 増加の発現状況（100 人年あたりの発現件数）

TABLE 2.4__1.2.4.1.15

Treatment-Emergent Creatinine Phosphokinase (CPK) Elevation
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

	Upadacitinib			
System Organ Class MedDRA 22.0 Preferred Term	15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
Any Adverse Event	78 (12.0) [12.0]	121 (18.7) [18.7]	93 (11.4) [11.4]	140 (17.0) [17.0]
臨床検査	78 (12.0) [12.0]	121 (18.7) [18.7]	93 (11.4) [11.4]	140 (17.0) [17.0]
血中クレアチンホスホキナーゼ増加	78 (12.0) [12.0]	121 (18.7) [18.7]	93 (11.4) [11.4]	140 (17.0) [17.0]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-63.　プラセボ対照併合解析集団（投与 24 週時）で臨床的に意義があると判断した血液生化学検査値の基準に該当した被験者数

TABLE 2.5__1.1.4.1

Number and Percentage of Subjects Meeting Criteria for Potentially Clinically Significant Values
for Selected Chemistry Variables
(PBO-Controlled Analysis Set)

Variable (unit) Criteria	Placebo (N = 635) n/N_OBS (%) [SSA %]	---- Upadacitinib ----- 15 mg QD (N = 640) n/N_OBS (%) [SSA %]	 30 mg QD (N = 641) n/N_OBS (%) [SSA %]	--Treatment Comparison (95% CI)[A]-- 15 mg QD - Placebo	 30 mg QD - Placebo
ALANINE AMINOTRANSFERASE (U/L)					
GRADE 2 (>3.0-5.0 xULN)	7/626 (1.1) [1.1]	12/635 (1.9) [1.9]	25/638 (3.9) [3.9]	0.8 (-0.6, 2.1)	2.8 (1.1, 4.5)
GRADE 3 (>5.0-20.0 xULN)	8/626 (1.3) [1.3]	6/635 (0.9) [0.9]	6/638 (0.9) [0.9]	-0.3 (-1.5, 0.8)	-0.3 (-1.5, 0.8)
GRADE 4 (>20.0 xULN)	0/626	0/635	0/638	0.0	0.0
>= GRADE 3	8/626 (1.3) [1.3]	6/635 (0.9) [0.9]	6/638 (0.9) [0.9]	-0.3 (-1.5, 0.8)	-0.3 (-1.5, 0.8)
ASPARTATE AMINOTRANSFERASE (U/L)					
GRADE 2 (>3.0-5.0 xULN)	10/626 (1.6) [1.6]	7/635 (1.1) [1.1]	8/637 (1.3) [1.3]	-0.5 (-1.8, 0.8)	-0.3 (-1.7, 1.0)
GRADE 3 (>5.0-20.0 xULN)	3/626 (0.5) [0.5]	2/635 (0.3) [0.3]	3/637 (0.5) [0.5]	-0.2 (-0.9, 0.5)	-0.0 (-0.8, 0.8)
GRADE 4 (>20.0 xULN)	0/626	0/635	1/637 (0.2) [0.2]	0.0	0.2 (-0.2, 0.5)
>= GRADE 3	3/626 (0.5) [0.5]	2/635 (0.3) [0.3]	4/637 (0.6) [0.6]	-0.2 (-0.9, 0.5)	0.2 (-0.7, 1.0)

Note: Toxicity grading scale is based on NCI Common Terminology Criteria version 4.03. Grade must also be more extreme than the baseline grade.
N_OBS indicates the number of subjects with both baseline and post-baseline values up to Week 24 for the respective parameter.
xULN = Times upper limit of the normal range.
SSA = Study size adjusted.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

TABLE 2.5__1.1.4.1

Number and Percentage of Subjects Meeting Criteria for Potentially Clinically Significant Values
for Selected Chemistry Variables
(PBO-Controlled Analysis Set)

Variable (unit) Criteria	Placebo (N = 635) n/N_OBS (%) [SSA %]	---- Upadacitinib ----- 15 mg QD (N = 640) n/N_OBS (%) [SSA %]	 30 mg QD (N = 641) n/N_OBS (%) [SSA %]	--Treatment Comparison (95% CI)[A]-- 15 mg QD - Placebo	 30 mg QD - Placebo
ALKALINE PHOSPHATASE (U/L)					
GRADE 2 (>2.5-5.0 xULN)	1/627 (0.2) [0.2]	1/635 (0.2) [0.2]	0/638	-0.0 (-0.4, 0.4)	-0.2 (-0.5, 0.2)
GRADE 3 (>5.0-20.0 xULN)	0/627	0/635	0/638	0.0	0.0
GRADE 4 (>20.0 xULN)	0/627	0/635	0/638	0.0	0.0
>= GRADE 3	0/627	0/635	0/638	0.0	0.0
BILIRUBIN (UMOL/L)					
GRADE 2 (>1.5-3.0 xULN)	3/627 (0.5) [0.5]	9/635 (1.4) [1.4]	12/638 (1.9) [1.9]	0.9 (-0.1, 2.0)	1.4 (0.2, 2.6)
GRADE 3 (>3.0-10.0 xULN)	0/627	1/635 (0.2) [0.2]	0/638	0.2 (-0.2, 0.5)	0.0
GRADE 4 (>10.0 xULN)	0/627	0/635	0/638	0.0	0.0
>= GRADE 3	0/627	1/635 (0.2) [0.2]	0/638	0.2 (-0.2, 0.5)	0.0

Note: Toxicity grading scale is based on NCI Common Terminology Criteria version 4.03. Grade must also be more extreme than the baseline grade.
N_OBS indicates the number of subjects with both baseline and post-baseline values up to Week 24 for the respective parameter.
xULN = Times upper limit of the normal range.
SSA = Study size adjusted.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

TABLE 2.5__1.1.4.1

Number and Percentage of Subjects Meeting Criteria for Potentially Clinically Significant Values
for Selected Chemistry Variables
(PBO-Controlled Analysis Set)

Variable (unit) Criteria	Placebo (N = 635) n/N_OBS (%) [SSA %]	---- Upadacitinib ----- 15 mg QD (N = 640) n/N_OBS (%) [SSA %]	 30 mg QD (N = 641) n/N_OBS (%) [SSA %]	--Treatment Comparison (95% CI)[A]-- 15 mg QD - Placebo	 30 mg QD - Placebo
CREATINE KINASE (U/L)					
GRADE 2 (>2.5-5.0 xULN)	8/627 (1.3) [1.3]	35/635 (5.5) [5.5]	48/638 (7.5) [7.5]	4.2 (2.3, 6.2)	6.2 (4.0, 8.5)
GRADE 3 (>5.0-10.0 xULN)	4/627 (0.6) [0.6]	7/635 (1.1) [1.1]	12/638 (1.9) [1.9]	0.5 (-0.6, 1.5)	1.2 (0.0, 2.5)
GRADE 4 (>10.0 xULN)	3/627 (0.5) [0.5]	2/635 (0.3) [0.3]	4/638 (0.6) [0.6]	-0.2 (-0.9, 0.5)	0.2 (-0.7, 1.0)
>= GRADE 3	7/627 (1.1) [1.1]	9/635 (1.4) [1.4]	16/638 (2.5) [2.5]	0.3 (-0.9, 1.5)	1.4 (-0.1, 2.9)
CREATININE (UMOL/L)					
GRADE 2 (>1.5-3.0 xULN OR >1.5-3.0 xBASELINE)	16/627 (2.6) [2.6]	14/635 (2.2) [2.2]	22/638 (3.4) [3.4]	-0.3 (-2.0, 1.3)	0.9 (-1.0, 2.8)
GRADE 3 (>3.0-6.0 xULN OR >3.0 xBASELINE)	0/627	0/635	1/638 (0.2) [0.2]	0.0	0.2 (-0.1, 0.5)
GRADE 4 (>6.0 xULN)	0/627	0/635	0/638	0.0	0.0
>= GRADE 3	0/627	0/635	1/638 (0.2) [0.2]	0.0	0.2 (-0.1, 0.5)

Note: Toxicity grading scale is based on NCI Common Terminology Criteria version 4.03. Grade must also be more extreme than the baseline grade.
N_OBS indicates the number of subjects with both baseline and post-baseline values up to Week 24 for the respective parameter.
xULN = Times upper limit of the normal range.
SSA = Study size adjusted.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

表 2.7.4.7-64.　　プラセボ対照併合解析集団（投与 24 週時）の腎機能障害の発現状況

TABLE 2.4__1.1.4.1.16

Number and Percentage of Subjects with Treatment-Emergent Renal Dysfunction
by Primary MedDRA System Organ Class and Preferred Term
(PBO-Controlled Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
Any adverse event	2 (0.3) [0.3]	0	1 (0.2) [0.2]
腎および尿路障害	2 (0.3) [0.3]	0	1 (0.2) [0.2]
急性腎障害	2 (0.3) [0.3]	0	1 (0.2) [0.2]
腎不全	1 (0.2) [0.2]	0	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-65.　全ウパダシチニブ併合解析集団（長期）で臨床的に意義があると判断した血液生化学検査値の基準に該当した被験者数

TABLE 2.5__1.2.4.1

Number and Percentage of Subjects Meeting Criteria for Potentially Clinically Significant Values
for Selected Chemistry Variables
(Any Upadacitinib Analysis Set)

Variable (unit) Criteria	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n/N_OBS (%) [SSA %]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n/N_OBS (%) [SSA %]	Upadacitinib Any 15 mg QD (N = 907) n/N_OBS (%) [SSA %]	Upadacitinib Any 30 mg QD (N = 920) n/N_OBS (%) [SSA %]
ALANINE AMINOTRANSFERASE (U/L)				
GRADE 2 (>3.0-5.0 xULN)	14/635 (2.2) [2.2]	35/638 (5.5) [5.5]	21/878 (2.4) [2.4]	43/896 (4.8) [4.8]
GRADE 3 (>5.0-20.0 xULN)	8/635 (1.3) [1.3]	7/638 (1.1) [1.1]	9/878 (1.0) [1.0]	7/896 (0.8) [0.8]
GRADE 4 (>20.0 xULN)	0/635	0/638	0/878	1/896 (0.1) [0.1]
>= GRADE 3	8/635 (1.3) [1.3]	7/638 (1.1) [1.1]	9/878 (1.0) [1.0]	8/896 (0.9) [0.9]
ASPARTATE AMINOTRANSFERASE (U/L)				
GRADE 2 (>3.0-5.0 xULN)	9/635 (1.4) [1.4]	12/637 (1.9) [1.9]	12/878 (1.4) [1.4]	19/895 (2.1) [2.1]
GRADE 3 (>5.0-20.0 xULN)	4/635 (0.6) [0.6]	7/637 (1.1) [1.1]	6/878 (0.7) [0.7]	7/895 (0.8) [0.8]
GRADE 4 (>20.0 xULN)	0/635	1/637 (0.2) [0.2]	0/878	2/895 (0.2) [0.2]
>= GRADE 3	4/635 (0.6) [0.6]	8/637 (1.3) [1.3]	6/878 (0.7) [0.7]	9/895 (1.0) [1.0]

Note: Patients could be included in more than one treatment group.
Toxicity grading scale is based on NCI Common Terminology Criteria version 4.03. Grade must also be more extreme than the baseline grade.
N_OBS indicates the number of subjects with both baseline and post-baseline values for the respective parameter.
xULN = Times upper limit of the normal range.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.2.4.1

Number and Percentage of Subjects Meeting Criteria for Potentially Clinically Significant Values
for Selected Chemistry Variables
(Any Upadacitinib Analysis Set)

Variable (unit) Criteria	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n/N_OBS (%) [SSA %]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n/N_OBS (%) [SSA %]	Upadacitinib Any 15 mg QD (N = 907) n/N_OBS (%) [SSA %]	Upadacitinib Any 30 mg QD (N = 920) n/N_OBS (%) [SSA %]
ALKALINE PHOSPHATASE (U/L)				
GRADE 2 (>2.5-5.0 xULN)	1/635 (0.2) [0.2]	0/638	1/878 (0.1) [0.1]	0/896
GRADE 3 (>5.0-20.0 xULN)	0/635	0/638	0/878	0/896
GRADE 4 (>20.0 xULN)	0/635	0/638	0/878	0/896
>= GRADE 3	0/635	0/638	0/878	0/896
BILIRUBIN (UMOL/L)				
GRADE 2 (>1.5-3.0 xULN)	11/635 (1.7) [1.7]	14/638 (2.2) [2.2]	12/878 (1.4) [1.4]	20/896 (2.2) [2.2]
GRADE 3 (>3.0-10.0 xULN)	1/635 (0.2) [0.2]	0/638	1/878 (0.1) [0.1]	0/896
GRADE 4 (>10.0 xULN)	0/635	0/638	0/878	0/896
>= GRADE 3	1/635 (0.2) [0.2]	0/638	1/878 (0.1) [0.1]	0/896

Note: Patients could be included in more than one treatment group.
Toxicity grading scale is based on NCI Common Terminology Criteria version 4.03. Grade must also be more extreme than the baseline grade.
N_OBS indicates the number of subjects with both baseline and post-baseline values for the respective parameter.
xULN = Times upper limit of the normal range.
SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.2.4.1

Number and Percentage of Subjects Meeting Criteria for Potentially Clinically Significant Values
for Selected Chemistry Variables
(Any Upadacitinib Analysis Set)

Variable (unit) Criteria	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n/N_OBS (%) [SSA %]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n/N_OBS (%) [SSA %]	Upadacitinib Any 15 mg QD (N = 907) n/N_OBS (%) [SSA %]	Upadacitinib Any 30 mg QD (N = 920) n/N_OBS (%) [SSA %]
CREATINE KINASE (U/L)				
GRADE 2 (>2.5-5.0 xULN)	56/635 (8.8) [8.8]	82/638 (12.9) [12.8]	68/878 (7.7) [7.7]	103/896 (11.5) [11.5]
GRADE 3 (>5.0-10.0 xULN)	12/635 (1.9) [1.9]	15/638 (2.4) [2.4]	14/878 (1.6) [1.6]	17/896 (1.9) [1.9]
GRADE 4 (>10.0 xULN)	6/635 (0.9) [0.9]	6/638 (0.9) [0.9]	7/878 (0.8) [0.8]	9/896 (1.0) [1.0]
>= GRADE 3	18/635 (2.8) [2.8]	21/638 (3.3) [3.3]	21/878 (2.4) [2.4]	26/896 (2.9) [2.9]
CREATININE (UMOL/L)				
GRADE 2 (>1.5-3.0 xULN OR >1.5-3.0 xBASELINE)	34/635 (5.4) [5.4]	34/638 (5.3) [5.3]	39/878 (4.4) [4.4]	39/896 (4.4) [4.3]
GRADE 3 (>3.0-6.0 xULN OR >3.0 xBASELINE)	0/635	1/638 (0.2) [0.2]	0/878	2/896 (0.2) [0.2]
GRADE 4 (>6.0 xULN)	0/635	1/638 (0.2) [0.2]	0/878	1/896 (0.1) [0.1]
>= GRADE 3	0/635	2/638 (0.3) [0.3]	0/878	3/896 (0.3) [0.3]

Note: Patients could be included in more than one treatment group.
Toxicity grading scale is based on NCI Common Terminology Criteria version 4.03. Grade must also be more extreme than the baseline grade.
N_OBS indicates the number of subjects with both baseline and post-baseline values for the respective parameter.
xULN = Times upper limit of the normal range.
SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-66.　全ウパダシチニブ併合解析集団（長期）の腎機能障害の発現状況（100 人年あたりの発現件数）

TABLE 2.4__1.2.4.1.16

Treatment-Emergent Renal Dysfunction in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 651.8) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 647.1) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 816.9) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) (PYs = 822.3) Events (E/100 PYs) [SSA E/100 PYs]
Any Adverse Event	2 (0.3) [0.3]	1 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.1) [0.1]
腎および尿路障害	2 (0.3) [0.3]	1 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.1) [0.1]
急性腎障害	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
腎機能障害	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-67. プラセボ対照併合解析集団（投与 24 週時）の MACE 及びその他の委員会判定された心血管イベントの発現状況

TABLE 2.4__1.1.4.1.18

Number and Percentage of Subjects with Treatment-Emergent
Adjudicated MACE and Other Cardiovascular Events by Adjudicated Term
(PBO-Controlled Analysis Set)

Event Category Adjudicated Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
Any adverse event	3 (0.5) [0.5]	1 (0.2) [0.2]	3 (0.5) [0.5]
MACE *	1 (0.2) [0.2]	1 (0.2) [0.2]	0
Cardiovascular death	0	0	0
Fatal acute myocardial infarction	0	0	0
Sudden cardiac death	0	0	0
Heart failure	0	0	0
Cardiovascular procedure-related death	0	0	0
Death due to cardiovascular hemorrhage	0	0	0
Fatal stroke	0	0	0
Pulmonary embolism **	0	0	0
Venous thrombosis **	0	0	0
Non-cardiac/non-neurologic arterial thrombosis	0	0	0
Other	0	0	0
Non-fatal myocardial infarction	1 (0.2) [0.2]	1 (0.2) [0.2]	0
Non-fatal stroke	0	0	0
Undetermined/UNK cause of death	1 (0.2) [0.2]	0	0
Undetermined/UNK cause of death	1 (0.2) [0.2]	0	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
SSA = Study Size Adjusted.
* MACE (Major Adverse Cardiovascular Events), defined as cardiovascular death, non-fatal myocardial infarction and non-fatal stroke.
** Pulmonary embolism and venous thrombosis (under cardiovascular death) is also included in the adjudicated thromboembolic events table.

Program Source Code: [redacted]

TABLE 2.4__1.1.4.1.18

Number and Percentage of Subjects with Treatment-Emergent
Adjudicated MACE and Other Cardiovascular Events by Adjudicated Term
(PBO-Controlled Analysis Set)

Event Category Adjudicated Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
Other cardiovascular events (non-fatal)	1 (0.2) [0.2]	0	3 (0.5) [0.5]
Cardiovascular procedures	0	0	2 (0.3) [0.3]
Unstable angina requiring hospitalization	1 (0.2) [0.2]	0	0
Hospital based treatment for heart failure	0	0	0
Transient ischemic attack	0	0	1 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
SSA = Study Size Adjusted.
* MACE (Major Adverse Cardiovascular Events), defined as cardiovascular death, non-fatal myocardial infarction and non-fatal stroke.
** Pulmonary embolism and venous thrombosis (under cardiovascular death) is also included in the adjudicated thromboembolic events table.

Program Source Code: [redacted]

表 2.7.4.7-68.　全ウパダシチニブ併合解析集団（長期）の MACE 及びその他の委員会判定された心血管イベントの発現状況（100 人年あたりの発現被験者数）

TABLE 2.4__1.2.4.1.18

Treatment-Emergent Adjudicated MACE and Other Cardiovascular Events in Exposure-Adjusted Incidence Rate per 100 Patient Years by Adjudicated Term
(Any Upadacitinib Analysis Set)

Event Category Adjudicated Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) n/PYs (n/100 PYs) [SSA n/100 PYs]
Any Adverse Event	4/649.1 (0.6) [0.6]	5/643.9 (0.8) [0.8]	4/814.2 (0.5) [0.5]	6/819.1 (0.7) [0.7]
MACE *	4/649.1 (0.6) [0.6]	1/646.0 (0.2) [0.2]	4/814.2 (0.5) [0.5]	2/821.2 (0.2) [0.2]
Cardiovascular death	0/651.8	0/647.1	0/816.9	0/822.3
Fatal acute myocardial infarction	0/651.8	0/647.1	0/816.9	0/822.3
Sudden cardiac death	0/651.8	0/647.1	0/816.9	0/822.3
Heart failure	0/651.8	0/647.1	0/816.9	0/822.3
Cardiovascular procedure-related death	0/651.8	0/647.1	0/816.9	0/822.3
Death due to cardiovascular hemorrhage	0/651.8	0/647.1	0/816.9	0/822.3
Fatal stroke	0/651.8	0/647.1	0/816.9	0/822.3
Pulmonary embolism **	0/651.8	0/647.1	0/816.9	0/822.3
Venous thrombosis **	0/651.8	0/647.1	0/816.9	0/822.3
Non-cardiac/non-neurologic arterial thrombosis	0/651.8	0/647.1	0/816.9	0/822.3
Other	0/651.8	0/647.1	0/816.9	0/822.3
Non-fatal myocardial infarction	2/650.1 (0.3) [0.3]	1/646.0 (0.2) [0.2]	2/815.2 (0.2) [0.2]	1/821.2 (0.1) [0.1]
Non-fatal stroke	2/650.8 (0.3) [0.3]	0/647.1	2/815.9 (0.2) [0.2]	1/822.3 (0.1) [0.1]
Undetermined/UNK cause of death	0/651.8	0/647.1	0/816.9	0/822.3
Undetermined/UNK cause of death	0/651.8	0/647.1	0/816.9	0/822.3

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
n/100 PYs = Number of subjects with at least one event per 100 patient-years; SSA = Study size adjusted.
* MACE (Major Adverse Cardiovascular Events), defined as cardiovascular death, non-fatal myocardial infarction and non-fatal stroke.
** Pulmonary embolism and venous thrombosis (under cardiovascular death) is also included in the adjudicated thromboembolic events table.

Program Source Code: [redacted]

TABLE 2.4__1.2.4.1.18

Treatment-Emergent Adjudicated MACE and Other Cardiovascular Events in Exposure-Adjusted Incidence Rate per 100 Patient Years by Adjudicated Term
(Any Upadacitinib Analysis Set)

Event Category Adjudicated Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) n/PYs (n/100 PYs) [SSA n/100 PYs]
Other cardiovascular events (non-fatal)	0/651.8	4/644.9 (0.6) [0.6]	0/816.9	4/820.1 (0.5) [0.5]
Cardiovascular procedures	0/651.8	2/645.9 (0.3) [0.3]	0/816.9	2/821.1 (0.2) [0.2]
Unstable angina requiring hospitalization	0/651.8	0/647.1	0/816.9	0/822.3
Hospital based treatment for heart failure	0/651.8	0/647.1	0/816.9	0/822.3
Transient ischemic attack	0/651.8	2/646.1 (0.3) [0.3]	0/816.9	2/821.2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
n/100 PYs = Number of subjects with at least one event per 100 patient-years; SSA = Study size adjusted.
* MACE (Major Adverse Cardiovascular Events), defined as cardiovascular death, non-fatal myocardial infarction and non-fatal stroke.
** Pulmonary embolism and venous thrombosis (under cardiovascular death) is also included in the adjudicated thromboembolic events table.

Program Source Code: [redacted]

表 2.7.4.7-69.　　プラセボ対照併合解析集団（投与 24 週時）の血栓症の発現状況

TABLE 2.4__1.1.4.1.19

Number and Percentage of Subjects with Treatment-Emergent
Adjudicated Thrombotic Events by Adjudicated Term
(PBO-Controlled Analysis Set)

Event Category Adjudicated Term	Placebo (N = 635) n (%) [SSA%]	Upadacitinib 15 mg QD (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (N = 641) n (%) [SSA%]
Any adverse event	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.2) [0.2]
Venous thromboembolic events (fatal and non-fatal)	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.2) [0.2]
Venous thromboembolic events (fatal) *	0	0	0
Pulmonary embolism	0	0	0
Venous thrombosis	0	0	0
Venous thromboembolic events (non-fatal) **	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.2) [0.2]
Deep vein thrombosis (DVT)	1 (0.2) [0.2]	0	0
Pulmonary embolism (PE)	0	1 (0.2) [0.2]	1 (0.2) [0.2]
DVT and PE (concurrent)	0	0	0
Other venous thrombosis (non-fatal)	0	0	0
Other venous thrombosis (non-fatal)	0	0	0
Arterial thromboembolic events (non-cardiac, non-neurologic)(non-fatal)	0	0	0
Arterial thromboembolic events (non-cardiac, non-neurologic)(non-fatal)	0	0	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
SSA = Study Size Adjusted.
* Venous thromboembolic events (fatal) are also counted under cardiovascular death in the MACE table.
** Venous thromboembolic events (non-fatal) include deep vein thrombosis (DVT) and pulmonary embolism (PE). A concurrent DVT and PE event will be counted under both the 'DVT' row and the 'PE' row as well as under the 'DVT and PE (concurrent)' row.

Program Source Code: [redacted]

表 2.7.4.7-70.　全ウパダシチニブ併合解析集団（長期）の血栓症の発現状況（100 人年あたりの発現被験者数）

TABLE 2.4__1.2.4.1.19

Treatment-Emergent Adjudicated Thrombotic Events in Exposure-Adjusted Incidence Rate per 100 Patient Years by Adjudicated Term
(Any Upadacitinib Analysis Set)

Event Category Adjudicated Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) n/PYs (n/100 PYs) [SSA n/100 PYs]	Upadacitinib Any 30 mg QD (N = 920) n/PYs (n/100 PYs) [SSA n/100 PYs]
Any Adverse Event	4/651.1 (0.6) [0.6]	2/647.1 (0.3) [0.3]	4/816.2 (0.5) [0.5]	2/822.3 (0.2) [0.2]
Venous thromboembolic events (fatal and non-fatal)	4/651.1 (0.6) [0.6]	2/647.1 (0.3) [0.3]	4/816.2 (0.5) [0.5]	2/822.3 (0.2) [0.2]
Venous thromboembolic events (fatal) *	0/651.8	0/647.1	0/816.9	0/822.3
Pulmonary embolism	0/651.8	0/647.1	0/816.9	0/822.3
Venous thrombosis	0/651.8	0/647.1	0/816.9	0/822.3
Venous thromboembolic events (non-fatal) **	4/651.1 (0.6) [0.6]	2/647.1 (0.3) [0.3]	4/816.2 (0.5) [0.5]	2/822.3 (0.2) [0.2]
Deep vein thrombosis (DVT)	2/651.1 (0.3) [0.3]	0/647.1	2/816.2 (0.2) [0.2]	0/822.3
Pulmonary embolism (PE)	3/651.8 (0.5) [0.5]	2/647.1 (0.3) [0.3]	3/816.9 (0.4) [0.4]	2/822.3 (0.2) [0.2]
DVT and PE (concurrent)	1/651.8 (0.2) [0.2]	0/647.1	1/816.9 (0.1) [0.1]	0/822.3
Other venous thrombosis (non-fatal)	0/651.8	0/647.1	0/816.9	0/822.3
Other venous thrombosis (non-fatal)	0/651.8	0/647.1	0/816.9	0/822.3
Arterial thromboembolic events (non-cardiac, non-neurologic)(non-fatal)	0/651.8	0/647.1	0/816.9	0/822.3
Arterial thromboembolic events (non-cardiac, non-neurologic)(non-fatal)	0/651.8	0/647.1	0/816.9	0/822.3

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
n/100 PYs = Number of subjects with at least one event per 100 patient-years; SSA = Study size adjusted.
* Venous thromboembolic events (fatal) are also counted under cardiovascular death in the MACE table.
** Venous thromboembolic events (non-fatal) include deep vein thrombosis (DVT) and pulmonary embolism (PE). A concurrent DVT and PE event will be counted under both the 'DVT' row and the 'PE' row as well as under the 'DVT and PE (concurrent)' row.

Program Source Code: [redacted]

表 2.7.4.7-71. プラセボ対照併合解析集団（投与 24 週時）の臨床検査値のベースラインから投与後のシフトテーブル

TABLE 2.5__1.1.2

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set)

Variable / Treatment / Baseline Value	Minimum Value: Grade 0 n (%) [SSA %]	Grade 1 n (%) [SSA %]	Grade 2 n (%) [SSA %]	Grade 3 n (%) [SSA %]	Grade 4 n (%) [SSA %]	Missing n (%) [SSA %]
HEMOGLOBIN (G/L)						
Placebo (N = 635)						
GRADE 0	509 (80.2) [80.2]	65 (10.2) [10.2]	4 (0.6) [0.6]	0	0	7 (1.1) [1.1]
GRADE 1	3 (0.5) [0.5]	36 (5.7) [5.7]	8 (1.3) [1.3]	0	0	1 (0.2) [0.2]
GRADE 2	0	0	2 (0.3) [0.3]	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 15 mg QD (N = 640)						
GRADE 0	521 (81.4) [81.4]	57 (8.9) [8.9]	1 (0.2) [0.2]	0	0	2 (0.3) [0.3]
GRADE 1	5 (0.8) [0.8]	37 (5.8) [5.8]	9 (1.4) [1.4]	0	0	3 (0.5) [0.5]
GRADE 2	1 (0.2) [0.2]	1 (0.2) [0.2]	3 (0.5) [0.5]	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 30 mg QD (N = 641)						
GRADE 0	440 (68.6) [68.7]	126 (19.7) [19.6]	12 (1.9) [1.9]	2 (0.3) [0.3]	0	3 (0.5) [0.5]
GRADE 1	9 (1.4) [1.4]	39 (6.1) [6.1]	7 (1.1) [1.1]	1 (0.2) [0.2]	0	0
GRADE 2	0	0	2 (0.3) [0.3]	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set)

Variable / Treatment / Baseline Value	Maximum Value: Grade 0 n (%) [SSA %]	Grade 1 n (%) [SSA %]	Grade 2 n (%) [SSA %]	Grade 3 n (%) [SSA %]	Grade 4 n (%) [SSA %]	Missing n (%) [SSA %]
PLATELETS (10^9/L)						
Placebo (N = 635)						
GRADE 0	607 (95.6) [95.6]	13 (2.0) [2.0]	0	0	0	9 (1.4) [1.4]
GRADE 1	3 (0.5) [0.5]	2 (0.3) [0.3]	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	1 (0.2) [0.2]	0	0	0	0	0
Upadacitinib 15 mg QD (N = 640)						
GRADE 0	615 (96.1) [96.1]	11 (1.7) [1.7]	2 (0.3) [0.3]	0	0	4 (0.6) [0.6]
GRADE 1	0	7 (1.1) [1.1]	0	0	0	1 (0.2) [0.2]
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 30 mg QD (N = 641)						
GRADE 0	608 (94.9) [94.8]	17 (2.7) [2.7]	2 (0.3) [0.3]	0	0	3 (0.5) [0.5]
GRADE 1	5 (0.8) [0.8]	4 (0.6) [0.6]	0	1 (0.2) [0.2]	0	1 (0.2) [0.2]
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set)

Variable / Treatment / Baseline Value	Minimum Value: Grade 0 n (%) [SSA %]	Grade 1 n (%) [SSA %]	Grade 2 n (%) [SSA %]	Grade 3 n (%) [SSA %]	Grade 4 n (%) [SSA %]	Missing n (%) [SSA %]
LEUKOCYTES (10^9/L)						
Placebo (N = 635)						
GRADE 0	586 (92.3) [92.3]	31 (4.9) [4.9]	0	1 (0.2) [0.2]	0	8 (1.3) [1.3]
GRADE 1	2 (0.3) [0.3]	7 (1.1) [1.1]	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 15 mg QD (N = 640)						
GRADE 0	549 (85.8) [85.8]	58 (9.1) [9.0]	19 (3.0) [3.0]	0	0	5 (0.8) [0.8]
GRADE 1	2 (0.3) [0.3]	2 (0.3) [0.3]	4 (0.6) [0.6]	0	0	0
GRADE 2	0	0	1 (0.2) [0.2]	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 30 mg QD (N = 641)						
GRADE 0	520 (81.1) [81.1]	83 (12.9) [12.9]	25 (3.9) [3.9]	2 (0.3) [0.3]	0	3 (0.5) [0.5]
GRADE 1	3 (0.5) [0.5]	3 (0.5) [0.5]	1 (0.2) [0.2]	0	0	0
GRADE 2	0	0	1 (0.2) [0.2]	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set)

Variable / Treatment / Baseline Value	Minimum Value: Grade 0 n (%) [SSA %]	Grade 1 n (%) [SSA %]	Grade 2 n (%) [SSA %]	Grade 3 n (%) [SSA %]	Grade 4 n (%) [SSA %]	Missing n (%) [SSA %]
NEUTROPHILS (10^9/L)						
Placebo (N = 635)						
GRADE 0	593 (93.4) [93.4]	19 (3.0) [3.0]	5 (0.8) [0.8]	2 (0.3) [0.3]	0	7 (1.1) [1.1]
GRADE 1	5 (0.8) [0.8]	2 (0.3) [0.3]	0	0	0	1 (0.2) [0.2]
GRADE 2	0	1 (0.2) [0.2]	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 15 mg QD (N = 640)						
GRADE 0	536 (83.8) [83.7]	72 (11.3) [11.2]	19 (3.0) [3.0]	2 (0.3) [0.3]	0	5 (0.8) [0.8]
GRADE 1	0	3 (0.5) [0.5]	1 (0.2) [0.2]	2 (0.3) [0.3]	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 30 mg QD (N = 641)						
GRADE 0	487 (76.0) [76.0]	94 (14.7) [14.7]	42 (6.6) [6.6]	10 (1.6) [1.6]	0	3 (0.5) [0.5]
GRADE 1	0	2 (0.3) [0.3]	1 (0.2) [0.2]	0	0	0
GRADE 2	0	1 (0.2) [0.2]	0	0	0	0
GRADE 3	1 (0.2) [0.2]	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set)

Variable / Treatment / Baseline Value	Minimum Value: Grade 0 n (%) [SSA %]	Grade 1 n (%) [SSA %]	Grade 2 n (%) [SSA %]	Grade 3 n (%) [SSA %]	Grade 4 n (%) [SSA %]	Missing n (%) [SSA %]
LYMPHOCYTES (10^9/L)						
Placebo (N = 635)						
GRADE 0	571 (89.9) [89.9]	20 (3.1) [3.1]	22 (3.5) [3.5]	1 (0.2) [0.2]	0	7 (1.1) [1.1]
GRADE 1	3 (0.5) [0.5]	0	2 (0.3) [0.3]	0	0	1 (0.2) [0.2]
GRADE 2	3 (0.5) [0.5]	1 (0.2) [0.2]	3 (0.5) [0.5]	0	0	0
GRADE 3	0	0	1 (0.2) [0.2]	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 15 mg QD (N = 640)						
GRADE 0	575 (89.8) [89.9]	13 (2.0) [2.0]	30 (4.7) [4.7]	5 (0.8) [0.8]	0	4 (0.6) [0.6]
GRADE 1	5 (0.8) [0.8]	0	2 (0.3) [0.3]	0	0	0
GRADE 2	0	1 (0.2) [0.2]	2 (0.3) [0.3]	0	0	1 (0.2) [0.2]
GRADE 3	1 (0.2) [0.2]	0	0	1 (0.2) [0.2]	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 30 mg QD (N = 641)						
GRADE 0	541 (84.4) [84.4]	19 (3.0) [3.0]	50 (7.8) [7.8]	10 (1.6) [1.6]	0	3 (0.5) [0.5]
GRADE 1	4 (0.6) [0.6]	1 (0.2) [0.2]	4 (0.6) [0.6]	0	0	0
GRADE 2	4 (0.6) [0.6]	1 (0.2) [0.2]	3 (0.5) [0.5]	1 (0.2) [0.2]	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set)

Variable / Treatment / Baseline Value	Maximum Value: Grade 0 n (%) [SSA %]	Grade 1 n (%) [SSA %]	Grade 2 n (%) [SSA %]	Grade 3 n (%) [SSA %]	Grade 4 n (%) [SSA %]	Missing n (%) [SSA %]
ALANINE AMINOTRANSFERASE (U/L)						
Placebo (N = 635)						
GRADE 0	416 (65.5) [65.5]	113 (17.8) [17.8]	5 (0.8) [0.8]	4 (0.6) [0.6]	0	9 (1.4) [1.4]
GRADE 1	16 (2.5) [2.5]	62 (9.8) [9.8]	2 (0.3) [0.3]	3 (0.5) [0.5]	0	0
GRADE 2	0	3 (0.5) [0.5]	0	1 (0.2) [0.2]	0	0
GRADE 3	0	0	0	1 (0.2) [0.2]	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 15 mg QD (N = 640)						
GRADE 0	351 (54.8) [54.9]	192 (30.0) [30.0]	6 (0.9) [0.9]	4 (0.6) [0.6]	0	5 (0.8) [0.8]
GRADE 1	6 (0.9) [0.9]	67 (10.5) [10.5]	6 (0.9) [0.9]	1 (0.2) [0.2]	0	0
GRADE 2	0	0	1 (0.2) [0.2]	1 (0.2) [0.2]	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 30 mg QD (N = 641)						
GRADE 0	308 (48.0) [48.0]	226 (35.3) [35.2]	9 (1.4) [1.4]	5 (0.8) [0.8]	0	2 (0.3) [0.3]
GRADE 1	12 (1.9) [1.9]	59 (9.2) [9.2]	16 (2.5) [2.5]	1 (0.2) [0.2]	0	1 (0.2) [0.2]
GRADE 2	0	2 (0.3) [0.3]	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set)

Variable / Treatment / Baseline Value	Maximum Value: Grade 0 n (%) [SSA %]	Grade 1 n (%) [SSA %]	Grade 2 n (%) [SSA %]	Grade 3 n (%) [SSA %]	Grade 4 n (%) [SSA %]	Missing n (%) [SSA %]
ASPARTATE AMINOTRANSFERASE (U/L)						
Placebo (N = 635)						
GRADE 0	484 (76.2) [76.2]	81 (12.8) [12.8]	7 (1.1) [1.1]	0	0	9 (1.4) [1.4]
GRADE 1	12 (1.9) [1.9]	33 (5.2) [5.2]	3 (0.5) [0.5]	3 (0.5) [0.5]	0	0
GRADE 2	0	1 (0.2) [0.2]	0	0	0	0
GRADE 3	0	1 (0.2) [0.2]	0	1 (0.2) [0.2]	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 15 mg QD (N = 640)						
GRADE 0	415 (64.8) [64.9]	168 (26.3) [26.2]	5 (0.8) [0.8]	2 (0.3) [0.3]	0	5 (0.8) [0.8]
GRADE 1	3 (0.5) [0.5]	40 (6.3) [6.2]	2 (0.3) [0.3]	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 30 mg QD (N = 641)						
GRADE 0	353 (55.1) [55.1]	225 (35.1) [35.1]	6 (0.9) [0.9]	3 (0.5) [0.5]	1 (0.2) [0.2]	2 (0.3) [0.3]
GRADE 1	11 (1.7) [1.7]	36 (5.6) [5.6]	2 (0.3) [0.3]	0	0	1 (0.2) [0.2]
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	1 (0.2) [0.2]	0	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set)

Variable / Treatment / Baseline Value	Maximum Value: Grade 0 n (%) [SSA %]	Grade 1 n (%) [SSA %]	Grade 2 n (%) [SSA %]	Grade 3 n (%) [SSA %]	Grade 4 n (%) [SSA %]	Missing n (%) [SSA %]
CREATINE KINASE (U/L)						
Placebo (N = 635)						
GRADE 0	511 (80.5) [80.5]	69 (10.9) [10.9]	4 (0.6) [0.6]	3 (0.5) [0.5]	3 (0.5) [0.5]	8 (1.3) [1.3]
GRADE 1	7 (1.1) [1.1]	18 (2.8) [2.8]	4 (0.6) [0.6]	1 (0.2) [0.2]	0	0
GRADE 2	3 (0.5) [0.5]	2 (0.3) [0.3]	1 (0.2) [0.2]	0	0	0
GRADE 3	1 (0.2) [0.2]	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 15 mg QD (N = 640)						
GRADE 0	375 (58.6) [58.6]	202 (31.6) [31.5]	25 (3.9) [3.9]	6 (0.9) [0.9]	2 (0.3) [0.3]	5 (0.8) [0.8]
GRADE 1	2 (0.3) [0.3]	12 (1.9) [1.9]	10 (1.6) [1.6]	1 (0.2) [0.2]	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 30 mg QD (N = 641)						
GRADE 0	269 (42.0) [42.0]	292 (45.6) [45.6]	40 (6.2) [6.2]	10 (1.6) [1.6]	4 (0.6) [0.6]	3 (0.5) [0.5]
GRADE 1	0	9 (1.4) [1.4]	9 (1.4) [1.4]	2 (0.3) [0.3]	0	0
GRADE 2	1 (0.2) [0.2]	0	0	0	0	0
GRADE 3	0	2 (0.3) [0.3]	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set)

Variable / Treatment / Baseline Value	Maximum Value: Grade 0 n (%) [SSA %]	Grade 1 n (%) [SSA %]	Grade 2 n (%) [SSA %]	Grade 3 n (%) [SSA %]	Grade 4 n (%) [SSA %]	Missing n (%) [SSA %]
CREATININE (UMOL/L)						
Placebo (N = 635)						
GRADE 0	137 (21.6) [21.6]	472 (74.3) [74.3]	16 (2.5) [2.5]	0	0	7 (1.1) [1.1]
GRADE 1	0	2 (0.3) [0.3]	0	0	0	1 (0.2) [0.2]
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 15 mg QD (N = 640)						
GRADE 0	73 (11.4) [11.4]	543 (84.8) [84.8]	13 (2.0) [2.0]	0	0	5 (0.8) [0.8]
GRADE 1	3 (0.5) [0.5]	2 (0.3) [0.3]	1 (0.2) [0.2]	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 30 mg QD (N = 641)						
GRADE 0	46 (7.2) [7.1]	562 (87.7) [87.7]	22 (3.4) [3.4]	1 (0.2) [0.2]	0	3 (0.5) [0.5]
GRADE 1	0	7 (1.1) [1.1]	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set)

Variable / Treatment / Baseline Value	Maximum Value: < 5.17 n (%) [SSA %]	Maximum Value: >= 5.17 and < 6.21 n (%) [SSA %]	Maximum Value: >= 6.21 n (%) [SSA %]	Maximum Value: Missing n (%) [SSA %]
CHOLESTEROL (MMOL/L)				
Placebo (N = 635)				
< 5.17	265 (41.7) [41.7]	67 (10.6) [10.5]	16 (2.5) [2.5]	13 (2.0) [2.0]
>= 5.17 and < 6.21	15 (2.4) [2.4]	125 (19.7) [19.7]	49 (7.7) [7.7]	8 (1.3) [1.3]
>= 6.21	1 (0.2) [0.2]	14 (2.2) [2.2]	57 (9.0) [9.0]	0
Missing	2 (0.3) [0.3]	2 (0.3) [0.3]	1 (0.2) [0.2]	0
Upadacitinib 15 mg QD (N = 640)				
< 5.17	158 (24.7) [24.7]	151 (23.6) [23.6]	51 (8.0) [8.0]	9 (1.4) [1.4]
>= 5.17 and < 6.21	7 (1.1) [1.1]	53 (8.3) [8.3]	125 (19.5) [19.5]	3 (0.5) [0.5]
>= 6.21	1 (0.2) [0.2]	5 (0.8) [0.8]	72 (11.3) [11.3]	1 (0.2) [0.2]
Missing	0	1 (0.2) [0.2]	3 (0.5) [0.5]	0
Upadacitinib 30 mg QD (N = 641)				
< 5.17	142 (22.2) [22.1]	158 (24.6) [24.6]	79 (12.3) [12.3]	3 (0.5) [0.5]
>= 5.17 and < 6.21	3 (0.5) [0.5]	41 (6.4) [6.4]	117 (18.3) [18.3]	1 (0.2) [0.2]
>= 6.21	0	4 (0.6) [0.6]	87 (13.6) [13.6]	1 (0.2) [0.2]
Missing	1 (0.2) [0.2]	1 (0.2) [0.2]	3 (0.5) [0.5]	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set)

Variable Treatment Baseline Value	Maximum Value < 1.03 n (%) [SSA %]	Maximum Value >= 1.03 n (%) [SSA %]	Maximum Value Missing n (%) [SSA %]
HDL CHOLESTEROL (MMOL/L)			
Placebo (N = 635)			
< 1.03	65 (10.2) [10.2]	57 (9.0) [9.0]	3 (0.5) [0.5]
>= 1.03	17 (2.7) [2.7]	470 (74.0) [74.0]	18 (2.8) [2.8]
Missing	1 (0.2) [0.2]	4 (0.6) [0.6]	0
Upadacitinib 15 mg QD (N = 640)			
< 1.03	21 (3.3) [3.3]	92 (14.4) [14.4]	3 (0.5) [0.5]
>= 1.03	1 (0.2) [0.2]	508 (79.4) [79.3]	10 (1.6) [1.6]
Missing	1 (0.2) [0.2]	4 (0.6) [0.6]	0
Upadacitinib 30 mg QD (N = 641)			
< 1.03	21 (3.3) [3.3]	103 (16.1) [16.0]	0
>= 1.03	1 (0.2) [0.2]	506 (78.9) [79.0]	5 (0.8) [0.8]
Missing	0	5 (0.8) [0.8]	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set)

Variable Treatment Baseline Value	Maximum Value < 3.36 n (%) [SSA %]	Maximum Value >= 3.36 and < 4.14 n (%) [SSA %]	Maximum Value >= 4.14 n (%) [SSA %]	Maximum Value Missing n (%) [SSA %]
LDL CHOLESTEROL (MMOL/L)				
Placebo (N = 635)				
< 3.36	337 (53.1) [53.1]	72 (11.3) [11.3]	20 (3.1) [3.1]	20 (3.1) [3.2]
>= 3.36 and < 4.14	17 (2.7) [2.7]	69 (10.9) [10.9]	39 (6.1) [6.1]	2 (0.3) [0.3]
>= 4.14	1 (0.2) [0.2]	12 (1.9) [1.9]	34 (5.4) [5.4]	0
Missing	8 (1.3) [1.3]	1 (0.2) [0.2]	3 (0.5) [0.5]	0
Upadacitinib 15 mg QD (N = 640)				
< 3.36	271 (42.3) [42.4]	110 (17.2) [17.2]	48 (7.5) [7.5]	12 (1.9) [1.9]
>= 3.36 and < 4.14	5 (0.8) [0.8]	47 (7.3) [7.3]	70 (10.9) [10.9]	2 (0.3) [0.3]
>= 4.14	0	5 (0.8) [0.8]	51 (8.0) [8.0]	0
Missing	7 (1.1) [1.1]	4 (0.6) [0.6]	6 (0.9) [0.9]	2 (0.3) [0.3]
Upadacitinib 30 mg QD (N = 641)				
< 3.36	255 (39.8) [39.7]	125 (19.5) [19.5]	60 (9.4) [9.3]	5 (0.8) [0.8]
>= 3.36 and < 4.14	11 (1.7) [1.7]	30 (4.7) [4.7]	73 (11.4) [11.4]	2 (0.3) [0.3]
>= 4.14	0	3 (0.5) [0.5]	60 (9.4) [9.4]	1 (0.2) [0.2]
Missing	5 (0.8) [0.8]	3 (0.5) [0.5]	5 (0.8) [0.8]	3 (0.5) [0.5]

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set)

Variable / Treatment / Baseline Value	Maximum Value: < 1.69 n (%) [SSA %]	Maximum Value: >= 1.69 and < 2.26 n (%) [SSA %]	Maximum Value: >= 2.26 n (%) [SSA %]	Maximum Value: Missing n (%) [SSA %]
TRIGLYCERIDES (MMOL/L)				
Placebo (N = 635)				
< 1.69	273 (43.0) [43.0]	74 (11.7) [11.7]	32 (5.0) [5.0]	12 (1.9) [1.9]
>= 1.69 and < 2.26	30 (4.7) [4.7]	44 (6.9) [6.9]	38 (6.0) [6.0]	6 (0.9) [0.9]
>= 2.26	5 (0.8) [0.8]	16 (2.5) [2.5]	96 (15.1) [15.1]	3 (0.5) [0.5]
Missing	4 (0.6) [0.6]	2 (0.3) [0.3]	0	0
Upadacitinib 15 mg QD (N = 640)				
< 1.69	276 (43.1) [43.1]	82 (12.8) [12.8]	59 (9.2) [9.2]	8 (1.3) [1.2]
>= 1.69 and < 2.26	12 (1.9) [1.9]	27 (4.2) [4.2]	67 (10.5) [10.5]	2 (0.3) [0.3]
>= 2.26	3 (0.5) [0.5]	9 (1.4) [1.4]	88 (13.8) [13.8]	1 (0.2) [0.2]
Missing	1 (0.2) [0.2]	2 (0.3) [0.3]	2 (0.3) [0.3]	1 (0.2) [0.2]
Upadacitinib 30 mg QD (N = 641)				
< 1.69	263 (41.0) [41.0]	92 (14.4) [14.4]	71 (11.1) [11.1]	4 (0.6) [0.6]
>= 1.69 and < 2.26	22 (3.4) [3.4]	21 (3.3) [3.3]	61 (9.5) [9.5]	1 (0.2) [0.2]
>= 2.26	5 (0.8) [0.8]	11 (1.7) [1.7]	85 (13.3) [13.3]	0
Missing	1 (0.2) [0.2]	2 (0.3) [0.3]	2 (0.3) [0.3]	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-72. プラセボ対照併合解析集団（投与 24 週時）の日本人部分集団の臨床検査値のベースラインから投与後のシフトテーブル

TABLE 2.5__1.1.2_J

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set, Japanese Population)

Variable / Treatment / Baseline Value	Minimum Value: Grade 0 n (%) [SSA %]	Grade 1 n (%) [SSA %]	Grade 2 n (%) [SSA %]	Grade 3 n (%) [SSA %]	Grade 4 n (%) [SSA %]	Missing n (%) [SSA %]
HEMOGLOBIN (G/L)						
Placebo (N = 15)						
GRADE 0	14 (93.3) [93.5]	1 (6.7) [6.5]	0	0	0	0
GRADE 1	0	0	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 15 mg QD (N = 17)						
GRADE 0	14 (82.4) [82.0]	1 (5.9) [6.0]	0	0	0	0
GRADE 1	1 (5.9) [6.0]	0	1 (5.9) [6.0]	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 30 mg QD (N = 18)						
GRADE 0	9 (50.0) [50.1]	5 (27.8) [27.8]	0	1 (5.6) [5.6]	0	0
GRADE 1	0	1 (5.6) [5.5]	1 (5.6) [5.5]	1 (5.6) [5.6]	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2_J

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set, Japanese Population)

Variable / Treatment / Baseline Value	Maximum Value: Grade 0 n (%) [SSA %]	Grade 1 n (%) [SSA %]	Grade 2 n (%) [SSA %]	Grade 3 n (%) [SSA %]	Grade 4 n (%) [SSA %]	Missing n (%) [SSA %]
PLATELETS (10^9/L)						
Placebo (N = 15)						
GRADE 0	15 (100) [100]	0	0	0	0	0
GRADE 1	0	0	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 15 mg QD (N = 17)						
GRADE 0	16 (94.1) [94.0]	0	0	0	0	0
GRADE 1	0	1 (5.9) [6.0]	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 30 mg QD (N = 18)						
GRADE 0	18 (100) [100]	0	0	0	0	0
GRADE 1	0	0	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2_J

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set, Japanese Population)

Variable / Treatment / Baseline Value	Minimum Value: Grade 0 n (%) [SSA %]	Grade 1 n (%) [SSA %]	Grade 2 n (%) [SSA %]	Grade 3 n (%) [SSA %]	Grade 4 n (%) [SSA %]	Missing n (%) [SSA %]
LEUKOCYTES (10^9/L)						
Placebo (N = 15)						
GRADE 0	14 (93.3) [93.5]	1 (6.7) [6.5]	0	0	0	0
GRADE 1	0	0	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 15 mg QD (N = 17)						
GRADE 0	13 (76.5) [76.5]	2 (11.8) [11.5]	1 (5.9) [6.0]	0	0	0
GRADE 1	0	0	1 (5.9) [6.0]	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 30 mg QD (N = 18)						
GRADE 0	14 (77.8) [77.9]	2 (11.1) [11.1]	0	0	0	0
GRADE 1	1 (5.6) [5.6]	0	1 (5.6) [5.5]	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2_J

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set, Japanese Population)

Variable / Treatment / Baseline Value	Minimum Value: Grade 0 n (%) [SSA %]	Grade 1 n (%) [SSA %]	Grade 2 n (%) [SSA %]	Grade 3 n (%) [SSA %]	Grade 4 n (%) [SSA %]	Missing n (%) [SSA %]
NEUTROPHILS (10^9/L)						
Placebo (N = 15)						
GRADE 0	14 (93.3) [93.5]	1 (6.7) [6.5]	0	0	0	0
GRADE 1	0	0	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 15 mg QD (N = 17)						
GRADE 0	13 (76.5) [76.0]	1 (5.9) [6.0]	2 (11.8) [12.0]	0	0	0
GRADE 1	0	0	0	1 (5.9) [6.0]	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 30 mg QD (N = 18)						
GRADE 0	12 (66.7) [66.7]	4 (22.2) [22.2]	0	1 (5.6) [5.5]	0	0
GRADE 1	0	0	0	0	0	0
GRADE 2	0	1 (5.6) [5.6]	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2_J

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set, Japanese Population)

Variable / Treatment / Baseline Value	Minimum Value: Grade 0 n (%) [SSA %]	Grade 1 n (%) [SSA %]	Grade 2 n (%) [SSA %]	Grade 3 n (%) [SSA %]	Grade 4 n (%) [SSA %]	Missing n (%) [SSA %]
LYMPHOCYTES (10^9/L)						
Placebo (N = 15)						
GRADE 0	14 (93.3) [93.5]	0	1 (6.7) [6.5]	0	0	0
GRADE 1	0	0	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 15 mg QD (N = 17)						
GRADE 0	15 (88.2) [88.5]	0	2 (11.8) [11.5]	0	0	0
GRADE 1	0	0	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 30 mg QD (N = 18)						
GRADE 0	14 (77.8) [77.9]	1 (5.6) [5.5]	2 (11.1) [11.1]	0	0	0
GRADE 1	0	0	1 (5.6) [5.5]	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2_J

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set, Japanese Population)

Variable / Treatment / Baseline Value	Maximum Value: Grade 0 n (%) [SSA %]	Grade 1 n (%) [SSA %]	Grade 2 n (%) [SSA %]	Grade 3 n (%) [SSA %]	Grade 4 n (%) [SSA %]	Missing n (%) [SSA %]
ALANINE AMINOTRANSFERASE (U/L)						
Placebo (N = 15)						
GRADE 0	9 (60.0) [60.2]	3 (20.0) [20.3]	0	0	0	0
GRADE 1	0	3 (20.0) [19.5]	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 15 mg QD (N = 17)						
GRADE 0	9 (52.9) [53.0]	3 (17.6) [17.5]	1 (5.9) [5.5]	0	0	0
GRADE 1	0	3 (17.6) [18.0]	1 (5.9) [6.0]	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 30 mg QD (N = 18)						
GRADE 0	9 (50.0) [49.9]	8 (44.4) [44.5]	0	0	0	0
GRADE 1	0	1 (5.6) [5.6]	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2_J

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set, Japanese Population)

Variable / Treatment / Baseline Value	Maximum Value: Grade 0 n (%) [SSA %]	Grade 1 n (%) [SSA %]	Grade 2 n (%) [SSA %]	Grade 3 n (%) [SSA %]	Grade 4 n (%) [SSA %]	Missing n (%) [SSA %]
ASPARTATE AMINOTRANSFERASE (U/L)						
Placebo (N = 15)						
GRADE 0	12 (80.0) [80.5]	2 (13.3) [13.0]	0	0	0	0
GRADE 1	0	1 (6.7) [6.5]	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 15 mg QD (N = 17)						
GRADE 0	6 (35.3) [35.5]	7 (41.2) [40.5]	0	0	0	0
GRADE 1	0	4 (23.5) [24.0]	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 30 mg QD (N = 18)						
GRADE 0	9 (50.0) [49.9]	8 (44.4) [44.6]	0	0	0	0
GRADE 1	1 (5.6) [5.6]	0	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2_J

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set, Japanese Population)

Variable / Treatment / Baseline Value	Maximum Value: Grade 0 n (%) [SSA %]	Grade 1 n (%) [SSA %]	Grade 2 n (%) [SSA %]	Grade 3 n (%) [SSA %]	Grade 4 n (%) [SSA %]	Missing n (%) [SSA %]
CREATINE KINASE (U/L)						
Placebo (N = 15)						
GRADE 0	12 (80.0) [80.5]	2 (13.3) [13.0]	0	0	0	0
GRADE 1	0	0	0	0	0	0
GRADE 2	0	1 (6.7) [6.5]	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 15 mg QD (N = 17)						
GRADE 0	12 (70.6) [70.5]	4 (23.5) [24.0]	1 (5.9) [5.5]	0	0	0
GRADE 1	0	0	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 30 mg QD (N = 18)						
GRADE 0	7 (38.9) [38.9]	10 (55.6) [55.5]	1 (5.6) [5.6]	0	0	0
GRADE 1	0	0	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2_J

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set, Japanese Population)

Variable / Treatment / Baseline Value	Maximum Value: Grade 0 n (%) [SSA %]	Grade 1 n (%) [SSA %]	Grade 2 n (%) [SSA %]	Grade 3 n (%) [SSA %]	Grade 4 n (%) [SSA %]	Missing n (%) [SSA %]
CREATININE (UMOL/L)						
Placebo (N = 15)						
GRADE 0	5 (33.3) [32.5]	10 (66.7) [67.5]	0	0	0	0
GRADE 1	0	0	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 15 mg QD (N = 17)						
GRADE 0	3 (17.6) [17.5]	13 (76.5) [76.5]	1 (5.9) [6.0]	0	0	0
GRADE 1	0	0	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0
Upadacitinib 30 mg QD (N = 18)						
GRADE 0	1 (5.6) [5.5]	17 (94.4) [94.5]	0	0	0	0
GRADE 1	0	0	0	0	0	0
GRADE 2	0	0	0	0	0	0
GRADE 3	0	0	0	0	0	0
GRADE 4	0	0	0	0	0	0
Missing	0	0	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2_J

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set, Japanese Population)

Variable Treatment Baseline Value	Maximum Value < 5.17 n (%) [SSA %]	Maximum Value >= 5.17 and < 6.21 n (%) [SSA %]	Maximum Value >= 6.21 n (%) [SSA %]	Maximum Value Missing n (%) [SSA %]
CHOLESTEROL (MMOL/L)				
Placebo (N = 15)				
< 5.17	4 (26.7) [27.7]	2 (13.3) [13.0]	0	0
>= 5.17 and < 6.21	0	6 (40.0) [39.8]	0	0
>= 6.21	0	0	3 (20.0) [19.5]	0
Missing	0	0	0	0
Upadacitinib 15 mg QD (N = 17)				
< 5.17	2 (11.8) [12.0]	6 (35.3) [35.5]	3 (17.6) [17.5]	0
>= 5.17 and < 6.21	0	1 (5.9) [6.0]	1 (5.9) [5.5]	1 (5.9) [6.0]
>= 6.21	0	0	3 (17.6) [17.5]	0
Missing	0	0	0	0
Upadacitinib 30 mg QD (N = 18)				
< 5.17	4 (22.2) [22.3]	2 (11.1) [11.1]	6 (33.3) [33.3]	0
>= 5.17 and < 6.21	0	1 (5.6) [5.6]	3 (16.7) [16.6]	0
>= 6.21	0	0	2 (11.1) [11.1]	0
Missing	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2_J

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set, Japanese Population)

Variable Treatment Baseline Value	Maximum Value < 1.03 n (%) [SSA %]	Maximum Value >= 1.03 n (%) [SSA %]	Maximum Value Missing n (%) [SSA %]
HDL CHOLESTEROL (MMOL/L)			
Placebo (N = 15)			
< 1.03	1 (6.7) [7.3]	0	0
>= 1.03	1 (6.7) [6.5]	13 (86.7) [86.2]	0
Missing	0	0	0
Upadacitinib 15 mg QD (N = 17)			
< 1.03	0	3 (17.6) [18.0]	1 (5.9) [6.0]
>= 1.03	0	13 (76.5) [76.0]	0
Missing	0	0	0
Upadacitinib 30 mg QD (N = 18)			
< 1.03	1 (5.6) [5.6]	1 (5.6) [5.6]	0
>= 1.03	0	16 (88.9) [88.9]	0
Missing	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2_J

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set, Japanese Population)

Variable / Treatment / Baseline Value	Maximum Value: < 3.36 n (%) [SSA %]	Maximum Value: >= 3.36 and < 4.14 n (%) [SSA %]	Maximum Value: >= 4.14 n (%) [SSA %]	Maximum Value: Missing n (%) [SSA %]
LDL CHOLESTEROL (MMOL/L)				
Placebo (N = 15)				
< 3.36	7 (46.7) [47.2]	3 (20.0) [19.5]	0	0
>= 3.36 and < 4.14	0	2 (13.3) [13.8]	1 (6.7) [6.5]	0
>= 4.14	0	1 (6.7) [6.5]	1 (6.7) [6.5]	0
Missing	0	0	0	0
Upadacitinib 15 mg QD (N = 17)				
< 3.36	7 (41.2) [41.5]	3 (17.6) [17.5]	2 (11.8) [12.0]	0
>= 3.36 and < 4.14	1 (5.9) [6.0]	1 (5.9) [5.5]	1 (5.9) [5.5]	1 (5.9) [6.0]
>= 4.14	0	0	1 (5.9) [6.0]	0
Missing	0	0	0	0
Upadacitinib 30 mg QD (N = 18)				
< 3.36	4 (22.2) [22.3]	2 (11.1) [11.1]	6 (33.3) [33.3]	0
>= 3.36 and < 4.14	0	1 (5.6) [5.6]	3 (16.7) [16.6]	0
>= 4.14	0	0	2 (11.1) [11.1]	0
Missing	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.5__1.1.2_J

Shift Analysis from Baseline to Post-Baseline in Selected Laboratory Values
(PBO-Controlled Analysis Set, Japanese Population)

Variable Treatment Baseline Value	Maximum Value < 1.69 n (%) [SSA %]	Maximum Value >= 1.69 and < 2.26 n (%) [SSA %]	Maximum Value >= 2.26 n (%) [SSA %]	Maximum Value Missing n (%) [SSA %]
TRIGLYCERIDES (MMOL/L)				
Placebo (N = 15)				
< 1.69	7 (46.7) [47.2]	1 (6.7) [6.5]	0	0
>= 1.69 and < 2.26	0	1 (6.7) [6.5]	4 (26.7) [26.8]	0
>= 2.26	0	0	2 (13.3) [13.0]	0
Missing	0	0	0	0
Upadacitinib 15 mg QD (N = 17)				
< 1.69	8 (47.1) [47.0]	3 (17.6) [18.0]	1 (5.9) [6.0]	0
>= 1.69 and < 2.26	0	1 (5.9) [5.5]	2 (11.8) [11.5]	0
>= 2.26	0	0	2 (11.8) [12.0]	0
Missing	0	0	0	0
Upadacitinib 30 mg QD (N = 18)				
< 1.69	8 (44.4) [44.4]	5 (27.8) [27.8]	3 (16.7) [16.6]	0
>= 1.69 and < 2.26	0	0	1 (5.6) [5.6]	0
>= 2.26	0	0	1 (5.6) [5.6]	0
Missing	0	0	0	0

Note: SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-73. 投与 24 週時データカットオフまでの有害事象の概要（安全性解析対象集団，日本人部分集団）：M15-572 試験

TABLE 14.3__1.1.1.3_J

Overview of Number and Percentage of Subjects with Treatment-Emergent Adverse Events - Long Term
(Safety Analysis Set, Japanese Population)

	---- UPA ------			-- UPA VS ADA (95% CI)[A] --	
	15 mg QD (N = 5) n (%)	30 mg QD (N = 6) n (%)	ADA 40 mg EOW (N = 4) n (%)	15 mg QD VS ADA	30 mg QD VS ADA
Subjects with:					
Any adverse event (AE)	4 (80.0)	6 (100)	3 (75.0)	5.0 (-50.0, 60.0)	25.0 (-17.4, 67.4)
Any serious AE (SAE)	0	1 (16.7)	1 (25.0)	-25.0 (-67.4, 17.4)	-8.3 (-60.2, 43.5)
Any AE leading to discontinuation of study drug	0	0	1 (25.0)	-25.0 (-67.4, 17.4)	-25.0 (-67.4, 17.4)
Any severe AE	0	2 (33.3)	2 (50.0)	-50.0 (-99.0, -1.0)	-16.7 (-78.5, 45.2)
Any AE with reasonable possibility of being related to study drug$	2 (40.0)	5 (83.3)	2 (50.0)	-10.0 (-75.2, 55.2)	33.3 (-24.0, 90.7)
Any AE leading to death	0	0	0	0.0	0.0
Deaths					
Occurring <= 30 days (ADA for 70 days) after last dose	0	0	0	0.0	0.0
Occurring > 30 days (ADA for 70 days) after last dose	0	0	0	0.0	0.0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30mg QD group include those who started UPA 15 mg QD/30mg QD at the beginning of the study and those who switched to UPA 15 mg/30mg QD at Week 24.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
[A]: The point estimate and 95% CI are based on normal approximation to binomial distribution.
$ As assessed by investigator.

Program Source Code: [redacted]

表 2.7.4.7-74. 投与 24 週時データカットオフまでの有害事象の概要（100 人年あたりの発現状況，安全性解析対象集団，日本人部分集団）：M15-572 試験

[redacted]
ABT-494 (PSA)
STUDY M15-572 - WEEK 24 (DATA CUTOFF - [redacted]20[redacted])
R&D/19/0849 - CLINICAL/STATISTICAL

TABLE 14.3__1.1.1.2.2_J

Overview of Treatment-Emergent Adverse Events in Exposure Adjusted Rate per 100 Patient Years - Long Term
(Safety Analysis Set, Japanese Population)

	UPA			-- UPA VS ADA (95% CI)[A] --	
	15 mg QD (N = 5) (PYs = 3.5)	30 mg QD (N = 6) (PYs = 8.2)	ADA 40 mg EOW (N = 4) (PYs = 5.2)	15 mg QD VS ADA	30 mg QD VS ADA
Exposure-adjusted event rate	Events (E/100 PYs)	Events (E/100 PYs)	Events (E/100 PYs)		
Any adverse event (AE)	12 (342.9)	34 (414.6)	8 (153.8)	189.0 (-32.3, 410.4)	260.8 (85.3, 436.3)
Any serious AE (SAE)	0	2 (24.4)	1 (19.2)	-19.2 (-56.9, 18.5)	5.2 (-45.5, 55.8)
Any AE leading to discontinuation of study drug	0	0	1 (19.2)	-19.2 (-56.9, 18.5)	-19.2 (-56.9, 18.5)
Any severe AE	0	3 (36.6)	3 (57.7)	-57.7 (-123.0, 7.6)	-21.1 (-98.4, 56.2)
Any AE with reasonable possibility of being related to study drug$	5 (142.9)	16 (195.1)	2 (38.5)	104.4 (-31.7, 240.5)	156.7 (47.2, 266.1)
Any AE leading to death	0	0	0	0.0	0.0
Exposure-adjusted incidence rate	n/PYs (n/100 PYs)	n/PYs (n/100 PYs)	n/PYs (n/100 PYs)		
Deaths					
Occurring <= 30 days (ADA for 70 days) after last dose	0/3.5	0/8.2	0/5.2	0.0	0.0
Occurring > 30 days (ADA for 70 days) after last dose	0/3.5	0/8.2	0/5.2	0.0	0.0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30mg QD group include those who started UPA 15 mg QD/30mg QD at the beginning of the study and those who switched to UPA 15 mg/30mg QD at Week 24.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years. n/100 PYs = Number of subjects with at least one event per 100 patient-years.
[A]: The point estimate and 95% CI are based on normal approximation to poisson distribution.
$ As assessed by investigator.

Program Source Code: [redacted]

表 2.7.4.7-75. 投与 24 週時までの有害事象（安全性解析対象集団，日本人部分集団）：
M15-572 試験

TABLE 14.3__1.2.1_J

Subjects with Treatment-Emergent Adverse Events by Primary MedDRA System Organ Class and Preferred Term
- up to Week 24
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 3) n (%)	ADA 40 mg EOW (N = 4) n (%)	UPA 15 mg QD (N = 4) n (%)	UPA 30 mg QD (N = 4) n (%)
Any adverse event	2 (66.7)	3 (75.0)	4 (100)	4 (100)
血液およびリンパ系障害	0	0	0	1 (25.0)
好中球減少症	0	0	0	1 (25.0)
先天性、家族性および遺伝性障害	0	0	0	1 (25.0)
2a型高脂血症	0	0	0	1 (25.0)
眼障害	1 (33.3)	0	0	0
硝子体剥離	1 (33.3)	0	0	0
胃腸障害	0	0	1 (25.0)	2 (50.0)
下痢	0	0	0	1 (25.0)
悪心	0	0	1 (25.0)	1 (25.0)
一般・全身障害および投与部位の状態	0	1 (25.0)	0	1 (25.0)
注射部位反応	0	1 (25.0)	0	0
発熱	0	0	0	1 (25.0)
肝胆道系障害	0	0	1 (25.0)	0
肝機能異常	0	0	1 (25.0)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA and up to 70 days for adalimumab, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

TABLE 14.3__1.2.1_J

Subjects with Treatment-Emergent Adverse Events by Primary MedDRA System Organ Class and Preferred Term
- up to Week 24
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 3) n (%)	ADA 40 mg EOW (N = 4) n (%)	UPA 15 mg QD (N = 4) n (%)	UPA 30 mg QD (N = 4) n (%)
感染症および寄生虫症	1 (33.3)	1 (25.0)	2 (50.0)	1 (25.0)
毛包炎	0	0	1 (25.0)	0
インフルエンザ	0	0	1 (25.0)	0
上咽頭炎	0	1 (25.0)	1 (25.0)	0
上気道感染	1 (33.3)	0	0	1 (25.0)
臨床検査	0	1 (25.0)	2 (50.0)	3 (75.0)
血中クレアチンホスホキナーゼ増加	0	1 (25.0)	1 (25.0)	2 (50.0)
肝機能検査値上昇	0	0	1 (25.0)	0
リンパ球数減少	0	0	0	1 (25.0)
骨髄球存在	0	0	0	1 (25.0)
白血球数減少	0	0	0	1 (25.0)
代謝および栄養障害	0	1 (25.0)	0	0
高トリグリセリド血症	0	1 (25.0)	0	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	1 (25.0)	1 (25.0)	0
皮膚乳頭腫	0	0	1 (25.0)	0
子宮癌	0	1 (25.0)	0	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA and up to 70 days for adalimumab, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

TABLE 14.3__1.2.1_J

Subjects with Treatment-Emergent Adverse Events by Primary MedDRA System Organ Class and Preferred Term
- up to Week 24
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 3) n (%)	ADA 40 mg EOW (N = 4) n (%)	UPA 15 mg QD (N = 4) n (%)	UPA 30 mg QD (N = 4) n (%)
神経系障害	0	0	1 (25.0)	0
頭痛	0	0	1 (25.0)	0
生殖系および乳房障害	0	1 (25.0)	0	0
子宮頚管ポリープ	0	1 (25.0)	0	0
呼吸器、胸郭および縦隔障害	0	0	1 (25.0)	0
上気道の炎症	0	0	1 (25.0)	0
血管障害	0	0	0	1 (25.0)
起立性低血圧	0	0	0	1 (25.0)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA and up to 70 days for adalimumab, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

表 2.7.4.7-76. 投与 24 週時までの治験薬と関連ありの有害事象（安全性解析対象集団，日本人部分集団）：M15-572 試験

TABLE 14.3__1.6.1_J

Subjects with Treatment-Emergent Adverse Events with Reasonable Possibly Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term - up to Week 24
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 3) n (%)	ADA 40 mg EOW (N = 4) n (%)	UPA 15 mg QD (N = 4) n (%)	UPA 30 mg QD (N = 4) n (%)
Any adverse event	2 (66.7)	2 (50.0)	2 (50.0)	3 (75.0)
血液およびリンパ系障害	0	0	0	1 (25.0)
好中球減少症	0	0	0	1 (25.0)
眼障害	1 (33.3)	0	0	0
硝子体剥離	1 (33.3)	0	0	0
胃腸障害	0	0	1 (25.0)	0
悪心	0	0	1 (25.0)	0
一般・全身障害および投与部位の状態	0	1 (25.0)	0	0
注射部位反応	0	1 (25.0)	0	0
感染症および寄生虫症	1 (33.3)	0	1 (25.0)	0
上咽頭炎	0	0	1 (25.0)	0
上気道感染	1 (33.3)	0	0	0
臨床検査	0	0	1 (25.0)	3 (75.0)
血中クレアチンホスホキナーゼ増加	0	0	0	1 (25.0)
肝機能検査値上昇	0	0	1 (25.0)	0
リンパ球数減少	0	0	0	1 (25.0)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA and up to 70 days for adalimumab, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 14.3__1.6.1_J

Subjects with Treatment-Emergent Adverse Events with Reasonable Possibly Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term - up to Week 24
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 3) n (%)	ADA 40 mg EOW (N = 4) n (%)	UPA 15 mg QD (N = 4) n (%)	UPA 30 mg QD (N = 4) n (%)
臨床検査 (Cont.)				
骨髄球存在	0	0	0	1 (25.0)
白血球数減少	0	0	0	1 (25.0)
代謝および栄養障害	0	1 (25.0)	0	0
高トリグリセリド血症	0	1 (25.0)	0	0
呼吸器、胸郭および縦隔障害	0	0	1 (25.0)	0
上気道の炎症	0	0	1 (25.0)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA and up to 70 days for adalimumab, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

表 2.7.4.7-77. 投与 24 週時までの Grade 3 以上の有害事象（安全性解析対象集団，日本人部分集団）：M15-572 試験

[redacted]
ABT-494 (PSA)
STUDY M15-572 - WEEK 24 (DATA CUTOFF - [redacted]20[redacted])
R&D/19/0849 - CLINICAL/STATISTICAL

TABLE 14.3__1.7.1_J

Subjects with Treatment-Emergent Severe Adverse Events by Primary MedDRA System Organ Class and Preferred Term
- up to Week 24
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 3) n (%)	ADA 40 mg EOW (N = 4) n (%)	UPA 15 mg QD (N = 4) n (%)	UPA 30 mg QD (N = 4) n (%)
Any adverse event	0	2 (50.0)	0	0
臨床検査	0	1 (25.0)	0	0
血中クレアチンホスホキナーゼ増加	0	1 (25.0)	0	0
代謝および栄養障害	0	1 (25.0)	0	0
高トリグリセリド血症	0	1 (25.0)	0	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	1 (25.0)	0	0
子宮癌	0	1 (25.0)	0	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA and up to 70 days for adalimumab, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.

Program Source Code: [redacted]

表 2.7.4.7-78. 投与 24 週時データカットオフまでの重篤な有害事象（100 人年あたりの発現件数，安全性解析対象集団，日本人部分集団）：M15-572 試験

[redacted]
ABT-494 (PSA)
STUDY M15-572 - WEEK 24 (DATA CUTOFF - [redacted]20[redacted])
R&D/19/0849 - CLINICAL/STATISTICAL

TABLE 14.3__2.1.2_J

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 5) (PYs = 3.5) Events (E/100 PYs)	UPA 30 mg QD (N = 6) (PYs = 8.2) Events (E/100 PYs)	ADA 40 mg EOW (N = 4) (PYs = 5.2) Events (E/100 PYs)
Any adverse event	0	2 (24.4)	1 (19.2)
感染症および寄生虫症	0	2 (24.4)	0
気管支炎	0	1 (12.2)	0
帯状疱疹	0	1 (12.2)	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	0	1 (19.2)
子宮癌	0	0	1 (19.2)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30mg QD group include those who started UPA 15 mg QD/30mg QD at the beginning of the study and those who switched to UPA 15 mg/30mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

表 2.7.4.7-79. 投与 24 週時データカットオフまでの有害事象の概要（安全性解析対象集団，日本人部分集団）：M15-554 試験

[redacted]

ABT-494 (PSA)
STUDY M15-554 - WEEK 24 (DATA CUTOFF - [redacted]20[redacted])
R&D/19/0848 - CLINICAL/STATISTICAL

TABLE 14.3__1.1.1.3_J

Overview of Number and Percentage of Subjects with Treatment-Emergent Adverse Events - Long Term
(Safety Analysis Set, Japanese Population)

	------- UPA -------	
	15 mg QD (N = 18) n (%)	30 mg QD (N = 20) n (%)
Subjects with:		
Any adverse event (AE)	17 (94.4)	20 (100)
Any serious AE (SAE)	4 (22.2)	7 (35.0)
Any AE leading to discontinuation of study drug	1 (5.6)	4 (20.0)
Any severe AE	3 (16.7)	6 (30.0)
Any AE with reasonable possibility of being related to study drug$	9 (50.0)	15 (75.0)
Any AE leading to death	0	1 (5.0)
Deaths		
Occurring <= 30 days after last dose	0	1 (5.0)
Occurring > 30 days after last dose	0	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30mg QD group include those who started UPA 15 mg QD/30mg QD at the beginning of the study and those who switched to UPA 15 mg/30mg QD at Week 24.
Severe adverse events are defined as events with grade 3 or above based on the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.
$ As assessed by investigator.

Program Source Code: [redacted]

表 2.7.4.7-80. 投与 24 週時データカットオフまでの有害事象の概要（100 人年あたりの発現状況，安全性解析対象集団，日本人部分集団）：M15-554 試験

TABLE 14.3__1.1.1.2.2_J

Overview of Treatment-Emergent Adverse Events in Exposure Adjusted Rate per 100 Patient Years - Long Term
(Safety Analysis Set, Japanese Population)

	UPA	
	15 mg QD (N = 18) (PYs = 19.5)	30 mg QD (N = 20) (PYs = 19.9)
Exposure-adjusted event rate	Events (E/100 PYs)	Events (E/100 PYs)
Any adverse event (AE)	76 (389.7)	125 (628.1)
Any serious AE (SAE)	4 (20.5)	14 (70.4)
Any AE leading to discontinuation of study drug	1 (5.1)	5 (25.1)
Any severe AE	3 (15.4)	16 (80.4)
Any AE with reasonable possibility of being related to study drug$	19 (97.4)	44 (221.1)
Any AE leading to death	0	1 (5.0)
Exposure-adjusted incidence rate	n/PYs (n/100 PYs)	n/PYs (n/100 PYs)
Deaths		
Occurring <= 30 days after last dose	0/19.5	1/20.0 (5.0)
Occurring > 30 days after last dose	0/19.5	0/19.9

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study. Severe AEs are defined as events with grade 3 or above based on the Common Terminology Criteria for AEs (CTCAE) version 5.0.
Subjects in UPA 15 mg QD/30mg QD group include those who started UPA 15 mg QD/30mg QD at the beginning of the study and those who switched to UPA 15 mg/30mg QD at Week 24.
E/100 PYs = Events per 100 patient-years. n/100 PYs = Number of subjects with at least one event per 100 patient-years.
$ As assessed by investigator.

Program Source Code: [redacted]

表 2.7.4.7-81.　投与 24 週時までの有害事象（安全性解析対象集団，日本人部分集団）：
M15-554 試験

TABLE 14.3__1.2.1_J

Subjects with Treatment-Emergent Adverse Events by Primary MedDRA System Organ Class and Preferred Term
- up to Week 24
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 12) n (%)	UPA 15 mg QD (N = 13) n (%)	UPA 30 mg QD (N = 14) n (%)
Any adverse event	7 (58.3)	10 (76.9)	12 (85.7)
血液およびリンパ系障害	0	2 (15.4)	2 (14.3)
貧血	0	0	1 (7.1)
鉄欠乏性貧血	0	1 (7.7)	0
リンパ球減少症	0	0	1 (7.1)
好中球減少症	0	1 (7.7)	0
心臓障害	0	1 (7.7)	0
動悸	0	1 (7.7)	0
耳および迷路障害	0	1 (7.7)	0
回転性めまい	0	1 (7.7)	0
眼障害	1 (8.3)	0	0
白内障	1 (8.3)	0	0
胃腸障害	3 (25.0)	4 (30.8)	4 (28.6)
腹部不快感	0	2 (15.4)	0
上腹部痛	1 (8.3)	0	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

TABLE 14.3__1.2.1_J

Subjects with Treatment-Emergent Adverse Events by Primary MedDRA System Organ Class and Preferred Term
- up to Week 24
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 12) n (%)	UPA 15 mg QD (N = 13) n (%)	UPA 30 mg QD (N = 14) n (%)
胃腸障害 (Cont.)			
便秘	0	2 (15.4)	1 (7.1)
下痢	1 (8.3)	0	0
小腸潰瘍	0	0	1 (7.1)
口内炎	1 (8.3)	0	1 (7.1)
嘔吐	0	0	1 (7.1)
一般・全身障害および投与部位の状態	1 (8.3)	1 (7.7)	1 (7.1)
倦怠感	1 (8.3)	0	0
発熱	0	1 (7.7)	1 (7.1)
肝胆道系障害	0	0	2 (14.3)
過形成性胆嚢症	0	0	1 (7.1)
肝損傷	0	0	1 (7.1)
免疫系障害	0	0	1 (7.1)
薬物過敏症	0	0	1 (7.1)
感染症および寄生虫症	4 (33.3)	7 (53.8)	10 (71.4)
細菌性膣症	0	1 (7.7)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

TABLE 14.3__1.2.1_J

Subjects with Treatment-Emergent Adverse Events by Primary MedDRA System Organ Class and Preferred Term
- up to Week 24
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 12) n (%)	UPA 15 mg QD (N = 13) n (%)	UPA 30 mg QD (N = 14) n (%)
感染症および寄生虫症 (Cont.)			
膀胱炎	1 (8.3)	0	0
毛包炎	0	1 (7.7)	1 (7.1)
胃腸炎	0	0	2 (14.3)
陰部ヘルペス	0	1 (7.7)	0
単純ヘルペス	0	0	1 (7.1)
帯状疱疹	0	1 (7.7)	1 (7.1)
麦粒腫	1 (8.3)	0	0
インフルエンザ	0	1 (7.7)	1 (7.1)
上咽頭炎	3 (25.0)	5 (38.5)	4 (28.6)
口腔カンジダ症	0	0	1 (7.1)
口腔ヘルペス	0	0	1 (7.1)
歯周炎	1 (8.3)	0	0
咽頭炎	0	0	1 (7.1)
肺炎	0	0	1 (7.1)
足部白癬	0	1 (7.7)	1 (7.1)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

TABLE 14.3__1.2.1_J

Subjects with Treatment-Emergent Adverse Events by Primary MedDRA System Organ Class and Preferred Term
- up to Week 24
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 12) n (%)	UPA 15 mg QD (N = 13) n (%)	UPA 30 mg QD (N = 14) n (%)
感染症および寄生虫症 (Cont.)			
癜風	1 (8.3)	0	0
上気道感染	0	0	1 (7.1)
尿路感染	0	0	1 (7.1)
傷害、中毒および処置合併症	2 (16.7)	2 (15.4)	0
つち指	0	1 (7.7)	0
処置による疼痛	1 (8.3)	0	0
皮膚裂傷	0	1 (7.7)	0
歯牙破折	1 (8.3)	0	0
臨床検査	0	2 (15.4)	1 (7.1)
血中ビリルビン増加	0	1 (7.7)	0
血中クレアチンホスホキナーゼ増加	0	1 (7.7)	1 (7.1)
ヘモグロビン減少	0	0	1 (7.1)
リンパ球数減少	0	1 (7.7)	0
リンパ球形態異常	0	1 (7.7)	0
白血球数減少	0	1 (7.7)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

TABLE 14.3__1.2.1_J

Subjects with Treatment-Emergent Adverse Events by Primary MedDRA System Organ Class and Preferred Term
- up to Week 24
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 12) n (%)	UPA 15 mg QD (N = 13) n (%)	UPA 30 mg QD (N = 14) n (%)
代謝および栄養障害	0	1 (7.7)	0
高脂血症	0	1 (7.7)	0
筋骨格系および結合組織障害	2 (16.7)	2 (15.4)	1 (7.1)
背部痛	1 (8.3)	0	0
筋肉痛	0	1 (7.7)	1 (7.1)
乾癬性関節症	0	1 (7.7)	0
変形性脊椎症	1 (8.3)	0	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	0	1 (7.1)
子宮内膜癌	0	0	1 (7.1)
卵巣癌	0	0	1 (7.1)
神経系障害	0	0	3 (21.4)
手根管症候群	0	0	1 (7.1)
頭痛	0	0	1 (7.1)
ヘルペス後神経痛	0	0	1 (7.1)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

TABLE 14.3__1.2.1_J

Subjects with Treatment-Emergent Adverse Events by Primary MedDRA System Organ Class and Preferred Term
- up to Week 24
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 12) n (%)	UPA 15 mg QD (N = 13) n (%)	UPA 30 mg QD (N = 14) n (%)
精神障害	0	1 (7.7)	0
不眠症	0	1 (7.7)	0
生殖系および乳房障害	1 (8.3)	1 (7.7)	0
亀頭包皮炎	0	1 (7.7)	0
乳房嚢胞	1 (8.3)	0	0
呼吸器、胸郭および縦隔障害	2 (16.7)	1 (7.7)	1 (7.1)
咳嗽	1 (8.3)	1 (7.7)	0
口腔咽頭痛	0	0	1 (7.1)
アレルギー性鼻炎	1 (8.3)	0	0
皮膚および皮下組織障害	0	1 (7.7)	3 (21.4)
ざ瘡	0	1 (7.7)	0
薬疹	0	0	1 (7.1)
汗疹	0	0	1 (7.1)
発疹	0	0	1 (7.1)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

表 2.7.4.7-82. 投与 24 週時までの治験薬と関連ありの有害事象（安全性解析対象集団，日本人部分集団）：M15-554 試験

TABLE 14.3__1.6.1_J

Subjects with Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term - up to Week 24
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 12) n (%)	UPA 15 mg QD (N = 13) n (%)	UPA 30 mg QD (N = 14) n (%)
Any adverse event	3 (25.0)	5 (38.5)	9 (64.3)
血液およびリンパ系障害	0	0	2 (14.3)
貧血	0	0	1 (7.1)
リンパ球減少症	0	0	1 (7.1)
耳および迷路障害	0	1 (7.7)	0
回転性めまい	0	1 (7.7)	0
胃腸障害	0	0	2 (14.3)
小腸潰瘍	0	0	1 (7.1)
嘔吐	0	0	1 (7.1)
一般・全身障害および投与部位の状態	1 (8.3)	0	0
倦怠感	1 (8.3)	0	0
肝胆道系障害	0	0	1 (7.1)
肝損傷	0	0	1 (7.1)
感染症および寄生虫症	2 (16.7)	3 (23.1)	4 (28.6)
細菌性膣症	0	1 (7.7)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

TABLE 14.3__1.6.1_J

Subjects with Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term - up to Week 24
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 12) n (%)	UPA 15 mg QD (N = 13) n (%)	UPA 30 mg QD (N = 14) n (%)
感染症および寄生虫症 (Cont.)			
膀胱炎	1 (8.3)	0	0
単純ヘルペス	0	0	1 (7.1)
帯状疱疹	0	1 (7.7)	1 (7.1)
上咽頭炎	1 (8.3)	1 (7.7)	0
歯周炎	1 (8.3)	0	0
咽頭炎	0	0	1 (7.1)
肺炎	0	0	1 (7.1)
足部白癬	0	1 (7.7)	1 (7.1)
癜風	1 (8.3)	0	0
尿路感染	0	0	1 (7.1)
傷害、中毒および処置合併症	1 (8.3)	0	0
歯牙破折	1 (8.3)	0	0
臨床検査	0	1 (7.7)	1 (7.1)
血中クレアチンホスホキナーゼ増加	0	0	1 (7.1)
リンパ球数減少	0	1 (7.7)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

TABLE 14.3__1.6.1_J

Subjects with Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term - up to Week 24
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 12) n (%)	UPA 15 mg QD (N = 13) n (%)	UPA 30 mg QD (N = 14) n (%)
代謝および栄養障害	0	1 (7.7)	0
高脂血症	0	1 (7.7)	0
筋骨格系および結合組織障害	0	2 (15.4)	0
筋肉痛	0	1 (7.7)	0
乾癬性関節症	0	1 (7.7)	0
呼吸器、胸郭および縦隔障害	1 (8.3)	0	0
咳嗽	1 (8.3)	0	0
皮膚および皮下組織障害	0	1 (7.7)	0
ざ瘡	0	1 (7.7)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

表 2.7.4.7-83. 投与 24 週時までの Grade 3 以上の有害事象（安全性解析対象集団，日本人部分集団）：M15-554 試験

[redacted]
ABT-494 (PSA)
STUDY M15-554 - WEEK 24 (DATA CUTOFF - [redacted]20[redacted])
R&D/19/0848 - CLINICAL/STATISTICAL

TABLE 14.3__1.7.1_J

Subjects with Treatment-Emergent Severe Adverse Events by Primary MedDRA System Organ Class and Preferred Term
- up to Week 24
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 12) n (%)	UPA 15 mg QD (N = 13) n (%)	UPA 30 mg QD (N = 14) n (%)
Any adverse event	0	1 (7.7)	3 (21.4)
胃腸障害	0	0	1 (7.1)
小腸潰瘍	0	0	1 (7.1)
感染症および寄生虫症	0	0	2 (14.3)
肺炎	0	0	1 (7.1)
尿路感染	0	0	1 (7.1)
臨床検査	0	1 (7.7)	0
リンパ球数減少	0	1 (7.7)	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	0	1 (7.1)
卵巣癌	0	0	1 (7.1)
神経系障害	0	0	1 (7.1)
ヘルペス後神経痛	0	0	1 (7.1)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Severe AE are defined as events with grade 3 or above based on the Common Terminology Criteria for AE (CTCAE) version 5.0.

Program Source Code: [redacted]

表 2.7.4.7-84.　投与 24 週時までの重篤な有害事象（安全性解析対象集団，日本人部分集団）：M15-554 試験

[redacted]
ABT-494 (PSA)
STUDY M15-554 - WEEK 24 (DATA CUTOFF - [redacted]20[redacted])
R&D/19/0848 - CLINICAL/STATISTICAL

TABLE 14.3__2.1.1_J

Subjects with Treatment-Emergent Serious Adverse Events by Primary MedDRA System Organ Class and Preferred Term
- up to Week 24
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 12) n (%)	UPA 15 mg QD (N = 13) n (%)	UPA 30 mg QD (N = 14) n (%)
Any adverse event	0	1 (7.7)	3 (21.4)
胃腸障害	0	0	1 (7.1)
小腸潰瘍	0	0	1 (7.1)
感染症および寄生虫症	0	0	2 (14.3)
肺炎	0	0	1 (7.1)
尿路感染	0	0	1 (7.1)
筋骨格系および結合組織障害	0	1 (7.7)	0
乾癬性関節症	0	1 (7.7)	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	0	1 (7.1)
卵巣癌	0	0	1 (7.1)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

表 2.7.4.7-85. 投与 24 週時データカットオフまでの重篤な有害事象（100 人年あたりの発現件数，安全性解析対象集団，日本人部分集団）：M15-554 試験

[redacted]
ABT-494 (PSA)
STUDY M15-554 - WEEK 24 (DATA CUTOFF - [redacted]20[redacted])
R&D/19/0848 - CLINICAL/STATISTICAL

TABLE 14.3__2.1.2_J

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 18) (PYs = 19.5) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 19.9) Events (E/100 PYs)
Any adverse event	4 (20.5)	14 (70.4)
血液およびリンパ系障害	0	1 (5.0)
汎血球減少症	0	1 (5.0)
胃腸障害	0	2 (10.1)
十二指腸潰瘍	0	1 (5.0)
小腸潰瘍	0	1 (5.0)
感染症および寄生虫症	1 (5.1)	6 (30.2)
サイトメガロウイルス感染	0	1 (5.0)
ウイルス性胃腸炎	1 (5.1)	1 (5.0)
帯状疱疹	0	1 (5.0)
ニューモシスチス・イロベチイ肺炎	0	1 (5.0)
肺炎	0	1 (5.0)
尿路感染	0	1 (5.0)
傷害、中毒および処置合併症	1 (5.1)	0
腱断裂	1 (5.1)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30mg QD group include those who started UPA 15 mg QD/30mg QD at the beginning of the study and those who switched to UPA 15 mg/30mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__2.1.2_J

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 18) (PYs = 19.5) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 19.9) Events (E/100 PYs)
代謝および栄養障害	1 (5.1)	0
糖尿病	1 (5.1)	0
筋骨格系および結合組織障害	1 (5.1)	0
乾癬性関節症	1 (5.1)	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	2 (10.1)
肛門性器疣贅	0	1 (5.0)
卵巣癌	0	1 (5.0)
神経系障害	0	1 (5.0)
顔面麻痺	0	1 (5.0)
呼吸器、胸郭および縦隔障害	0	2 (10.1)
間質性肺疾患	0	1 (5.0)
気胸	0	1 (5.0)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30mg QD group include those who started UPA 15 mg QD/30mg QD at the beginning of the study and those who switched to UPA 15 mg/30mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

表 2.7.4.7-86. 投与 24 週時までの治験薬の投与中止に至った有害事象（安全性解析対象集団，日本人部分集団）：M15-554 試験

[redacted]
ABT-494 (PSA)
STUDY M15-554 - WEEK 24 (DATA CUTOFF - [redacted]20[redacted])
R&D/19/0848 - CLINICAL/STATISTICAL

TABLE 14.3__2.2.1_J

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by Primary MedDRA System Organ Class and Preferred Term - up to Week 24
(Safety Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Placebo (N = 12) n (%)	UPA 15 mg QD (N = 13) n (%)	UPA 30 mg QD (N = 14) n (%)
Any adverse event	0	1 (7.7)	3 (21.4)
胃腸障害	0	0	1 (7.1)
小腸潰瘍	0	0	1 (7.1)
感染症および寄生虫症	0	0	2 (14.3)
肺炎	0	0	1 (7.1)
尿路感染	0	0	1 (7.1)
筋骨格系および結合組織障害	0	1 (7.7)	0
乾癬性関節症	0	1 (7.7)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug in Period 1 and prior to the Week 24 dose date, or up to 30 days after the last dose of placebo or UPA, if subject discontinued study drug prematurely before Week 24 dosing.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Program Source Code: [redacted]

表 2.7.4.7-87. 全ウパダシチニブ併合解析集団（20[redacted]年[redacted]月[redacted]日データカットオフ）の有害事象の概要

TABLE 2.4__1.1

Overview of Number and Percentage of Subjects
with Treatment-Emergent Adverse Events
(Any Upadacitinib Analysis Set)

	Upadacitinib					Treatment Comparison (95% CI) [A]	
	15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA %]	30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA %]	Any 15 mg QD (N = 907) n (%) [SSA %]	Any 30 mg QD (N = 921) n (%) [SSA %]	Adalimumab 40 mg EOW (N = 429) n (%)	30 mg QD - 15 mg QD (No Cross-Over from Placebo)	Any 30 mg QD - Any 15 mg QD
Subjects with:							
Any adverse event (AE)	537 (83.9) [83.9]	557 (86.9) [86.9]	728 (80.3) [80.3]	758 (82.3) [82.3]	347 (80.9)	2.9 (-0.9, 6.8)	1.9 (-1.6, 5.5)
COVID-19 related AE	3 (0.5) [0.5]	5 (0.8) [0.8]	5 (0.6) [0.6]	8 (0.9) [0.9]	2 (0.5)	0.3 (-0.6, 1.2)	0.3 (-0.5, 1.1)
Any serious AE	66 (10.3) [10.3]	98 (15.3) [15.3]	86 (9.5) [9.5]	129 (14.0) [14.0]	44 (10.3)	4.9 (1.3, 8.6)	4.5 (1.5, 7.4)
Any AE leading to discontinuation of study drug	47 (7.3) [7.4]	63 (9.8) [9.8]	63 (6.9) [7.0]	77 (8.4) [8.3]	32 (7.5)	2.4 (-0.6, 5.5)	1.3 (-1.1, 3.8)
Any severe AE	72 (11.3) [11.3]	102 (15.9) [15.9]	92 (10.1) [10.2]	131 (14.2) [14.2]	54 (12.6)	4.6 (0.9, 8.4)	4.0 (1.0, 7.0)
Any AE with reasonable possibility of being related to study drug$	308 (48.1) [48.1]	358 (55.9) [55.9]	400 (44.1) [44.1]	472 (51.2) [51.3]	211 (49.2)	7.8 (2.3, 13.2)	7.2 (2.6, 11.8)
Any AE leading to death	2 (0.3) [0.3]	0	2 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.2)	-0.3 (-0.7, 0.1)	-0.0 (-0.4, 0.4)

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo, and no more than 70 days after the last dose of adalimumab.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
SSA = Study size adjusted.
[A] Study size adjusted risk difference between treatment groups.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 2.4__1.1

Overview of Number and Percentage of Subjects
with Treatment-Emergent Adverse Events
(Any Upadacitinib Analysis Set)

	Upadacitinib					Treatment Comparison (95% CI) [A]	
	15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA %]	30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA %]	Any 15 mg QD (N = 907) n (%) [SSA %]	Any 30 mg QD (N = 921) n (%) [SSA %]	Adalimumab 40 mg EOW (N = 429) n (%)	30 mg QD - 15 mg QD (No Cross-Over from Placebo)	Any 30 mg QD - Any 15 mg QD
Deaths	2 (0.3) [0.3]	1 (0.2) [0.2]	2 (0.2) [0.2]	3 (0.3) [0.3]	1 (0.2)	-0.2 (-0.7, 0.4)	0.1 (-0.4, 0.6)
Treatment-emergent deaths	1 (0.2) [0.2]	0	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (0.2)	-0.2 (-0.5, 0.1)	0.1 (-0.3, 0.5)
COVID-19 related	0	0	0	1 (0.1) [0.1]	0	0.0	0.1 (-0.1, 0.3)
Non-treatment-emergent deaths	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]	0	0.0 (-0.4, 0.4)	0.0 (-0.3, 0.3)
COVID-19 related	0	0	0	0	0	0.0	0.0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo, and no more than 70 days after the last dose of adalimumab.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
SSA = Study size adjusted.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

表 2.7.4.7-88. 全ウパダシチニブ併合解析集団（20[redacted]年[redacted]月[redacted]日データカットオフ）の日本人部分集団の有害事象の概要

TABLE 2.4__1.2.1.1_J

Overview of Number and Percentage of Subjects
with Treatment-Emergent Adverse Events
(Any Upadacitinib Analysis Set, Japanese Population)

	Upadacitinib					Treatment Comparison (95% CI) [A]	
	15 mg QD (No Cross-Over from Placebo) (N = 17) n (%) [SSA %]	30 mg QD (No Cross-Over from Placebo) (N = 18) n (%) [SSA %]	Any 15 mg QD (N = 23) n (%) [SSA %]	Any 30 mg QD (N = 26) n (%) [SSA %]	Adalimumab 40 mg EOW (N = 4) n (%)	30 mg QD - 15 mg QD (No Cross-Over from Placebo)	Any 30 mg QD - Any 15 mg QD
Subjects with:							
Any adverse event (AE)	16 (94.1) [94.1]	18 (100) [100.0]	21 (91.3) [91.2]	26 (100) [100]	4 (100)	5.9 (-5.2, 17.1)	8.8 (-2.6, 20.2)
COVID-19 related AE	0	0	0	0	0	0.0	0.0
Any serious AE	3 (17.6) [17.8]	8 (44.4) [44.3]	4 (17.4) [17.2]	11 (42.3) [42.5]	1 (25.0)	26.5 (-2.1, 55.0)	25.3 (1.7, 48.9)
Any AE leading to discontinuation of study drug	1 (5.9) [5.9]	4 (22.2) [22.0]	1 (4.3) [4.3]	6 (23.1) [23.3]	1 (25.0)	16.1 (-5.3, 37.5)	19.0 (1.4, 36.6)
Any severe AE	3 (17.6) [17.8]	8 (44.4) [44.3]	4 (17.4) [17.2]	12 (46.2) [46.3]	2 (50.0)	26.5 (-2.1, 55.0)	29.0 (4.9, 53.2)
Any AE with reasonable possibility of being related to study drug$	10 (58.8) [58.9]	15 (83.3) [83.5]	14 (60.9) [60.7]	20 (76.9) [76.9]	3 (75.0)	24.6 (-4.0, 53.1)	16.2 (-9.1, 41.5)
Any AE leading to death	0	0	0	1 (3.8) [3.9]	0	0.0	3.9 (-3.5, 11.3)

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo, and no more than 70 days after the last dose of adalimumab.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
SSA = Study size adjusted.
[A] Study size adjusted risk difference between treatment groups.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 2.4__1.2.1.1_J

Overview of Number and Percentage of Subjects
with Treatment-Emergent Adverse Events
(Any Upadacitinib Analysis Set, Japanese Population)

	Upadacitinib					Treatment Comparison (95% CI) [A]	
	15 mg QD (No Cross-Over from Placebo) (N = 17) n (%) [SSA %]	30 mg QD (No Cross-Over from Placebo) (N = 18) n (%) [SSA %]	Any 15 mg QD (N = 23) n (%) [SSA %]	Any 30 mg QD (N = 26) n (%) [SSA %]	Adalimumab 40 mg EOW (N = 4) n (%)	30 mg QD - 15 mg QD (No Cross-Over from Placebo)	Any 30 mg QD - Any 15 mg QD
Deaths	0	0	0	1 (3.8) [3.9]	0	0.0	3.9 (-3.5, 11.3)
Treatment-emergent deaths	0	0	0	1 (3.8) [3.9]	0	0.0	3.9 (-3.5, 11.3)
COVID-19 related	0	0	0	0	0	0.0	0.0
Non-treatment-emergent deaths	0	0	0	0	0	0.0	0.0
COVID-19 related	0	0	0	0	0	0.0	0.0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo, and no more than 70 days after the last dose of adalimumab.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
SSA = Study size adjusted.
[A] Study size adjusted risk difference between treatment groups.

Program Source Code: [redacted]

表 2.7.4.7-89. 全ウパダシチニブ併合解析集団（20[redacted]年[redacted]月[redacted]日データカットオフ）の有害事象（100 人年あたりの発現件数）

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
Any Adverse Event	2638 (277.2) [277.3]	3263 (345.1) [345.1]	3291 (263.9) [263.9]	4043 (321.5) [321.5]
*** Not Coded ***	8 (0.8) [0.8]	10 (1.1) [1.1]	11 (0.9) [0.9]	13 (1.0) [1.0]
*** Not Coded ***	8 (0.8) [0.8]	10 (1.1) [1.1]	11 (0.9) [0.9]	13 (1.0) [1.0]
血液およびリンパ系障害	85 (8.9) [8.9]	163 (17.2) [17.2]	98 (7.9) [7.9]	196 (15.6) [15.6]
貧血	13 (1.4) [1.4]	31 (3.3) [3.3]	15 (1.2) [1.2]	37 (2.9) [2.9]
大球性貧血	1 (0.1) [0.1]	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]
慢性疾患の貧血	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
自己免疫性貧血	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
好塩基球増加症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
失血性貧血	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
骨髄浮腫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
血球減少症	0	0	0	2 (0.2) [0.2]
播種性血管内凝固	0	0	0	1 (<0.1) [<0.1]
好酸球増加症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
赤血球減少症	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
顆粒球減少症	0	1 (0.1) [0.1]	0	3 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
血液およびリンパ系障害 (Cont.)				
内出血発生の増加傾向	3 (0.3) [0.3]	1 (0.1) [0.1]	4 (0.3) [0.3]	1 (<0.1) [<0.1]
鉄欠乏性貧血	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]	3 (0.2) [0.2]
白血球増加症	0	3 (0.3) [0.3]	0	3 (0.2) [0.2]
白血球減少症	20 (2.1) [2.1]	26 (2.8) [2.7]	22 (1.8) [1.8]	35 (2.8) [2.8]
リンパ節炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
リンパ節症	3 (0.3) [0.3]	0	3 (0.2) [0.2]	1 (<0.1) [<0.1]
リンパ球増加症	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
リンパ組織過形成	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
リンパ球減少症	20 (2.1) [2.1]	30 (3.2) [3.2]	21 (1.7) [1.7]	32 (2.5) [2.5]
単球増加症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
好中球減少症	16 (1.7) [1.7]	35 (3.7) [3.7]	20 (1.6) [1.6]	42 (3.3) [3.3]
好中球増加症	2 (0.2) [0.2]	4 (0.4) [0.4]	2 (0.2) [0.2]	4 (0.3) [0.3]
正色素性貧血	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
汎血球減少症	0	0	0	1 (<0.1) [<0.1]
脾肉芽腫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
血小板減少症	1 (0.1) [0.1]	6 (0.6) [0.6]	2 (0.2) [0.2]	6 (0.5) [0.5]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
血液およびリンパ系障害 (Cont.)				
血小板増加症	0	6 (0.6) [0.6]	1 (<0.1) [<0.1]	6 (0.5) [0.5]
心臓障害	40 (4.2) [4.2]	32 (3.4) [3.4]	46 (3.7) [3.7]	48 (3.8) [3.8]
急性心筋梗塞	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
狭心症	1 (0.1) [0.1]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
不安定狭心症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
大動脈弁硬化症	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
大動脈弁狭窄	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
不整脈	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
冠動脈硬化症	0	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
心房細動	4 (0.4) [0.4]	6 (0.6) [0.6]	5 (0.4) [0.4]	8 (0.6) [0.6]
心房粗動	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
心房頻脈	0	0	0	1 (<0.1) [<0.1]
房室ブロック	0	0	0	1 (<0.1) [<0.1]
第一度房室ブロック	1 (0.1) [0.1]	0	2 (0.2) [0.2]	0
第二度房室ブロック	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
徐脈	3 (0.3) [0.3]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
心臓障害 (Cont.)				
右脚ブロック	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
心不全	1 (0.1) [0.1]	1 (0.1) [0.1]	2 (0.2) [0.2]	2 (0.2) [0.2]
うっ血性心不全	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
心肺停止	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
心拡大	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
心腎症候群	0	0	0	1 (<0.1) [<0.1]
うっ血性心筋症	0	0	0	1 (<0.1) [<0.1]
冠動脈疾患	0	3 (0.3) [0.3]	0	3 (0.2) [0.2]
冠動脈狭窄	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
チアノーゼ	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
期外収縮	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
左室肥大	0	0	0	1 (<0.1) [<0.1]
僧帽弁閉鎖不全症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
僧帽弁硬化症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
心筋梗塞	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]
心筋虚血	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
心臓障害 (Cont.)				
動悸	10 (1.1) [1.0]	1 (0.1) [0.1]	11 (0.9) [0.9]	1 (<0.1) [<0.1]
起立性頻脈症候群	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肺動脈弁閉鎖不全症	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
洞性徐脈	0	2 (0.2) [0.2]	0	3 (0.2) [0.2]
洞性頻脈	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
上室性頻脈	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
頻脈	4 (0.4) [0.4]	1 (0.1) [0.1]	4 (0.3) [0.3]	3 (0.2) [0.2]
発作性頻脈	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
三尖弁閉鎖不全症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
心室細動	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
先天性、家族性および遺伝性障害	1 (0.1) [0.1]	4 (0.4) [0.4]	4 (0.3) [0.3]	4 (0.3) [0.3]
発育性股関節形成不全	0	0	1 (<0.1) [<0.1]	0
胃腸管動静脈奇形	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
陰嚢水瘤	1 (0.1) [0.1]	2 (0.2) [0.2]	3 (0.2) [0.2]	2 (0.2) [0.2]
2a型高脂血症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
耳および迷路障害	7 (0.7) [0.7]	10 (1.1) [1.1]	11 (0.9) [0.9]	13 (1.0) [1.0]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
耳および迷路障害 (Cont.)				
耳垢栓塞	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
耳閉	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
耳不快感	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
耳痛	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
外耳の炎症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
内耳障害	0	0	0	1 (<0.1) [<0.1]
耳鳴	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
回転性めまい	4 (0.4) [0.4]	3 (0.3) [0.3]	5 (0.4) [0.4]	4 (0.3) [0.3]
頭位性回転性めまい	1 (0.1) [0.1]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
前庭障害	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
内分泌障害	8 (0.8) [0.8]	13 (1.4) [1.4]	9 (0.7) [0.7]	14 (1.1) [1.1]
副腎石灰化	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
アンドロゲン欠乏症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
自己免疫性甲状腺炎	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
甲状腺腫	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]	2 (0.2) [0.2]
甲状腺機能亢進症	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
内分泌障害 (Cont.)				
甲状腺機能低下症	2 (0.2) [0.2]	4 (0.4) [0.4]	3 (0.2) [0.2]	4 (0.3) [0.3]
甲状腺腫瘤	0	3 (0.3) [0.3]	0	3 (0.2) [0.2]
眼障害	33 (3.5) [3.5]	36 (3.8) [3.8]	34 (2.7) [2.7]	43 (3.4) [3.4]
一過性黒内障	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
閉塞隅角緑内障	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
動脈硬化性網膜症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
眼精疲労	0	0	0	1 (<0.1) [<0.1]
眼瞼炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
眼瞼痙攣	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
境界域緑内障	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
白内障	2 (0.2) [0.2]	10 (1.1) [1.1]	3 (0.2) [0.2]	12 (1.0) [1.0]
核性白内障	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
霰粒腫	1 (0.1) [0.1]	4 (0.4) [0.4]	1 (<0.1) [<0.1]	4 (0.3) [0.3]
結膜出血	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
結膜充血	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
アレルギー性結膜炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
眼障害 (Cont.)				
角膜混濁	0	0	0	1 (<0.1) [<0.1]
眼瞼皮膚弛緩症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
糖尿病網膜症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
複視	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ドライアイ	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
眼痛	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
眼瞼下垂	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
緑内障	3 (0.3) [0.3]	5 (0.5) [0.5]	3 (0.2) [0.2]	6 (0.5) [0.5]
虹彩毛様体炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
角膜炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
流涙増加	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
水晶体脱臼	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
黄斑変性	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
瞼板腺炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
眼部不快感	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
眼窩周囲腫脹	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
眼障害 (Cont.)				
光視症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
後嚢部混濁	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
眼瞼腫脹	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
ぶどう膜炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
霧視	4 (0.4) [0.4]	0	4 (0.3) [0.3]	0
視力低下	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
視力障害	4 (0.4) [0.4]	0	4 (0.3) [0.3]	0
硝子体浮遊物	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
胃腸障害	246 (25.9) [25.9]	281 (29.7) [29.7]	301 (24.1) [24.1]	336 (26.7) [26.7]
腹部不快感	8 (0.8) [0.8]	3 (0.3) [0.3]	11 (0.9) [0.9]	5 (0.4) [0.4]
腹部膨満	4 (0.4) [0.4]	3 (0.3) [0.3]	5 (0.4) [0.4]	4 (0.3) [0.3]
腹部腫瘤	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
腹痛	10 (1.1) [1.1]	7 (0.7) [0.7]	13 (1.0) [1.0]	9 (0.7) [0.7]
下腹部痛	1 (0.1) [0.1]	0	2 (0.2) [0.2]	0
上腹部痛	12 (1.3) [1.3]	14 (1.5) [1.5]	16 (1.3) [1.3]	14 (1.1) [1.1]
腹壁嚢胞	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
胃腸障害 (Cont.)				
裂肛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
痔瘻	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
口角口唇炎	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
アフタ性潰瘍	3 (0.3) [0.3]	3 (0.3) [0.3]	3 (0.2) [0.2]	5 (0.4) [0.4]
根尖肉芽腫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
腹水	0	0	0	1 (<0.1) [<0.1]
バレット食道	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
慢性胃炎	0	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]
大腸炎	1 (0.1) [0.1]	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]
結腸異形成	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
便秘	14 (1.5) [1.5]	14 (1.5) [1.5]	14 (1.1) [1.1]	14 (1.1) [1.1]
クローン病	0	0	1 (<0.1) [<0.1]	0
齲歯	3 (0.3) [0.3]	6 (0.6) [0.6]	3 (0.2) [0.2]	6 (0.5) [0.5]
横隔膜ヘルニア	0	0	1 (<0.1) [<0.1]	0
下痢	37 (3.9) [3.9]	52 (5.5) [5.5]	46 (3.7) [3.7]	60 (4.8) [4.8]
憩室	3 (0.3) [0.3]	3 (0.3) [0.3]	5 (0.4) [0.4]	3 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
胃腸障害 (Cont.)				
腸憩室	0	2 (0.2) [0.2]	0	3 (0.2) [0.2]
食道憩室	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
口内乾燥	2 (0.2) [0.2]	4 (0.4) [0.4]	2 (0.2) [0.2]	5 (0.4) [0.4]
十二指腸潰瘍	0	2 (0.2) [0.2]	0	3 (0.2) [0.2]
出血性十二指腸潰瘍	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
十二指腸炎	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
排便困難	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
消化不良	16 (1.7) [1.7]	9 (1.0) [1.0]	18 (1.4) [1.4]	12 (1.0) [1.0]
嚥下障害	0	3 (0.3) [0.3]	0	4 (0.3) [0.3]
小腸炎	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
腸炎	0	0	0	2 (0.2) [0.2]
腸膀胱瘻	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
心窩部不快感	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
びらん性十二指腸炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
びらん性食道炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
おくび	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
胃腸障害 (Cont.)				
糞塊	0	0	0	1 (<0.1) [<0.1]
変色便	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
鼓腸	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
食中毒	2 (0.2) [0.2]	4 (0.4) [0.4]	3 (0.2) [0.2]	4 (0.3) [0.3]
胃前庭部毛細血管拡張症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
胃出血	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
穿孔性胃潰瘍	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
胃炎	9 (0.9) [0.9]	9 (1.0) [1.0]	11 (0.9) [0.9]	10 (0.8) [0.8]
びらん性胃炎	3 (0.3) [0.3]	1 (0.1) [0.1]	4 (0.3) [0.3]	1 (<0.1) [<0.1]
胃十二指腸出血	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
胃十二指腸潰瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
胃腸障害	0	0	1 (<0.1) [<0.1]	0
胃腸出血	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
消化器痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
胃食道逆流性疾患	9 (0.9) [0.9]	8 (0.8) [0.8]	11 (0.9) [0.9]	10 (0.8) [0.8]
歯肉退縮	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
胃腸障害 (Cont.)				
歯肉腫脹	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
潰瘍性歯肉炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
舌炎	0	0	1 (<0.1) [<0.1]	0
吐血	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
血便排泄	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
痔出血	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
痔核	6 (0.6) [0.6]	2 (0.2) [0.2]	6 (0.5) [0.5]	5 (0.4) [0.4]
裂孔ヘルニア	4 (0.4) [0.4]	2 (0.2) [0.2]	4 (0.3) [0.3]	3 (0.2) [0.2]
鼠径ヘルニア	0	1 (0.1) [0.1]	0	3 (0.2) [0.2]
腸閉塞	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
過敏性腸症候群	0	0	1 (<0.1) [<0.1]	0
大腸ポリープ	3 (0.3) [0.3]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
口唇乾燥	0	0	1 (<0.1) [<0.1]	0
口唇潰瘍	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
腰ヘルニア	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
口腔嚢胞	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
胃腸障害 (Cont.)				
口腔内潰瘍形成	5 (0.5) [0.5]	5 (0.5) [0.5]	5 (0.4) [0.4]	9 (0.7) [0.7]
悪心	28 (2.9) [2.9]	42 (4.4) [4.4]	30 (2.4) [2.4]	46 (3.7) [3.7]
嚥下痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
食道痙攣	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
食道潰瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
食道潰瘍出血	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
口腔挫傷	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
口腔障害	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
口腔粘膜びらん	0	0	0	1 (<0.1) [<0.1]
口腔粘膜水疱形成	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
膵臓障害	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
膵脂肪変性	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
膵炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
急性膵炎	0	0	0	1 (<0.1) [<0.1]
慢性膵炎	0	0	1 (<0.1) [<0.1]	0
耳下腺腫大	0	0	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
胃腸障害 (Cont.)				
消化性潰瘍	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
歯周の炎症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
直腸出血	2 (0.2) [0.2]	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]
直腸潰瘍	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
逆流性胃炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
吐き戻し	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
レッチング	0	0	1 (<0.1) [<0.1]	0
小腸出血	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
小腸潰瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
口内炎	4 (0.4) [0.4]	10 (1.1) [1.1]	6 (0.5) [0.5]	12 (1.0) [1.0]
舌潰瘍	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
歯の障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
埋伏歯	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
歯の脱落	0	0	1 (<0.1) [<0.1]	0
歯痛	6 (0.6) [0.6]	7 (0.7) [0.7]	8 (0.6) [0.6]	7 (0.6) [0.6]
臍ヘルニア	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
胃腸障害 (Cont.)				
上部消化管出血	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
嘔吐	14 (1.5) [1.5]	16 (1.7) [1.7]	19 (1.5) [1.5]	20 (1.6) [1.6]
一般・全身障害および投与部位の状態	57 (6.0) [6.0]	87 (9.2) [9.2]	75 (6.0) [6.0]	110 (8.7) [8.7]
医薬品副作用	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
無力症	3 (0.3) [0.3]	4 (0.4) [0.4]	3 (0.2) [0.2]	5 (0.4) [0.4]
胸部不快感	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
胸痛	2 (0.2) [0.2]	2 (0.2) [0.2]	3 (0.2) [0.2]	4 (0.3) [0.3]
悪寒	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	2 (0.2) [0.2]
不快感	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
薬物不耐性	2 (0.2) [0.2]	5 (0.5) [0.5]	3 (0.2) [0.2]	6 (0.5) [0.5]
粘膜疹	0	0	0	1 (<0.1) [<0.1]
顔面痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
疲労	12 (1.3) [1.3]	12 (1.3) [1.3]	18 (1.4) [1.4]	16 (1.3) [1.3]
歩行障害	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
高熱	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
低体温	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
一般・全身障害および投与部位の状態 (Cont.)				
炎症	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
インフルエンザ様疾患	4 (0.4) [0.4]	5 (0.5) [0.5]	4 (0.3) [0.3]	5 (0.4) [0.4]
注射部位内出血	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
注射部位疼痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
注射部位反応	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
倦怠感	6 (0.6) [0.6]	0	6 (0.5) [0.5]	0
医療機器使用部位関節腫脹	0	0	0	1 (<0.1) [<0.1]
小結節	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
非心臓性胸痛	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
浮腫	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
末梢性浮腫	5 (0.5) [0.5]	8 (0.8) [0.8]	12 (1.0) [1.0]	11 (0.9) [0.9]
疼痛	2 (0.2) [0.2]	3 (0.3) [0.3]	2 (0.2) [0.2]	4 (0.3) [0.3]
末梢腫脹	4 (0.4) [0.4]	5 (0.5) [0.5]	4 (0.3) [0.3]	5 (0.4) [0.4]
発熱	11 (1.2) [1.2]	26 (2.8) [2.7]	14 (1.1) [1.1]	34 (2.7) [2.7]
腫脹	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
全身性炎症反応症候群	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
肝胆道系障害	28 (2.9) [2.9]	55 (5.8) [5.8]	43 (3.4) [3.4]	67 (5.3) [5.3]
胆管結石	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
胆道仙痛	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
胆嚢炎	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
慢性胆嚢炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
胆石症	4 (0.4) [0.4]	9 (1.0) [1.0]	7 (0.6) [0.6]	10 (0.8) [0.8]
薬物性肝障害	0	3 (0.3) [0.3]	0	4 (0.3) [0.3]
胆嚢ポリープ	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肝硬変	0	0	0	1 (<0.1) [<0.1]
肝嚢胞	0	4 (0.4) [0.4]	0	4 (0.3) [0.3]
肝機能異常	9 (0.9) [0.9]	9 (1.0) [0.9]	13 (1.0) [1.0]	12 (1.0) [1.0]
肝腫瘤	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
脂肪肝	6 (0.6) [0.6]	14 (1.5) [1.5]	8 (0.6) [0.6]	18 (1.4) [1.4]
肝炎	0	0	1 (<0.1) [<0.1]	0
肝腫大	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
肝毒性	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
肝胆道系障害 (Cont.)				
高ビリルビン血症	1 (0.1) [0.1]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
過形成性胆嚢症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
高トランスアミナーゼ血症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
黄疸	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肝障害	0	2 (0.2) [0.2]	2 (0.2) [0.2]	3 (0.2) [0.2]
肝損傷	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
非アルコール性脂肪性肝炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
非アルコール性脂肪性肝疾患	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
胆管穿孔	0	0	1 (<0.1) [<0.1]	0
脂肪性肝炎	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
免疫系障害	10 (1.1) [1.1]	15 (1.6) [1.6]	14 (1.1) [1.1]	16 (1.3) [1.3]
アレルギー性浮腫	0	0	1 (<0.1) [<0.1]	0
節足動物咬傷アレルギー	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
造影剤アレルギー	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
薬物過敏症	2 (0.2) [0.2]	5 (0.5) [0.5]	2 (0.2) [0.2]	5 (0.4) [0.4]
食物アレルギー	2 (0.2) [0.2]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
免疫系障害 (Cont.)				
過敏症	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
ダニアレルギー	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
季節性アレルギー	5 (0.5) [0.5]	4 (0.4) [0.4]	7 (0.6) [0.6]	4 (0.3) [0.3]
感染症および寄生虫症	849 (89.2) [89.2]	1071 (113.3) [113.3]	1101 (88.3) [88.3]	1356 (107.8) [107.8]
腹部膿瘍	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
腹壁膿瘍	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
膿瘍	1 (0.1) [0.1]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
四肢膿瘍	0	5 (0.5) [0.5]	0	6 (0.5) [0.5]
口腔膿瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ダニ皮膚炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
急性副鼻腔炎	4 (0.4) [0.4]	4 (0.4) [0.4]	6 (0.5) [0.5]	4 (0.3) [0.3]
肛門膿瘍	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
肛門カンジダ症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
肛門直腸蜂巣炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
虫垂炎	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
細菌性関節炎	0	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
無症候性細菌尿	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
異型肺炎	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
バベシア症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
菌血症	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
細菌感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
細菌性膣症	3 (0.3) [0.3]	0	3 (0.2) [0.2]	1 (<0.1) [<0.1]
細菌尿	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
体部白癬	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]	3 (0.2) [0.2]
細気管支炎	0	0	1 (<0.1) [<0.1]	0
気管支炎	62 (6.5) [6.5]	71 (7.5) [7.5]	85 (6.8) [6.8]	88 (7.0) [7.0]
細菌性気管支炎	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
気管支肺アスペルギルス症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
感染性滑液包炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
カンジダ感染	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
カンジダ性尿道炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
気管カンジダ症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
蜂巣炎	10 (1.1) [1.0]	11 (1.2) [1.2]	11 (0.9) [0.9]	12 (1.0) [1.0]
ブドウ球菌性蜂巣炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
コクシジオイデス症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
結膜炎	5 (0.5) [0.5]	1 (0.1) [0.1]	7 (0.6) [0.6]	3 (0.2) [0.2]
ウイルス性結膜炎	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
コロナウイルス感染	1 (0.1) [0.1]	5 (0.5) [0.5]	3 (0.2) [0.2]	8 (0.6) [0.6]
クリプトスポリジウム感染	0	0	1 (<0.1) [<0.1]	0
膀胱炎	13 (1.4) [1.4]	15 (1.6) [1.6]	15 (1.2) [1.2]	18 (1.4) [1.4]
大腸菌性膀胱炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
サイトメガロウイルス感染	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
毛嚢虫症	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
デング熱	0	0	0	1 (<0.1) [<0.1]
爪の皮膚糸状菌症	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
感染性下痢	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
憩室炎	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
耳感染	8 (0.8) [0.8]	4 (0.4) [0.4]	13 (1.0) [1.0]	5 (0.4) [0.4]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
エンテロウイルス感染	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
精巣上体炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
丹毒	2 (0.2) [0.2]	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]
大腸菌感染	0	0	1 (<0.1) [<0.1]	0
大腸菌性尿路感染	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	2 (0.2) [0.2]
硬膜外膿瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
眼感染	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
毛包炎	16 (1.7) [1.7]	11 (1.2) [1.2]	16 (1.3) [1.3]	17 (1.4) [1.4]
真菌感染	1 (0.1) [0.1]	0	2 (0.2) [0.2]	0
皮膚真菌感染	7 (0.7) [0.7]	13 (1.4) [1.4]	9 (0.7) [0.7]	15 (1.2) [1.2]
せつ	3 (0.3) [0.3]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
ウイルス性胃炎	0	0	0	1 (<0.1) [<0.1]
胃腸炎	20 (2.1) [2.1]	35 (3.7) [3.7]	27 (2.2) [2.2]	41 (3.3) [3.3]
ウイルス性胃腸炎	7 (0.7) [0.7]	20 (2.1) [2.1]	11 (0.9) [0.9]	23 (1.8) [1.8]
消化管感染	3 (0.3) [0.3]	0	3 (0.2) [0.2]	0
ウイルス性消化管感染	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
性器カンジダ症	0	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
陰部ヘルペス	5 (0.5) [0.5]	4 (0.4) [0.4]	6 (0.5) [0.5]	4 (0.3) [0.3]
陰部単純ヘルペス	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
陰部帯状疱疹	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
真菌性性器感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
泌尿生殖器感染	0	0	1 (<0.1) [<0.1]	0
ジアルジア症	0	0	1 (<0.1) [<0.1]	0
歯肉膿瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
歯肉炎	3 (0.3) [0.3]	5 (0.5) [0.5]	3 (0.2) [0.2]	6 (0.5) [0.5]
単径部膿瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
H1N1インフルエンザ	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
手足口病	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
ヘリコバクター感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
B型肝炎	0	0	0	1 (<0.1) [<0.1]
B型肝炎再活性化	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
ヘルペス眼感染	0	0	0	1 (<0.1) [<0.1]

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Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
単純ヘルペス	6 (0.6) [0.6]	17 (1.8) [1.8]	7 (0.6) [0.6]	20 (1.6) [1.6]
ヘルペスウイルス感染	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
帯状疱疹	30 (3.2) [3.2]	50 (5.3) [5.3]	43 (3.4) [3.4]	73 (5.8) [5.8]
皮膚播種性帯状疱疹	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
神経合併症を伴う帯状疱疹感染	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
麦粒腫	6 (0.6) [0.6]	3 (0.3) [0.3]	7 (0.6) [0.6]	4 (0.3) [0.3]
膿痂疹	0	3 (0.3) [0.3]	0	3 (0.2) [0.2]
伝染性単核症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
インフルエンザ	41 (4.3) [4.3]	36 (3.8) [3.8]	48 (3.8) [3.8]	46 (3.7) [3.7]
注射部位感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
腎感染	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
クレブシエラ感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
迷路炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
喉頭炎	4 (0.4) [0.4]	5 (0.5) [0.5]	6 (0.5) [0.5]	8 (0.6) [0.6]
潜伏結核	3 (0.3) [0.3]	4 (0.4) [0.4]	9 (0.7) [0.7]	9 (0.7) [0.7]
肝膿瘍	0	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
限局性感染	1 (0.1) [0.1]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
下気道感染	6 (0.6) [0.6]	4 (0.4) [0.4]	6 (0.5) [0.5]	7 (0.6) [0.6]
肺感染	0	4 (0.4) [0.4]	2 (0.2) [0.2]	6 (0.5) [0.5]
リンパ管炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
髄膜炎	0	0	0	1 (<0.1) [<0.1]
ムンプス	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
爪床感染	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
爪感染	3 (0.3) [0.3]	4 (0.4) [0.4]	3 (0.2) [0.2]	6 (0.5) [0.5]
鼻ヘルペス	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
上咽頭炎	94 (9.9) [9.9]	102 (10.8) [10.8]	117 (9.4) [9.4]	136 (10.8) [10.8]
食道カンジダ症	0	0	1 (<0.1) [<0.1]	0
爪真菌症	3 (0.3) [0.3]	1 (0.1) [0.1]	3 (0.2) [0.2]	3 (0.2) [0.2]
眼部単純ヘルペス	0	0	0	1 (<0.1) [<0.1]
口腔カンジダ症	8 (0.8) [0.8]	9 (1.0) [1.0]	9 (0.7) [0.7]	11 (0.9) [0.9]
口腔真菌感染	0	2 (0.2) [0.2]	0	4 (0.3) [0.3]
口腔ヘルペス	19 (2.0) [2.0]	54 (5.7) [5.7]	23 (1.8) [1.8]	63 (5.0) [5.0]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
口腔感染	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
中咽頭カンジダ症	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
外耳炎	0	4 (0.4) [0.4]	1 (<0.1) [<0.1]	5 (0.4) [0.4]
中耳炎	0	6 (0.6) [0.6]	2 (0.2) [0.2]	6 (0.5) [0.5]
急性中耳炎	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
子宮傍組織炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
爪囲炎	2 (0.2) [0.2]	5 (0.5) [0.5]	3 (0.2) [0.2]	5 (0.4) [0.4]
軟骨膜炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
歯冠周囲炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
歯周炎	5 (0.5) [0.5]	3 (0.3) [0.3]	6 (0.5) [0.5]	3 (0.2) [0.2]
咽頭炎	19 (2.0) [2.0]	19 (2.0) [2.0]	27 (2.2) [2.2]	30 (2.4) [2.4]
細菌性咽頭炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
レンサ球菌性咽頭炎	5 (0.5) [0.5]	2 (0.2) [0.2]	7 (0.6) [0.6]	3 (0.2) [0.2]
咽頭扁桃炎	1 (0.1) [0.1]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
毛巣嚢胞	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
ニューモシスチス・イロベチイ肺炎	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
肺炎	16 (1.7) [1.7]	14 (1.5) [1.5]	21 (1.7) [1.7]	22 (1.7) [1.7]
細菌性肺炎	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
インフルエンザ性肺炎	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
レンサ球菌性肺炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
処置後蜂巣炎	0	0	1 (<0.1) [<0.1]	0
処置後感染	0	3 (0.3) [0.3]	0	3 (0.2) [0.2]
前立腺感染	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
シュードモナス感染	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
歯髄炎	6 (0.6) [0.6]	0	6 (0.5) [0.5]	0
化膿性分泌物	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
腎盂腎炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
急性腎盂腎炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
膿尿	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
膿疱性皮疹	1 (0.1) [0.1]	4 (0.4) [0.4]	1 (<0.1) [<0.1]	5 (0.4) [0.4]
気道感染	17 (1.8) [1.8]	17 (1.8) [1.8]	20 (1.6) [1.6]	21 (1.7) [1.7]
ウイルス性気道感染	10 (1.1) [1.1]	14 (1.5) [1.5]	17 (1.4) [1.4]	17 (1.4) [1.4]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
鼻炎	7 (0.7) [0.7]	8 (0.8) [0.8]	8 (0.6) [0.6]	10 (0.8) [0.8]
卵管炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
敗血症	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	2 (0.2) [0.2]
副鼻腔炎	32 (3.4) [3.4]	34 (3.6) [3.6]	43 (3.4) [3.4]	44 (3.5) [3.5]
細菌性副鼻腔炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
皮膚細菌感染	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
皮膚カンジダ	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
皮膚感染	2 (0.2) [0.2]	3 (0.3) [0.3]	3 (0.2) [0.2]	4 (0.3) [0.3]
ブドウ球菌性菌血症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ブドウ球菌感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
ブドウ球菌性敗血症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ブドウ球菌皮膚感染	3 (0.3) [0.3]	3 (0.3) [0.3]	3 (0.2) [0.2]	3 (0.2) [0.2]
皮下組織膿瘍	0	1 (0.1) [0.1]	3 (0.2) [0.2]	2 (0.2) [0.2]
股部白癬	0	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]
白癬感染	1 (0.1) [0.1]	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]
手白癬	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
足部白癬	3 (0.3) [0.3]	7 (0.7) [0.7]	6 (0.5) [0.5]	10 (0.8) [0.8]
癜風	2 (0.2) [0.2]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
扁桃炎	8 (0.8) [0.8]	10 (1.1) [1.1]	11 (0.9) [0.9]	13 (1.0) [1.0]
細菌性扁桃炎	4 (0.4) [0.4]	1 (0.1) [0.1]	4 (0.3) [0.3]	1 (<0.1) [<0.1]
歯膿瘍	7 (0.7) [0.7]	5 (0.5) [0.5]	10 (0.8) [0.8]	5 (0.4) [0.4]
歯感染	5 (0.5) [0.5]	12 (1.3) [1.3]	6 (0.5) [0.5]	16 (1.3) [1.3]
気管炎	0	4 (0.4) [0.4]	3 (0.2) [0.2]	4 (0.3) [0.3]
気管気管支炎	3 (0.3) [0.3]	5 (0.5) [0.5]	4 (0.3) [0.3]	5 (0.4) [0.4]
細菌性気管気管支炎	0	0	0	1 (<0.1) [<0.1]
上気道感染	133 (14.0) [14.0]	167 (17.7) [17.6]	168 (13.5) [13.5]	193 (15.3) [15.4]
尿道炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
尿路感染	77 (8.1) [8.1]	85 (9.0) [9.0]	91 (7.3) [7.3]	109 (8.7) [8.7]
細菌性尿路感染	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
腸球菌性尿路感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
尿路性敗血症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
膣感染	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
ウイルス血症	0	0	1 (<0.1) [<0.1]	0
ウイルス感染	5 (0.5) [0.5]	10 (1.1) [1.1]	5 (0.4) [0.4]	14 (1.1) [1.1]
ウイルス性筋炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
ウイルス性咽頭炎	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
ウイルス性発疹	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
ウイルス性副鼻腔炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ウイルス性扁桃炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
ウイルス性気管炎	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
ウイルス性上気道感染	10 (1.1) [1.1]	11 (1.2) [1.2]	18 (1.4) [1.4]	19 (1.5) [1.5]
外陰部炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
外陰部腟カンジダ症	5 (0.5) [0.5]	8 (0.8) [0.8]	5 (0.4) [0.4]	8 (0.6) [0.6]
外陰腟真菌感染	4 (0.4) [0.4]	11 (1.2) [1.2]	4 (0.3) [0.3]	11 (0.9) [0.9]
外陰腟炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
傷害、中毒および処置合併症	130 (13.7) [13.6]	126 (13.3) [13.3]	158 (12.7) [12.7]	154 (12.2) [12.2]
動物咬傷	2 (0.2) [0.2]	6 (0.6) [0.6]	2 (0.2) [0.2]	6 (0.5) [0.5]
足関節部骨折	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]	3 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
傷害、中毒および処置合併症 (Cont.)				
節足動物咬傷	5 (0.5) [0.5]	2 (0.2) [0.2]	5 (0.4) [0.4]	3 (0.2) [0.2]
節足動物刺傷	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
剥離骨折	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
背部損傷	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
骨挫傷	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
骨亀裂	0	0	1 (<0.1) [<0.1]	0
第1度熱傷	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
第2度熱傷	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
軟骨損傷	0	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
頚椎骨折	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
化学熱傷	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
鎖骨骨折	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
粉砕骨折	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
脳振盪	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
挫傷	16 (1.7) [1.7]	14 (1.5) [1.5]	18 (1.4) [1.4]	16 (1.3) [1.3]
角膜擦過傷	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
傷害、中毒および処置合併症 (Cont.)				
上顎炎	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	2 (0.2) [0.2]
眼挫傷	0	0	0	1 (<0.1) [<0.1]
転倒	10 (1.1) [1.0]	14 (1.5) [1.5]	10 (0.8) [0.8]	17 (1.4) [1.4]
大腿骨頚部骨折	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
大腿骨骨折	0	0	0	1 (<0.1) [<0.1]
腓骨骨折	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
足骨折	7 (0.7) [0.7]	2 (0.2) [0.2]	7 (0.6) [0.6]	2 (0.2) [0.2]
体内異物	0	0	2 (0.2) [0.2]	0
眼内異物	0	0	1 (<0.1) [<0.1]	0
仙骨骨折	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
凍傷	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
手骨折	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]
上腕骨骨折	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
損傷	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
関節脱臼	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
関節損傷	3 (0.3) [0.3]	4 (0.4) [0.4]	5 (0.4) [0.4]	5 (0.4) [0.4]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
傷害、中毒および処置合併症 (Cont.)				
靭帯損傷	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
靭帯断裂	1 (0.1) [0.1]	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]
靭帯捻挫	4 (0.4) [0.4]	7 (0.7) [0.7]	5 (0.4) [0.4]	8 (0.6) [0.6]
四肢圧挫損傷	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
四肢損傷	8 (0.8) [0.8]	1 (0.1) [0.1]	9 (0.7) [0.7]	2 (0.2) [0.2]
口唇損傷	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
腰椎骨折	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
つち指	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
半月板損傷	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
筋損傷	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
筋断裂	0	0	2 (0.2) [0.2]	0
肉離れ	6 (0.6) [0.6]	4 (0.4) [0.4]	7 (0.6) [0.6]	5 (0.4) [0.4]
膝蓋骨骨折	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
椎弓切除後症候群	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
処置後胆汁漏出	0	0	1 (<0.1) [<0.1]	0
処置後出血	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
傷害、中毒および処置合併症 (Cont.)				
処置後甲状腺機能低下症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
外傷後頚部症候群	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
処置による疼痛	4 (0.4) [0.4]	2 (0.2) [0.2]	5 (0.4) [0.4]	3 (0.2) [0.2]
恥骨骨折	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
橈骨骨折	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	3 (0.2) [0.2]
肋骨骨折	0	3 (0.3) [0.3]	1 (<0.1) [<0.1]	4 (0.3) [0.3]
交通事故	3 (0.3) [0.3]	3 (0.3) [0.3]	5 (0.4) [0.4]	4 (0.3) [0.3]
引っかき傷	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
皮膚擦過傷	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]
皮膚裂傷	9 (0.9) [0.9]	4 (0.4) [0.4]	10 (0.8) [0.8]	6 (0.5) [0.5]
脊椎圧迫骨折	0	3 (0.3) [0.3]	0	3 (0.2) [0.2]
胸骨骨折	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ストレス骨折	1 (0.1) [0.1]	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]
滑膜断裂	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
腱損傷	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
腱断裂	2 (0.2) [0.2]	4 (0.4) [0.4]	2 (0.2) [0.2]	5 (0.4) [0.4]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
傷害、中毒および処置合併症 (Cont.)				
熱傷	2 (0.2) [0.2]	3 (0.3) [0.3]	4 (0.3) [0.3]	4 (0.3) [0.3]
胸椎骨折	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
脛骨骨折	0	0	1 (<0.1) [<0.1]	0
歯牙破折	8 (0.8) [0.8]	6 (0.6) [0.6]	8 (0.6) [0.6]	6 (0.5) [0.5]
各種物質毒性	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
外傷性関節炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
外傷性血腫	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
外傷性血胸	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
上肢骨折	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
創傷	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
手首関節骨折	0	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
臨床検査	287 (30.2) [30.2]	428 (45.3) [45.2]	358 (28.7) [28.7]	528 (42.0) [42.0]
アラニンアミノトランスフェラーゼ増加	58 (6.1) [6.1]	62 (6.6) [6.6]	67 (5.4) [5.4]	76 (6.0) [6.0]
アルドラーゼ増加	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
αヒドロキシ酪酸脱水素酵素増加	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
抗甲状腺抗体陽性	0	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
臨床検査 (Cont.)				
アスパラギン酸アミノトランスフェラーゼ増加	37 (3.9) [3.9]	44 (4.7) [4.7]	44 (3.5) [3.5]	59 (4.7) [4.7]
細菌検査陽性	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
血中アルカリホスファターゼ増加	2 (0.2) [0.2]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
血中ビリルビン増加	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]	3 (0.2) [0.2]
血中コレステロール増加	6 (0.6) [0.6]	6 (0.6) [0.6]	7 (0.6) [0.6]	7 (0.6) [0.6]
血中クレアチン増加	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
血中クレアチンホスホキナーゼ増加	93 (9.8) [9.8]	139 (14.7) [14.7]	113 (9.1) [9.1]	173 (13.8) [13.8]
血中クレアチニン増加	2 (0.2) [0.2]	9 (1.0) [1.0]	6 (0.5) [0.5]	9 (0.7) [0.7]
血中葉酸減少	0	0	1 (<0.1) [<0.1]	0
血中ブドウ糖異常	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
血中ブドウ糖増加	6 (0.6) [0.6]	5 (0.5) [0.5]	6 (0.5) [0.5]	8 (0.6) [0.6]
血中乳酸脱水素酵素増加	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
血中リン減少	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
血中カリウム増加	3 (0.3) [0.3]	5 (0.5) [0.5]	3 (0.2) [0.2]	7 (0.6) [0.6]
血圧上昇	5 (0.5) [0.5]	8 (0.8) [0.8]	8 (0.6) [0.6]	8 (0.6) [0.6]
収縮期血圧上昇	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
臨床検査 (Cont.)				
血中テストステロン減少	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
血中甲状腺刺激ホルモン減少	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
血中トリグリセリド増加	1 (0.1) [0.1]	2 (0.2) [0.2]	4 (0.3) [0.3]	2 (0.2) [0.2]
血中尿素増加	0	5 (0.5) [0.5]	1 (<0.1) [<0.1]	5 (0.4) [0.4]
血中尿酸増加	3 (0.3) [0.3]	4 (0.4) [0.4]	5 (0.4) [0.4]	4 (0.3) [0.3]
体温上昇	0	0	1 (<0.1) [<0.1]	0
心雑音	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
心電図T波逆転	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
γ－グルタミルトランスフェラーゼ増加	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
ヘマトクリット減少	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
ヘモグロビン減少	2 (0.2) [0.2]	8 (0.8) [0.8]	2 (0.2) [0.2]	11 (0.9) [0.9]
心拍数減少	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
ヘリコバクター検査陽性	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肝酵素上昇	3 (0.3) [0.3]	12 (1.3) [1.3]	5 (0.4) [0.4]	14 (1.1) [1.1]
高比重リポ蛋白増加	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
未熟顆粒球数増加	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
臨床検査 (Cont.)				
深吸気量減少	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
眼圧上昇	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肝機能検査値上昇	7 (0.7) [0.7]	9 (1.0) [1.0]	8 (0.6) [0.6]	12 (1.0) [1.0]
低比重リポ蛋白増加	3 (0.3) [0.3]	3 (0.3) [0.3]	3 (0.2) [0.2]	3 (0.2) [0.2]
リンパ球数減少	6 (0.6) [0.6]	5 (0.5) [0.5]	6 (0.5) [0.5]	6 (0.5) [0.5]
リンパ球数増加	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
リンパ球形態異常	1 (0.1) [0.1]	0	2 (0.2) [0.2]	0
平均赤血球容積増加	3 (0.3) [0.3]	7 (0.7) [0.7]	3 (0.2) [0.2]	11 (0.9) [0.9]
筋酵素上昇	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
骨髄球存在	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
好中球数減少	2 (0.2) [0.2]	16 (1.7) [1.7]	2 (0.2) [0.2]	19 (1.5) [1.5]
好中球数増加	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
核磁気共鳴画像異常	0	0	1 (<0.1) [<0.1]	0
血小板数増加	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
前立腺特異性抗原	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
前立腺特異性抗原異常	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
臨床検査 (Cont.)				
前立腺特異性抗原増加	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
総蛋白増加	0	0	1 (<0.1) [<0.1]	0
尿中蛋白陽性	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
赤血球数減少	1 (0.1) [0.1]	7 (0.7) [0.7]	1 (<0.1) [<0.1]	8 (0.6) [0.6]
血沈亢進	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
血清フェリチン減少	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ブドウ球菌検査陽性	0	0	0	1 (<0.1) [<0.1]
レンサ球菌検査陽性	0	0	0	1 (<0.1) [<0.1]
トランスアミナーゼ上昇	6 (0.6) [0.6]	12 (1.3) [1.3]	8 (0.6) [0.6]	14 (1.1) [1.1]
尿検査異常	0	0	0	2 (0.2) [0.2]
尿中白血球エステラーゼ陽性	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
超低比重リポ蛋白増加	2 (0.2) [0.2]	7 (0.7) [0.7]	2 (0.2) [0.2]	7 (0.6) [0.6]
体重減少	1 (0.1) [0.1]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
体重増加	5 (0.5) [0.5]	8 (0.8) [0.8]	10 (0.8) [0.8]	9 (0.7) [0.7]
白血球数減少	5 (0.5) [0.5]	16 (1.7) [1.7]	6 (0.5) [0.5]	20 (1.6) [1.6]
白血球数増加	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
代謝および栄養障害	96 (10.1) [10.1]	102 (10.8) [10.8]	117 (9.4) [9.4]	119 (9.5) [9.5]
異常体重減少	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
炭水化物不耐症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
食欲減退	0	3 (0.3) [0.3]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
脱水	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
糖尿病	11 (1.2) [1.2]	4 (0.4) [0.4]	13 (1.0) [1.0]	5 (0.4) [0.4]
コントロール不良の糖尿病	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
脂質異常症	7 (0.7) [0.7]	14 (1.5) [1.5]	8 (0.6) [0.6]	15 (1.2) [1.2]
体液貯留	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
耐糖能障害	2 (0.2) [0.2]	1 (0.1) [0.1]	4 (0.3) [0.3]	1 (<0.1) [<0.1]
グルテン過敏症	0	0	0	1 (<0.1) [<0.1]
痛風	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
高カルシウム血症	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
高コレステロール血症	7 (0.7) [0.7]	16 (1.7) [1.7]	10 (0.8) [0.8]	18 (1.4) [1.4]
高血糖	9 (0.9) [0.9]	11 (1.2) [1.2]	11 (0.9) [0.9]	13 (1.0) [1.0]
高カリウム血症	3 (0.3) [0.3]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
代謝および栄養障害 (Cont.)				
高脂血症	12 (1.3) [1.3]	9 (1.0) [1.0]	14 (1.1) [1.1]	12 (1.0) [1.0]
高トリグリセリド血症	3 (0.3) [0.3]	5 (0.5) [0.5]	3 (0.2) [0.2]	7 (0.6) [0.6]
高尿酸血症	7 (0.7) [0.7]	9 (1.0) [0.9]	9 (0.7) [0.7]	10 (0.8) [0.8]
低カルシウム血症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
低血糖	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
低カリウム血症	3 (0.3) [0.3]	0	3 (0.2) [0.2]	0
低ナトリウム血症	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
低リン酸血症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
空腹時血中ブドウ糖不良	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
食欲亢進	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
インスリン抵抗性	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]
鉄欠乏	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
栄養障害	0	0	0	1 (<0.1) [<0.1]
肥満	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
1型糖尿病	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
2型糖尿病	8 (0.8) [0.8]	8 (0.8) [0.8]	11 (0.9) [0.9]	8 (0.6) [0.6]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
代謝および栄養障害 (Cont.)				
ビタミンB群欠乏	1 (0.1) [0.1]	0	2 (0.2) [0.2]	0
ビタミンB12欠乏	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]	2 (0.2) [0.2]
ビタミンD欠乏	6 (0.6) [0.6]	5 (0.5) [0.5]	7 (0.6) [0.6]	7 (0.6) [0.6]
筋骨格系および結合組織障害	193 (20.3) [20.3]	200 (21.2) [21.2]	237 (19.0) [19.0]	256 (20.4) [20.4]
関節痛	16 (1.7) [1.7]	21 (2.2) [2.2]	20 (1.6) [1.6]	25 (2.0) [2.0]
関節炎	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
関節障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
背部痛	26 (2.7) [2.7]	30 (3.2) [3.2]	28 (2.2) [2.2]	37 (2.9) [2.9]
骨侵食	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
骨腫脹	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
滑液包炎	7 (0.7) [0.7]	9 (1.0) [1.0]	7 (0.6) [0.6]	11 (0.9) [0.9]
頚部脊柱管狭窄症	0	0	1 (<0.1) [<0.1]	0
軟骨疾患	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
尾骨痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肋軟骨炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
外骨腫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
筋骨格系および結合組織障害 (Cont.)				
顎骨の外骨腫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
顔面非対称	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
瘻孔	0	0	1 (<0.1) [<0.1]	0
側腹部痛	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
足変形	3 (0.3) [0.3]	0	3 (0.2) [0.2]	0
出血性関節症	0	0	1 (<0.1) [<0.1]	0
椎間板線維輪断裂	0	0	0	1 (<0.1) [<0.1]
椎間板変性症	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
椎間板障害	2 (0.2) [0.2]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
椎間板突出	2 (0.2) [0.2]	8 (0.8) [0.8]	3 (0.2) [0.2]	8 (0.6) [0.6]
関節滲出液	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
関節過伸展	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
関節雑音	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
関節硬直	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
関節腫脹	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
腰部脊柱管狭窄症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

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E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
筋骨格系および結合組織障害 (Cont.)				
半月板変性	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
筋拘縮	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
筋肉疲労	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
筋痙縮	12 (1.3) [1.3]	8 (0.8) [0.8]	13 (1.0) [1.0]	14 (1.1) [1.1]
筋緊張	0	0	1 (<0.1) [<0.1]	0
筋力低下	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
筋骨格系胸痛	1 (0.1) [0.1]	4 (0.4) [0.4]	2 (0.2) [0.2]	6 (0.5) [0.5]
筋骨格痛	2 (0.2) [0.2]	3 (0.3) [0.3]	4 (0.3) [0.3]	8 (0.6) [0.6]
筋骨格硬直	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
筋肉痛	6 (0.6) [0.6]	5 (0.5) [0.5]	6 (0.5) [0.5]	6 (0.5) [0.5]
筋膜疼痛症候群	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ミオパチー	0	0	0	1 (<0.1) [<0.1]
筋炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
頚部痛	1 (0.1) [0.1]	4 (0.4) [0.4]	1 (<0.1) [<0.1]	6 (0.5) [0.5]
変形性関節症	8 (0.8) [0.8]	13 (1.4) [1.4]	15 (1.2) [1.2]	16 (1.3) [1.3]
骨端症	1 (0.1) [0.1]	0	3 (0.2) [0.2]	0

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Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
筋骨格系および結合組織障害 (Cont.)				
骨壊死	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	4 (0.3) [0.3]
骨減少症	3 (0.3) [0.3]	0	3 (0.2) [0.2]	0
骨粗鬆症	3 (0.3) [0.3]	2 (0.2) [0.2]	4 (0.3) [0.3]	3 (0.2) [0.2]
四肢痛	4 (0.4) [0.4]	6 (0.6) [0.6]	5 (0.4) [0.4]	6 (0.5) [0.5]
関節周囲炎	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
足底筋膜炎	2 (0.2) [0.2]	5 (0.5) [0.5]	2 (0.2) [0.2]	5 (0.4) [0.4]
多発性関節炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
乾癬性関節症	44 (4.6) [4.6]	39 (4.1) [4.1]	53 (4.2) [4.3]	50 (4.0) [4.0]
急速進行性変形性関節症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
肩回旋筋腱板症候群	6 (0.6) [0.6]	2 (0.2) [0.2]	6 (0.5) [0.5]	2 (0.2) [0.2]
仙腸骨炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
側弯症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
軟部組織腫脹	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
脊椎不安定	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
変形性脊椎症	2 (0.2) [0.2]	3 (0.3) [0.3]	5 (0.4) [0.4]	6 (0.5) [0.5]
脊椎痛	2 (0.2) [0.2]	1 (0.1) [0.1]	4 (0.3) [0.3]	3 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
筋骨格系および結合組織障害 (Cont.)				
脊椎後方すべり症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
脊柱管狭窄症	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
滑液嚢腫	7 (0.7) [0.7]	2 (0.2) [0.2]	7 (0.6) [0.6]	3 (0.2) [0.2]
滑膜炎	0	0	1 (<0.1) [<0.1]	0
全身性エリテマトーデス	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
顎関節症候群	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
腱障害	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
腱炎	4 (0.4) [0.4]	1 (0.1) [0.1]	4 (0.3) [0.3]	2 (0.2) [0.2]
腱鞘炎	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
狭窄性腱鞘炎	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
胸部脊柱管狭窄症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
弾発指	1 (0.1) [0.1]	0	2 (0.2) [0.2]	0
椎間孔狭窄	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	26 (2.7) [2.7]	33 (3.5) [3.5]	38 (3.0) [3.0]	38 (3.0) [3.0]
肛門性器疣贅	1 (0.1) [0.1]	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]
基底細胞癌	3 (0.3) [0.3]	4 (0.4) [0.4]	7 (0.6) [0.6]	5 (0.4) [0.4]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
基底扁平上皮癌	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
副腎の良性新生物	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ボーエン病	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
乳癌	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
乳腺線維腫	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
大腸腺腫	1 (0.1) [0.1]	1 (0.1) [0.1]	2 (0.2) [0.2]	2 (0.2) [0.2]
子宮内膜腺癌	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
子宮内膜癌	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肝臓血管腫	0	0	0	1 (<0.1) [<0.1]
乳管内乳頭腫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
脂肪腫	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
乳房脂肪腫	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
肺腺癌	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
遠隔転移を伴う肺癌	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
悪性黒色腫	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
悪性黒色腫第3期	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

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Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
メラノサイト性母斑	3 (0.3) [0.3]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
単クローン性免疫グロブリン血症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
骨髄異形成症候群	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
神経内分泌癌	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
中咽頭扁平上皮癌	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
卵巣癌	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
良性副甲状腺腫瘍	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
形質細胞性骨髄腫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
前立腺癌	1 (0.1) [0.1]	0	2 (0.2) [0.2]	0
直腸腺癌	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
直腸癌	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
腎癌	0	0	0	1 (<0.1) [<0.1]
脂漏性角化症	0	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
皮膚乳頭腫	2 (0.2) [0.2]	5 (0.5) [0.5]	4 (0.3) [0.3]	5 (0.4) [0.4]
扁平上皮癌	0	0	0	1 (<0.1) [<0.1]
皮膚有棘細胞癌	3 (0.3) [0.3]	3 (0.3) [0.3]	3 (0.2) [0.2]	3 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
子宮平滑筋腫	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
神経系障害	95 (10.0) [10.0]	141 (14.9) [14.9]	122 (9.8) [9.8]	165 (13.1) [13.1]
味覚消失	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
異痛症	0	0	1 (<0.1) [<0.1]	0
健忘	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
無嗅覚	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
灼熱感	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
手根管症候群	5 (0.5) [0.5]	7 (0.7) [0.7]	5 (0.4) [0.4]	10 (0.8) [0.8]
中枢性肺胞性低換気	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
脳梗塞	0	0	0	1 (<0.1) [<0.1]
頚髄神経根障害	2 (0.2) [0.2]	3 (0.3) [0.3]	3 (0.2) [0.2]	4 (0.3) [0.3]
頚腕症候群	2 (0.2) [0.2]	1 (0.1) [0.1]	4 (0.3) [0.3]	1 (<0.1) [<0.1]
認知障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
脱髄	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
糖尿病性ニューロパチー	0	3 (0.3) [0.3]	0	3 (0.2) [0.2]
注意力障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

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Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
神経系障害 (Cont.)				
浮動性めまい	7 (0.7) [0.7]	12 (1.3) [1.3]	9 (0.7) [0.7]	15 (1.2) [1.2]
体位性めまい	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
味覚異常	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
顔面麻痺	0	0	0	1 (<0.1) [<0.1]
蟻走感	0	0	1 (<0.1) [<0.1]	0
頭部不快感	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
頭痛	35 (3.7) [3.7]	45 (4.8) [4.8]	43 (3.4) [3.4]	48 (3.8) [3.8]
知覚過敏	0	0	1 (<0.1) [<0.1]	0
感覚鈍麻	5 (0.5) [0.5]	5 (0.5) [0.5]	5 (0.4) [0.4]	6 (0.5) [0.5]
肋間神経痛	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
虚血性ニューロパチー	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
虚血性脳卒中	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
ラクナ脳卒中	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
嗜眠	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
腰髄神経根障害	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
腰仙部神経根障害	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]

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E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
神経系障害 (Cont.)				
記憶障害	1 (0.1) [0.1]	1 (0.1) [0.1]	2 (0.2) [0.2]	2 (0.2) [0.2]
片頭痛	4 (0.4) [0.4]	8 (0.8) [0.8]	5 (0.4) [0.4]	10 (0.8) [0.8]
モートン神経痛	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
神経圧迫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
神経痛	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
末梢性ニューロパチー	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
錯感覚	3 (0.3) [0.3]	6 (0.6) [0.6]	4 (0.3) [0.3]	7 (0.6) [0.6]
末梢性感覚ニューロパチー	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
腓骨神経麻痺	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
小発作てんかん	0	0	0	1 (<0.1) [<0.1]
多発ニューロパチー	0	0	0	1 (<0.1) [<0.1]
ヘルペス後神経痛	2 (0.2) [0.2]	7 (0.7) [0.7]	4 (0.3) [0.3]	9 (0.7) [0.7]
失神寸前の状態	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
神経根痛	0	0	1 (<0.1) [<0.1]	0
下肢静止不能症候群	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
坐骨神経痛	8 (0.8) [0.8]	6 (0.6) [0.6]	10 (0.8) [0.8]	6 (0.5) [0.5]

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E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
神経系障害 (Cont.)				
感覚障害	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
傾眠	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
会話障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
失神	1 (0.1) [0.1]	3 (0.3) [0.3]	2 (0.2) [0.2]	4 (0.3) [0.3]
緊張性頭痛	2 (0.2) [0.2]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
胸髄神経根障害	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
一過性全健忘	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
一過性脳虚血発作	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
振戦	2 (0.2) [0.2]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
三叉神経障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
三叉神経痛	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
椎骨脳底動脈不全	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
妊娠、産褥および周産期の状態	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
自然流産	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
異所性妊娠	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
製品の問題	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
製品の問題 (Cont.)				
医療機器破損	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
医療機器不具合	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
精神障害	53 (5.6) [5.6]	42 (4.4) [4.4]	66 (5.3) [5.3]	56 (4.5) [4.5]
急性ストレス反応	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
抑うつ気分を伴う適応障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
感情不安定	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
不安	9 (0.9) [0.9]	6 (0.6) [0.6]	14 (1.1) [1.1]	11 (0.9) [0.9]
不安障害	3 (0.3) [0.3]	1 (0.1) [0.1]	3 (0.2) [0.2]	2 (0.2) [0.2]
双極性障害	1 (0.1) [0.1]	0	2 (0.2) [0.2]	0
燃え尽き症候群	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
抑うつ気分	0	0	1 (<0.1) [<0.1]	0
うつ病	10 (1.1) [1.0]	18 (1.9) [1.9]	15 (1.2) [1.2]	20 (1.6) [1.6]
失見当識	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
薬物乱用	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
全般性不安障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
不眠症	19 (2.0) [2.0]	11 (1.2) [1.2]	19 (1.5) [1.5]	14 (1.1) [1.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
精神障害 (Cont.)				
リビドー減退	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
大うつ病	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
精神状態変化	0	0	0	1 (<0.1) [<0.1]
神経過敏	0	0	1 (<0.1) [<0.1]	0
神経症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
強迫性障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
パニック発作	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
睡眠障害	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
ストレス	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
自殺企図	0	0	0	1 (<0.1) [<0.1]
腎および尿路障害	54 (5.7) [5.7]	51 (5.4) [5.4]	61 (4.9) [4.9]	63 (5.0) [5.0]
急性腎障害	2 (0.2) [0.2]	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]
膀胱拡大	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
膀胱脱	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
膀胱結石	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
尿路結石	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
腎および尿路障害 (Cont.)				
着色尿	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
慢性腎臓病	3 (0.3) [0.3]	3 (0.3) [0.3]	3 (0.2) [0.2]	3 (0.2) [0.2]
結晶尿	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
腺性膀胱炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
糖尿病性腎症	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
排尿困難	3 (0.3) [0.3]	2 (0.2) [0.2]	4 (0.3) [0.3]	4 (0.3) [0.3]
糖尿	0	0	0	1 (<0.1) [<0.1]
血尿	11 (1.2) [1.2]	9 (1.0) [1.0]	11 (0.9) [0.9]	11 (0.9) [0.9]
緊張性膀胱	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
白血球尿	5 (0.5) [0.5]	6 (0.6) [0.6]	5 (0.4) [0.4]	7 (0.6) [0.6]
排尿異常	0	0	1 (<0.1) [<0.1]	0
尿意切迫	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
腎結石症	8 (0.8) [0.8]	7 (0.7) [0.7]	9 (0.7) [0.7]	10 (0.8) [0.8]
腎症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
頻尿	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
蛋白尿	4 (0.4) [0.4]	6 (0.6) [0.6]	6 (0.5) [0.5]	9 (0.7) [0.7]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
腎および尿路障害 (Cont.)				
腎盂腎杯拡張症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
腎仙痛	3 (0.3) [0.3]	0	4 (0.3) [0.3]	0
腎嚢胞	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
腎機能障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
腎乳頭壊死	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
腎静脈圧迫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
腹圧性尿失禁	0	0	1 (<0.1) [<0.1]	0
尿管結石症	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
尿失禁	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
尿閉	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
生殖系および乳房障害	45 (4.7) [4.7]	26 (2.8) [2.7]	52 (4.2) [4.2]	35 (2.8) [2.8]
腺筋症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
子宮付属器嚢胞	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
無月経	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
亀頭包皮炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
良性前立腺肥大症	2 (0.2) [0.2]	5 (0.5) [0.5]	2 (0.2) [0.2]	6 (0.5) [0.5]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
生殖系および乳房障害 (Cont.)				
乳房石灰化	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
乳房嚢胞	1 (0.1) [0.1]	0	3 (0.2) [0.2]	0
乳房障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
乳房線維化	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
乳房腫瘤	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
前立腺結石	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
子宮頚部嚢胞	0	0	0	1 (<0.1) [<0.1]
子宮頚部上皮異形成	1 (0.1) [0.1]	0	2 (0.2) [0.2]	0
子宮頚管ポリープ	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
膀胱瘤	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
機能不全性子宮出血	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
子宮頚外反	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
子宮頚管内膜症	0	0	1 (<0.1) [<0.1]	0
子宮内膜増殖症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
精巣上体嚢胞	0	0	1 (<0.1) [<0.1]	0
勃起不全	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
生殖系および乳房障害 (Cont.)				
卵管嚢胞	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
線維嚢胞性乳腺疾患	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
出血性卵巣嚢胞	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
閉経期症状	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
月経過多	4 (0.4) [0.4]	0	4 (0.3) [0.3]	1 (<0.1) [<0.1]
不規則月経	5 (0.5) [0.5]	1 (0.1) [0.1]	6 (0.5) [0.5]	1 (<0.1) [<0.1]
不正子宮出血	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
卵巣嚢胞	4 (0.4) [0.4]	3 (0.3) [0.3]	4 (0.3) [0.3]	4 (0.3) [0.3]
骨盤痛	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
前立腺石灰化	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
前立腺閉塞	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
前立腺炎	5 (0.5) [0.5]	1 (0.1) [0.1]	5 (0.4) [0.4]	1 (<0.1) [<0.1]
前立腺腫大	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
直腸瘤	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
陰嚢痛	0	0	1 (<0.1) [<0.1]	0
精巣障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
生殖系および乳房障害 (Cont.)				
子宮出血	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
子宮ポリープ	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
子宮脱	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
腟異形成	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
腟出血	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
呼吸器、胸郭および縦隔障害	100 (10.5) [10.5]	119 (12.6) [12.6]	112 (9.0) [9.0]	152 (12.1) [12.1]
急性呼吸不全	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
アレルギー性咽頭炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
喘息	3 (0.3) [0.3]	6 (0.6) [0.6]	3 (0.2) [0.2]	7 (0.6) [0.6]
無気肺	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
気管支反応性亢進	1 (0.1) [0.1]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
慢性気管支炎	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
気管支痙攣	3 (0.3) [0.3]	0	3 (0.2) [0.2]	1 (<0.1) [<0.1]
カタル	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
慢性閉塞性肺疾患	3 (0.3) [0.3]	6 (0.6) [0.6]	4 (0.3) [0.3]	10 (0.8) [0.8]
咳嗽	26 (2.7) [2.7]	41 (4.3) [4.3]	29 (2.3) [2.3]	50 (4.0) [4.0]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
呼吸器、胸郭および縦隔障害 (Cont.)				
発声障害	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
呼吸困難	6 (0.6) [0.6]	8 (0.8) [0.8]	6 (0.5) [0.5]	10 (0.8) [0.8]
労作性呼吸困難	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
鼻出血	6 (0.6) [0.6]	5 (0.5) [0.5]	7 (0.6) [0.6]	5 (0.4) [0.4]
間質性肺疾患	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
鼻閉	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
鼻部不快感	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
鼻の炎症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
鼻閉塞	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
鼻潰瘍	0	4 (0.4) [0.4]	0	4 (0.3) [0.3]
口腔咽頭痛	15 (1.6) [1.6]	12 (1.3) [1.3]	17 (1.4) [1.4]	17 (1.4) [1.4]
呼吸時疼痛	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
副鼻腔嚢胞	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
咽頭の炎症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
胸水	0	0	0	1 (<0.1) [<0.1]
胸膜炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
呼吸器、胸郭および縦隔障害 (Cont.)				
気胸	0	0	0	1 (<0.1) [<0.1]
自然気胸	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
湿性咳嗽	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
肺塞栓症	3 (0.3) [0.3]	3 (0.3) [0.3]	3 (0.2) [0.2]	4 (0.3) [0.3]
肺線維症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肺高血圧症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
肺腫瘤	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
逆流性喉頭炎	0	0	0	1 (<0.1) [<0.1]
呼吸窮迫	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
気道うっ血	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
アレルギー性鼻炎	4 (0.4) [0.4]	1 (0.1) [0.1]	6 (0.5) [0.5]	2 (0.2) [0.2]
鼻漏	3 (0.3) [0.3]	3 (0.3) [0.3]	4 (0.3) [0.3]	4 (0.3) [0.3]
副鼻腔うっ血	2 (0.2) [0.2]	0	2 (0.2) [0.2]	2 (0.2) [0.2]
副鼻腔障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
睡眠時無呼吸症候群	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
喀痰増加	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
呼吸器、胸郭および縦隔障害 (Cont.)				
咽喉刺激感	0	4 (0.4) [0.4]	0	4 (0.3) [0.3]
上気道の炎症	2 (0.2) [0.2]	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]
皮膚および皮下組織障害	112 (11.8) [11.8]	150 (15.9) [15.9]	139 (11.1) [11.1]	178 (14.2) [14.2]
黒色表皮腫	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
ざ瘡	10 (1.1) [1.0]	10 (1.1) [1.1]	11 (0.9) [0.9]	14 (1.1) [1.1]
光線性口唇炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
光線角化症	0	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]
脱毛症	3 (0.3) [0.3]	5 (0.5) [0.5]	3 (0.2) [0.2]	6 (0.5) [0.5]
血管浮腫	0	0	2 (0.2) [0.2]	0
皮脂欠乏症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
水疱	2 (0.2) [0.2]	3 (0.3) [0.3]	2 (0.2) [0.2]	5 (0.4) [0.4]
肝斑	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
慢性特発性蕁麻疹	0	0	1 (<0.1) [<0.1]	0
皮膚嚢腫	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]
皮膚炎	4 (0.4) [0.4]	6 (0.6) [0.6]	5 (0.4) [0.4]	7 (0.6) [0.6]
ざ瘡様皮膚炎	0	3 (0.3) [0.3]	0	3 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
皮膚および皮下組織障害 (Cont.)				
アレルギー性皮膚炎	2 (0.2) [0.2]	5 (0.5) [0.5]	4 (0.3) [0.3]	6 (0.5) [0.5]
アトピー性皮膚炎	1 (0.1) [0.1]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
接触皮膚炎	1 (0.1) [0.1]	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]
薬疹	0	4 (0.4) [0.4]	0	4 (0.3) [0.3]
皮膚乾燥	3 (0.3) [0.3]	3 (0.3) [0.3]	3 (0.2) [0.2]	3 (0.2) [0.2]
異汗性湿疹	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
斑状出血	1 (0.1) [0.1]	4 (0.4) [0.4]	1 (<0.1) [<0.1]	4 (0.3) [0.3]
湿疹	1 (0.1) [0.1]	2 (0.2) [0.2]	3 (0.2) [0.2]	3 (0.2) [0.2]
紅斑	2 (0.2) [0.2]	4 (0.4) [0.4]	2 (0.2) [0.2]	6 (0.5) [0.5]
結節性紅斑	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
毛髪成長異常	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
手皮膚炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
汗腺炎	0	0	0	1 (<0.1) [<0.1]
多汗症	3 (0.3) [0.3]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
嵌入爪	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
内方発育毛	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

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Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
皮膚および皮下組織障害 (Cont.)				
間擦疹	3 (0.3) [0.3]	0	3 (0.2) [0.2]	0
白斑症	0	0	0	1 (<0.1) [<0.1]
汗疹	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
爪郭の炎症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
爪成長異常	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
爪乾癬	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
寝汗	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
爪痛	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
爪破損	0	0	1 (<0.1) [<0.1]	0
爪甲剥離症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
爪甲脱落症	3 (0.3) [0.3]	0	3 (0.2) [0.2]	0
掌蹠膿疱症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
丘疹	0	0	0	1 (<0.1) [<0.1]
口囲皮膚炎	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
そう痒症	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
全身性そう痒症	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
皮膚および皮下組織障害 (Cont.)				
乾癬	12 (1.3) [1.3]	23 (2.4) [2.4]	14 (1.1) [1.1]	26 (2.1) [2.1]
老人性紫斑	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
膿疱性乾癬	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
発疹	6 (0.6) [0.6]	17 (1.8) [1.8]	8 (0.6) [0.6]	18 (1.4) [1.4]
紅斑性皮疹	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
毛孔性皮疹	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
全身性皮疹	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
斑状皮疹	4 (0.4) [0.4]	1 (0.1) [0.1]	4 (0.3) [0.3]	1 (<0.1) [<0.1]
斑状丘疹状皮疹	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
丘疹性皮疹	2 (0.2) [0.2]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
そう痒性皮疹	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
小水疱性皮疹	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
酒さ	8 (0.8) [0.8]	8 (0.8) [0.8]	10 (0.8) [0.8]	12 (1.0) [1.0]
痂皮	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
脂漏性皮膚炎	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
皮膚変色	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

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Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
皮膚および皮下組織障害 (Cont.)				
皮膚障害	0	0	0	1 (<0.1) [<0.1]
皮膚剥脱	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
皮膚亀裂	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
皮膚出血	0	0	1 (<0.1) [<0.1]	0
皮膚色素過剰	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
皮膚色素減少	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
皮膚刺激	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
皮膚病変	4 (0.4) [0.4]	5 (0.5) [0.5]	5 (0.4) [0.4]	5 (0.4) [0.4]
皮膚壊死	0	0	1 (<0.1) [<0.1]	0
皮膚潰瘍	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
顔面腫脹	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
一過性棘融解性皮膚症	0	0	1 (<0.1) [<0.1]	0
蕁麻疹	9 (0.9) [0.9]	6 (0.6) [0.6]	9 (0.7) [0.7]	7 (0.6) [0.6]
社会環境	4 (0.4) [0.4]	0	5 (0.4) [0.4]	1 (<0.1) [<0.1]
閉経	3 (0.3) [0.3]	0	4 (0.3) [0.3]	1 (<0.1) [<0.1]
職場でのストレス	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

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Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

[redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
血管障害	70 (7.4) [7.4]	65 (6.9) [6.9]	78 (6.3) [6.3]	79 (6.3) [6.3]
大動脈瘤	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
大動脈硬化症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
動脈硬化症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
深部静脈血栓症	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
本態性高血圧症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
大腿動脈瘤	0	0	0	1 (<0.1) [<0.1]
血腫	1 (0.1) [0.1]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
ほてり	3 (0.3) [0.3]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
高血圧	57 (6.0) [6.0]	41 (4.3) [4.3]	64 (5.1) [5.1]	52 (4.1) [4.1]
高血圧クリーゼ	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
高血圧切迫症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
低血圧	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
リンパ浮腫	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
起立性低血圧	0	3 (0.3) [0.3]	0	3 (0.2) [0.2]
末梢静脈疾患	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.2

Treatment-Emergent Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
血管障害 (Cont.)				
レイノー現象	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
血栓性静脈炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
表在性血栓性静脈炎	0	4 (0.4) [0.4]	0	4 (0.3) [0.3]
静脈瘤	0	1 (0.1) [0.1]	0	3 (0.2) [0.2]
血管拡張	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
静脈性高血圧	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
四肢静脈血栓症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
白衣性高血圧	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-90. 全ウパダシチニブ併合解析集団（20[redacted]年[redacted]月[redacted]日データカットオフ）の治験薬と関連ありの有害事象（100 人年あたりの発現件数）

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

	Upadacitinib			
System Organ Class MedDRA 22.0 Preferred Term	15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
Any Adverse Event	934 (98.2) [98.3]	1303 (137.8) [137.7]	1153 (92.4) [92.4]	1589 (126.4) [126.4]
*** Not Coded ***	3 (0.3) [0.3]	3 (0.3) [0.3]	4 (0.3) [0.3]	4 (0.3) [0.3]
*** Not Coded ***	3 (0.3) [0.3]	3 (0.3) [0.3]	4 (0.3) [0.3]	4 (0.3) [0.3]
血液およびリンパ系障害	64 (6.7) [6.7]	126 (13.3) [13.3]	76 (6.1) [6.1]	150 (11.9) [11.9]
貧血	10 (1.1) [1.1]	17 (1.8) [1.8]	11 (0.9) [0.9]	20 (1.6) [1.6]
大球性貧血	1 (0.1) [0.1]	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]
好塩基球増加症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
失血性貧血	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
骨髄浮腫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
血球減少症	0	0	0	2 (0.2) [0.2]
播種性血管内凝固	0	0	0	1 (<0.1) [<0.1]
好酸球増加症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
赤血球減少症	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
顆粒球減少症	0	1 (0.1) [0.1]	0	3 (0.2) [0.2]
内出血発生の増加傾向	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
鉄欠乏性貧血	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

	Upadacitinib			
System Organ Class MedDRA 22.0 Preferred Term	15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
血液およびリンパ系障害 (Cont.)				
白血球増加症	0	3 (0.3) [0.3]	0	3 (0.2) [0.2]
白血球減少症	18 (1.9) [1.9]	24 (2.5) [2.5]	20 (1.6) [1.6]	32 (2.5) [2.5]
リンパ節炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
リンパ節症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
リンパ球増加症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
リンパ組織過形成	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
リンパ球減少症	19 (2.0) [2.0]	26 (2.8) [2.7]	20 (1.6) [1.6]	27 (2.1) [2.1]
好中球減少症	12 (1.3) [1.3]	30 (3.2) [3.2]	16 (1.3) [1.3]	35 (2.8) [2.8]
好中球増加症	2 (0.2) [0.2]	4 (0.4) [0.4]	2 (0.2) [0.2]	4 (0.3) [0.3]
正色素性貧血	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
汎血球減少症	0	0	0	1 (<0.1) [<0.1]
血小板減少症	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
血小板増加症	0	4 (0.4) [0.4]	1 (<0.1) [<0.1]	4 (0.3) [0.3]
心臓障害	4 (0.4) [0.4]	1 (0.1) [0.1]	4 (0.3) [0.3]	4 (0.3) [0.3]
心房細動	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
房室ブロック	0	0	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
心臓障害 (Cont.)				
心肺停止	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
動悸	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
洞性徐脈	0	0	0	1 (<0.1) [<0.1]
頻脈	0	0	0	1 (<0.1) [<0.1]
発作性頻脈	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
心室細動	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
先天性、家族性および遺伝性障害	0	0	1 (<0.1) [<0.1]	0
陰嚢水瘤	0	0	1 (<0.1) [<0.1]	0
耳および迷路障害	1 (0.1) [0.1]	0	3 (0.2) [0.2]	0
耳痛	0	0	1 (<0.1) [<0.1]	0
回転性めまい	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
頭位性回転性めまい	0	0	1 (<0.1) [<0.1]	0
内分泌障害	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
アンドロゲン欠乏症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
甲状腺腫	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
眼障害	5 (0.5) [0.5]	4 (0.4) [0.4]	5 (0.4) [0.4]	5 (0.4) [0.4]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
眼障害 (Cont.)				
一過性黒内障	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
眼瞼痙攣	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
霰粒腫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ドライアイ	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
眼痛	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
虹彩毛様体炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
瞼板腺炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
眼部不快感	0	0	0	1 (<0.1) [<0.1]
霧視	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
視力障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
胃腸障害	71 (7.5) [7.5]	85 (9.0) [9.0]	83 (6.7) [6.7]	98 (7.8) [7.8]
腹部不快感	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
腹部膨満	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
腹痛	6 (0.6) [0.6]	2 (0.2) [0.2]	8 (0.6) [0.6]	3 (0.2) [0.2]
上腹部痛	5 (0.5) [0.5]	10 (1.1) [1.1]	5 (0.4) [0.4]	10 (0.8) [0.8]
口角口唇炎	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
胃腸障害 (Cont.)				
アフタ性潰瘍	2 (0.2) [0.2]	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]
根尖肉芽腫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
大腸炎	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
便秘	5 (0.5) [0.5]	3 (0.3) [0.3]	5 (0.4) [0.4]	3 (0.2) [0.2]
下痢	10 (1.1) [1.1]	14 (1.5) [1.5]	13 (1.0) [1.0]	16 (1.3) [1.3]
憩室	0	0	1 (<0.1) [<0.1]	0
口内乾燥	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
十二指腸潰瘍	0	0	0	1 (<0.1) [<0.1]
消化不良	4 (0.4) [0.4]	3 (0.3) [0.3]	4 (0.3) [0.3]	4 (0.3) [0.3]
小腸炎	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
腸炎	0	0	0	1 (<0.1) [<0.1]
びらん性十二指腸炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
変色便	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
鼓腸	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
食中毒	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
胃出血	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
胃腸障害 (Cont.)				
胃炎	2 (0.2) [0.2]	4 (0.4) [0.4]	2 (0.2) [0.2]	4 (0.3) [0.3]
びらん性胃炎	3 (0.3) [0.3]	0	3 (0.2) [0.2]	0
胃十二指腸出血	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
胃十二指腸潰瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
消化器痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
胃食道逆流性疾患	2 (0.2) [0.2]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
潰瘍性歯肉炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
舌炎	0	0	1 (<0.1) [<0.1]	0
血便排泄	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
痔核	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
口腔内潰瘍形成	2 (0.2) [0.2]	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]
悪心	11 (1.2) [1.2]	10 (1.1) [1.1]	11 (0.9) [0.9]	11 (0.9) [0.9]
食道潰瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
口腔障害	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
口腔粘膜水疱形成	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
膵脂肪変性	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
胃腸障害 (Cont.)				
膵炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
歯周の炎症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
レッチング	0	0	1 (<0.1) [<0.1]	0
小腸出血	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
小腸潰瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
口内炎	1 (0.1) [0.1]	3 (0.3) [0.3]	3 (0.2) [0.2]	5 (0.4) [0.4]
舌潰瘍	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
歯の障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
埋伏歯	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
歯痛	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
上部消化管出血	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
嘔吐	0	7 (0.7) [0.7]	1 (<0.1) [<0.1]	7 (0.6) [0.6]
一般・全身障害および投与部位の状態	12 (1.3) [1.3]	27 (2.9) [2.9]	17 (1.4) [1.4]	35 (2.8) [2.8]
無力症	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
胸痛	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
悪寒	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
一般・全身障害および投与部位の状態 (Cont.)				
疲労	3 (0.3) [0.3]	5 (0.5) [0.5]	5 (0.4) [0.4]	9 (0.7) [0.7]
炎症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
インフルエンザ様疾患	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
注射部位疼痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
注射部位反応	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
倦怠感	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
非心臓性胸痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
末梢性浮腫	1 (0.1) [0.1]	0	2 (0.2) [0.2]	0
疼痛	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
末梢腫脹	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
発熱	2 (0.2) [0.2]	9 (1.0) [0.9]	4 (0.3) [0.3]	10 (0.8) [0.8]
腫脹	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
全身性炎症反応症候群	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肝胆道系障害	12 (1.3) [1.3]	18 (1.9) [1.9]	16 (1.3) [1.3]	21 (1.7) [1.7]
薬物性肝障害	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
肝機能異常	7 (0.7) [0.7]	7 (0.7) [0.7]	10 (0.8) [0.8]	10 (0.8) [0.8]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
肝胆道系障害 (Cont.)				
肝腫瘤	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
脂肪肝	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
肝炎	0	0	1 (<0.1) [<0.1]	0
肝毒性	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
高ビリルビン血症	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
肝障害	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肝損傷	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
非アルコール性脂肪性肝炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
脂肪性肝炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
免疫系障害	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
食物アレルギー	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
過敏症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
感染症および寄生虫症	387 (40.7) [40.7]	504 (53.3) [53.3]	489 (39.2) [39.2]	630 (50.1) [50.1]
腹部膿瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
腹壁膿瘍	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
膿瘍	0	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

	Upadacitinib			
System Organ Class MedDRA 22.0 Preferred Term	15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
四肢膿瘍	0	4 (0.4) [0.4]	0	5 (0.4) [0.4]
急性副鼻腔炎	1 (0.1) [0.1]	4 (0.4) [0.4]	2 (0.2) [0.2]	4 (0.3) [0.3]
肛門膿瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肛門直腸蜂巣炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
虫垂炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
異型肺炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
菌血症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
細菌感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
細菌性膣症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
体部白癬	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
細気管支炎	0	0	1 (<0.1) [<0.1]	0
気管支炎	24 (2.5) [2.5]	31 (3.3) [3.3]	35 (2.8) [2.8]	38 (3.0) [3.0]
細菌性気管支炎	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
蜂巣炎	4 (0.4) [0.4]	4 (0.4) [0.4]	5 (0.4) [0.4]	5 (0.4) [0.4]
コクシジオイデス症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
結膜炎	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
ウイルス性結膜炎	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
コロナウイルス感染	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
膀胱炎	4 (0.4) [0.4]	3 (0.3) [0.3]	4 (0.3) [0.3]	3 (0.2) [0.2]
大腸菌性膀胱炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
サイトメガロウイルス感染	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
毛嚢虫症	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
憩室炎	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
耳感染	2 (0.2) [0.2]	2 (0.2) [0.2]	3 (0.2) [0.2]	2 (0.2) [0.2]
精巣上体炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
丹毒	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
大腸菌性尿路感染	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
眼感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
毛包炎	11 (1.2) [1.2]	4 (0.4) [0.4]	11 (0.9) [0.9]	8 (0.6) [0.6]
真菌感染	1 (0.1) [0.1]	0	2 (0.2) [0.2]	0
皮膚真菌感染	3 (0.3) [0.3]	8 (0.8) [0.8]	3 (0.2) [0.2]	10 (0.8) [0.8]
せつ	3 (0.3) [0.3]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

	Upadacitinib			
System Organ Class MedDRA 22.0 Preferred Term	15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
胃腸炎	8 (0.8) [0.8]	10 (1.1) [1.1]	10 (0.8) [0.8]	13 (1.0) [1.0]
ウイルス性胃腸炎	1 (0.1) [0.1]	4 (0.4) [0.4]	1 (<0.1) [<0.1]	6 (0.5) [0.5]
消化管感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
性器カンジダ症	0	0	0	1 (<0.1) [<0.1]
陰部ヘルペス	4 (0.4) [0.4]	1 (0.1) [0.1]	4 (0.3) [0.3]	1 (<0.1) [<0.1]
歯肉膿瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
歯肉炎	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
鼠径部膿瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
H1N1インフルエンザ	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
B型肝炎	0	0	0	1 (<0.1) [<0.1]
B型肝炎再活性化	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
ヘルペス眼感染	0	0	0	1 (<0.1) [<0.1]
単純ヘルペス	5 (0.5) [0.5]	12 (1.3) [1.3]	5 (0.4) [0.4]	14 (1.1) [1.1]
ヘルペスウイルス感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
帯状疱疹	25 (2.6) [2.6]	45 (4.8) [4.8]	38 (3.0) [3.0]	63 (5.0) [5.0]
皮膚播種性帯状疱疹	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

	Upadacitinib			
System Organ Class MedDRA 22.0 Preferred Term	15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
神経合併症を伴う帯状疱疹感染	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
麦粒腫	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
膿痂疹	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
伝染性単核症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
インフルエンザ	15 (1.6) [1.6]	17 (1.8) [1.8]	19 (1.5) [1.5]	19 (1.5) [1.5]
注射部位感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
クレブシエラ感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
喉頭炎	0	1 (0.1) [0.1]	0	3 (0.2) [0.2]
潜伏結核	1 (0.1) [0.1]	1 (0.1) [0.1]	5 (0.4) [0.4]	3 (0.2) [0.2]
限局性感染	0	0	1 (<0.1) [<0.1]	0
下気道感染	4 (0.4) [0.4]	2 (0.2) [0.2]	4 (0.3) [0.3]	3 (0.2) [0.2]
肺感染	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
リンパ管炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
髄膜炎	0	0	0	1 (<0.1) [<0.1]
ムンプス	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
爪感染	1 (0.1) [0.1]	4 (0.4) [0.4]	1 (<0.1) [<0.1]	5 (0.4) [0.4]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
上咽頭炎	27 (2.8) [2.8]	23 (2.4) [2.4]	34 (2.7) [2.7]	33 (2.6) [2.6]
爪真菌症	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
眼部単純ヘルペス	0	0	0	1 (<0.1) [<0.1]
口腔カンジダ症	2 (0.2) [0.2]	3 (0.3) [0.3]	2 (0.2) [0.2]	5 (0.4) [0.4]
口腔真菌感染	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
口腔ヘルペス	11 (1.2) [1.2]	44 (4.7) [4.6]	15 (1.2) [1.2]	50 (4.0) [4.0]
中咽頭カンジダ症	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
外耳炎	0	3 (0.3) [0.3]	0	3 (0.2) [0.2]
中耳炎	0	3 (0.3) [0.3]	0	3 (0.2) [0.2]
急性中耳炎	0	3 (0.3) [0.3]	0	3 (0.2) [0.2]
爪囲炎	2 (0.2) [0.2]	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]
歯周炎	2 (0.2) [0.2]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
咽頭炎	6 (0.6) [0.6]	5 (0.5) [0.5]	9 (0.7) [0.7]	7 (0.6) [0.6]
細菌性咽頭炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
レンサ球菌性咽頭炎	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]	2 (0.2) [0.2]
ニューモシスチス・イロベチイ肺炎	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
肺炎	7 (0.7) [0.7]	8 (0.8) [0.8]	7 (0.6) [0.6]	13 (1.0) [1.0]
細菌性肺炎	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
インフルエンザ性肺炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
レンサ球菌性肺炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
処置後感染	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
シュードモナス感染	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
歯髄炎	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
化膿性分泌物	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
腎盂腎炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
膿尿	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
膿疱性皮疹	0	3 (0.3) [0.3]	0	4 (0.3) [0.3]
気道感染	13 (1.4) [1.4]	12 (1.3) [1.3]	15 (1.2) [1.2]	13 (1.0) [1.0]
ウイルス性気道感染	1 (0.1) [0.1]	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]
鼻炎	1 (0.1) [0.1]	4 (0.4) [0.4]	1 (<0.1) [<0.1]	5 (0.4) [0.4]
卵管炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
敗血症	2 (0.2) [0.2]	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
副鼻腔炎	12 (1.3) [1.3]	18 (1.9) [1.9]	17 (1.4) [1.4]	19 (1.5) [1.5]
皮膚カンジダ	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
皮膚感染	1 (0.1) [0.1]	0	2 (0.2) [0.2]	0
ブドウ球菌性菌血症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ブドウ球菌感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
ブドウ球菌性敗血症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ブドウ球菌皮膚感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
皮下組織膿瘍	0	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
股部白癬	0	0	0	1 (<0.1) [<0.1]
白癬感染	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
手白癬	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
足部白癬	2 (0.2) [0.2]	3 (0.3) [0.3]	5 (0.4) [0.4]	3 (0.2) [0.2]
癜風	1 (0.1) [0.1]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
扁桃炎	4 (0.4) [0.4]	7 (0.7) [0.7]	5 (0.4) [0.4]	7 (0.6) [0.6]
細菌性扁桃炎	3 (0.3) [0.3]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
歯膿瘍	2 (0.2) [0.2]	1 (0.1) [0.1]	4 (0.3) [0.3]	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
歯感染	1 (0.1) [0.1]	5 (0.5) [0.5]	1 (<0.1) [<0.1]	7 (0.6) [0.6]
気管炎	0	3 (0.3) [0.3]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
気管気管支炎	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]
細菌性気管気管支炎	0	0	0	1 (<0.1) [<0.1]
上気道感染	72 (7.6) [7.6]	85 (9.0) [9.0]	88 (7.1) [7.1]	101 (8.0) [8.0]
尿路感染	43 (4.5) [4.5]	36 (3.8) [3.8]	47 (3.8) [3.8]	49 (3.9) [3.9]
細菌性尿路感染	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
腸球菌性尿路感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
尿路性敗血症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ウイルス感染	0	2 (0.2) [0.2]	0	4 (0.3) [0.3]
ウイルス性筋炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
ウイルス性咽頭炎	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
ウイルス性副鼻腔炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ウイルス性気管炎	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
ウイルス性上気道感染	1 (0.1) [0.1]	1 (0.1) [0.1]	5 (0.4) [0.4]	2 (0.2) [0.2]
外陰部炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
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E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
外陰部腟カンジダ症	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]	2 (0.2) [0.2]
外陰腟真菌感染	2 (0.2) [0.2]	6 (0.6) [0.6]	2 (0.2) [0.2]	6 (0.5) [0.5]
外陰腟炎	0	0	0	1 (<0.1) [<0.1]
傷害、中毒および処置合併症	1 (0.1) [0.1]	5 (0.5) [0.5]	1 (<0.1) [<0.1]	6 (0.5) [0.5]
節足動物咬傷	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
挫傷	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
大腿骨骨折	0	0	0	1 (<0.1) [<0.1]
仙骨骨折	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
処置による疼痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
皮膚擦過傷	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
歯牙破折	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
臨床検査	207 (21.8) [21.8]	308 (32.6) [32.5]	247 (19.8) [19.8]	369 (29.3) [29.4]
アラニンアミノトランスフェラーゼ増加	49 (5.1) [5.2]	47 (5.0) [5.0]	55 (4.4) [4.4]	56 (4.5) [4.5]
αヒドロキシ酪酸脱水素酵素増加	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
アスパラギン酸アミノトランスフェラーゼ増加	34 (3.6) [3.6]	33 (3.5) [3.5]	38 (3.0) [3.0]	42 (3.3) [3.3]
血中アルカリホスファターゼ増加	1 (0.1) [0.1]	0	2 (0.2) [0.2]	0

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Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
臨床検査 (Cont.)				
血中ビリルビン増加	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
血中コレステロール増加	5 (0.5) [0.5]	5 (0.5) [0.5]	6 (0.5) [0.5]	5 (0.4) [0.4]
血中クレアチン増加	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
血中クレアチンホスホキナーゼ増加	68 (7.1) [7.2]	109 (11.5) [11.5]	80 (6.4) [6.4]	130 (10.3) [10.3]
血中クレアチニン増加	2 (0.2) [0.2]	5 (0.5) [0.5]	6 (0.5) [0.5]	5 (0.4) [0.4]
血中ブドウ糖異常	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
血中ブドウ糖増加	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
血中乳酸脱水素酵素増加	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
血中リン減少	0	0	1 (<0.1) [<0.1]	0
血中カリウム増加	0	5 (0.5) [0.5]	0	5 (0.4) [0.4]
血圧上昇	2 (0.2) [0.2]	4 (0.4) [0.4]	2 (0.2) [0.2]	4 (0.3) [0.3]
血中甲状腺刺激ホルモン減少	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
血中トリグリセリド増加	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
血中尿素増加	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
血中尿酸増加	1 (0.1) [0.1]	4 (0.4) [0.4]	1 (<0.1) [<0.1]	4 (0.3) [0.3]
体温上昇	0	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
臨床検査 (Cont.)				
γ－グルタミルトランスフェラーゼ増加	0	0	1 (<0.1) [<0.1]	0
ヘマトクリット減少	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
ヘモグロビン減少	2 (0.2) [0.2]	5 (0.5) [0.5]	2 (0.2) [0.2]	7 (0.6) [0.6]
肝酵素上昇	1 (0.1) [0.1]	8 (0.8) [0.8]	2 (0.2) [0.2]	9 (0.7) [0.7]
高比重リポ蛋白増加	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
未熟顆粒球数増加	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
深吸気量減少	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肝機能検査値上昇	4 (0.4) [0.4]	7 (0.7) [0.7]	4 (0.3) [0.3]	8 (0.6) [0.6]
低比重リポ蛋白増加	3 (0.3) [0.3]	3 (0.3) [0.3]	3 (0.2) [0.2]	3 (0.2) [0.2]
リンパ球数減少	6 (0.6) [0.6]	4 (0.4) [0.4]	6 (0.5) [0.5]	5 (0.4) [0.4]
リンパ球数増加	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
平均赤血球容積増加	3 (0.3) [0.3]	4 (0.4) [0.4]	3 (0.2) [0.2]	8 (0.6) [0.6]
筋酵素上昇	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
骨髄球存在	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
好中球数減少	2 (0.2) [0.2]	15 (1.6) [1.6]	2 (0.2) [0.2]	18 (1.4) [1.4]
血小板数増加	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	3 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
臨床検査 (Cont.)				
総蛋白増加	0	0	1 (<0.1) [<0.1]	0
赤血球数減少	1 (0.1) [0.1]	6 (0.6) [0.6]	1 (<0.1) [<0.1]	7 (0.6) [0.6]
血沈亢進	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
ブドウ球菌検査陽性	0	0	0	1 (<0.1) [<0.1]
レンサ球菌検査陽性	0	0	0	1 (<0.1) [<0.1]
トランスアミナーゼ上昇	2 (0.2) [0.2]	6 (0.6) [0.6]	3 (0.2) [0.2]	8 (0.6) [0.6]
尿検査異常	0	0	0	1 (<0.1) [<0.1]
超低比重リポ蛋白増加	2 (0.2) [0.2]	5 (0.5) [0.5]	2 (0.2) [0.2]	5 (0.4) [0.4]
体重減少	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
体重増加	2 (0.2) [0.2]	3 (0.3) [0.3]	5 (0.4) [0.4]	4 (0.3) [0.3]
白血球数減少	4 (0.4) [0.4]	16 (1.7) [1.7]	5 (0.4) [0.4]	19 (1.5) [1.5]
代謝および栄養障害	16 (1.7) [1.7]	32 (3.4) [3.4]	23 (1.8) [1.8]	39 (3.1) [3.1]
脂質異常症	3 (0.3) [0.3]	8 (0.8) [0.8]	4 (0.3) [0.3]	8 (0.6) [0.6]
高カルシウム血症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
高コレステロール血症	1 (0.1) [0.1]	8 (0.8) [0.8]	3 (0.2) [0.2]	9 (0.7) [0.7]
高血糖	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	4 (0.3) [0.3]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
代謝および栄養障害 (Cont.)				
高脂血症	4 (0.4) [0.4]	7 (0.7) [0.7]	5 (0.4) [0.4]	9 (0.7) [0.7]
高トリグリセリド血症	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	2 (0.2) [0.2]
高尿酸血症	3 (0.3) [0.3]	2 (0.2) [0.2]	5 (0.4) [0.4]	3 (0.2) [0.2]
低血糖	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
低カリウム血症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
低リン酸血症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
ビタミンD欠乏	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
筋骨格系および結合組織障害	19 (2.0) [2.0]	15 (1.6) [1.6]	24 (1.9) [1.9]	23 (1.8) [1.8]
関節痛	0	0	1 (<0.1) [<0.1]	0
関節炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
背部痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
軟骨疾患	0	0	0	1 (<0.1) [<0.1]
瘻孔	0	0	1 (<0.1) [<0.1]	0
側腹部痛	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
関節雑音	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
関節硬直	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
筋骨格系および結合組織障害 (Cont.)				
筋痙縮	3 (0.3) [0.3]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
筋力低下	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
筋骨格系胸痛	0	1 (0.1) [0.1]	0	3 (0.2) [0.2]
筋肉痛	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]	3 (0.2) [0.2]
ミオパチー	0	0	0	1 (<0.1) [<0.1]
変形性関節症	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
骨端症	0	0	1 (<0.1) [<0.1]	0
骨粗鬆症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
四肢痛	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
乾癬性関節症	6 (0.6) [0.6]	3 (0.3) [0.3]	8 (0.6) [0.6]	6 (0.5) [0.5]
急速進行性変形性関節症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
脊椎痛	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	4 (0.4) [0.4]	14 (1.5) [1.5]	8 (0.6) [0.6]	16 (1.3) [1.3]
肛門性器疣贅	0	3 (0.3) [0.3]	0	3 (0.2) [0.2]
基底細胞癌	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
ボーエン病	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
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E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
乳癌	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
大腸腺腫	0	0	1 (<0.1) [<0.1]	0
遠隔転移を伴う肺癌	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
メラノサイト性母斑	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
形質細胞性骨髄腫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
直腸腺癌	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
直腸癌	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
脂漏性角化症	0	0	1 (<0.1) [<0.1]	0
皮膚乳頭腫	0	5 (0.5) [0.5]	2 (0.2) [0.2]	5 (0.4) [0.4]
扁平上皮癌	0	0	0	1 (<0.1) [<0.1]
皮膚有棘細胞癌	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
神経系障害	18 (1.9) [1.9]	42 (4.4) [4.4]	27 (2.2) [2.2]	47 (3.7) [3.7]
異痛症	0	0	1 (<0.1) [<0.1]	0
灼熱感	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
手根管症候群	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
頚髄神経根障害	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

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Patients could be included in more than one treatment group.
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E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
神経系障害 (Cont.)				
浮動性めまい	3 (0.3) [0.3]	3 (0.3) [0.3]	4 (0.3) [0.3]	4 (0.3) [0.3]
顔面麻痺	0	0	0	1 (<0.1) [<0.1]
頭痛	8 (0.8) [0.8]	18 (1.9) [1.9]	13 (1.0) [1.0]	18 (1.4) [1.4]
感覚鈍麻	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
ラクナ脳卒中	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
嗜眠	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
記憶障害	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
片頭痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
神経痛	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
錯感覚	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
末梢性感覚ニューロパチー	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
ヘルペス後神経痛	1 (0.1) [0.1]	4 (0.4) [0.4]	2 (0.2) [0.2]	5 (0.4) [0.4]
失神寸前の状態	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
感覚障害	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
傾眠	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
失神	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
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E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
神経系障害 (Cont.)				
緊張性頭痛	0	0	1 (<0.1) [<0.1]	0
三叉神経障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
三叉神経痛	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
精神障害	5 (0.5) [0.5]	7 (0.7) [0.7]	6 (0.5) [0.5]	7 (0.6) [0.6]
感情不安定	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
不安	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
うつ病	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
不眠症	3 (0.3) [0.3]	3 (0.3) [0.3]	3 (0.2) [0.2]	3 (0.2) [0.2]
睡眠障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
腎および尿路障害	6 (0.6) [0.6]	12 (1.3) [1.3]	7 (0.6) [0.6]	14 (1.1) [1.1]
急性腎障害	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
尿路結石	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
慢性腎臓病	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
腺性膀胱炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
糖尿病性腎症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
排尿困難	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
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E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
腎および尿路障害 (Cont.)				
血尿	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	4 (0.3) [0.3]
緊張性膀胱	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
白血球尿	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
尿意切迫	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
頻尿	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
蛋白尿	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
生殖系および乳房障害	6 (0.6) [0.6]	3 (0.3) [0.3]	8 (0.6) [0.6]	5 (0.4) [0.4]
無月経	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
乳房嚢胞	0	0	1 (<0.1) [<0.1]	0
前立腺結石	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
勃起不全	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
線維嚢胞性乳腺疾患	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
月経過多	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
不規則月経	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
不正子宮出血	0	0	0	1 (<0.1) [<0.1]
前立腺炎	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]

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Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
生殖系および乳房障害 (Cont.)				
陰嚢痛	0	0	1 (<0.1) [<0.1]	0
呼吸器、胸郭および縦隔障害	31 (3.3) [3.3]	40 (4.2) [4.2]	33 (2.6) [2.6]	49 (3.9) [3.9]
急性呼吸不全	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
気管支反応性亢進	0	0	1 (<0.1) [<0.1]	0
カタル	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
咳嗽	4 (0.4) [0.4]	16 (1.7) [1.7]	4 (0.3) [0.3]	20 (1.6) [1.6]
発声障害	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
呼吸困難	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
労作性呼吸困難	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
鼻出血	1 (0.1) [0.1]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
間質性肺疾患	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
鼻閉	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
鼻部不快感	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
鼻の炎症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
鼻潰瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
口腔咽頭痛	7 (0.7) [0.7]	4 (0.4) [0.4]	7 (0.6) [0.6]	5 (0.4) [0.4]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
呼吸器、胸郭および縦隔障害 (Cont.)				
咽頭の炎症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
胸膜炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
自然気胸	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
湿性咳嗽	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肺塞栓症	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]	3 (0.2) [0.2]
肺線維症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肺高血圧症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
呼吸窮迫	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
アレルギー性鼻炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
鼻漏	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
副鼻腔うっ血	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
咽喉刺激感	0	4 (0.4) [0.4]	0	4 (0.3) [0.3]
上気道の炎症	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
皮膚および皮下組織障害	44 (4.6) [4.6]	43 (4.5) [4.5]	53 (4.2) [4.2]	50 (4.0) [4.0]
ざ瘡	5 (0.5) [0.5]	4 (0.4) [0.4]	5 (0.4) [0.4]	4 (0.3) [0.3]
光線性口唇炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
皮膚および皮下組織障害 (Cont.)				
光線角化症	0	0	1 (<0.1) [<0.1]	0
脱毛症	2 (0.2) [0.2]	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]
水疱	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	4 (0.3) [0.3]
肝斑	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
慢性特発性蕁麻疹	0	0	1 (<0.1) [<0.1]	0
皮膚嚢腫	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
皮膚炎	3 (0.3) [0.3]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
ざ瘡様皮膚炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
アレルギー性皮膚炎	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
アトピー性皮膚炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
皮膚乾燥	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
異汗性湿疹	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
斑状出血	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
湿疹	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
紅斑	0	4 (0.4) [0.4]	0	6 (0.5) [0.5]
毛髪成長異常	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
皮膚および皮下組織障害 (Cont.)				
多汗症	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
間擦疹	3 (0.3) [0.3]	0	3 (0.2) [0.2]	0
爪郭の炎症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
爪成長異常	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
寝汗	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
爪破損	0	0	1 (<0.1) [<0.1]	0
爪甲剥離症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
丘疹	0	0	0	1 (<0.1) [<0.1]
そう痒症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
全身性そう痒症	0	0	1 (<0.1) [<0.1]	0
乾癬	8 (0.8) [0.8]	6 (0.6) [0.6]	9 (0.7) [0.7]	7 (0.6) [0.6]
膿疱性乾癬	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
発疹	4 (0.4) [0.4]	6 (0.6) [0.6]	5 (0.4) [0.4]	7 (0.6) [0.6]
毛孔性皮疹	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
全身性皮疹	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
斑状皮疹	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.5

Treatment-Emergent Adverse Events with Reasonable Possibility of Being Related to Study Drug
in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
皮膚および皮下組織障害 (Cont.)				
斑状丘疹状皮疹	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
酒さ	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
皮膚剥脱	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
皮膚刺激	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
皮膚病変	3 (0.3) [0.3]	0	4 (0.3) [0.3]	0
皮膚壊死	0	0	1 (<0.1) [<0.1]	0
顔面腫脹	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
血管障害	16 (1.7) [1.7]	12 (1.3) [1.3]	16 (1.3) [1.3]	15 (1.2) [1.2]
深部静脈血栓症	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
ほてり	3 (0.3) [0.3]	0	3 (0.2) [0.2]	0
高血圧	8 (0.8) [0.8]	9 (1.0) [1.0]	8 (0.6) [0.6]	12 (1.0) [1.0]
高血圧クリーゼ	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
低血圧	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
リンパ浮腫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
血栓性静脈炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
表在性血栓性静脈炎	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-91. 全ウパダシチニブ併合解析集団（20[redacted]年[redacted]月[redacted]日データカットオフ）の治験薬と関連ありの有害事象

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
Any adverse event	308 (48.1) [48.1]	358 (55.9) [55.9]	400 (44.1) [44.1]	472 (51.2) [51.3]
*** Not coded ***	2 (0.3) [0.3]	3 (0.5) [0.5]	3 (0.3) [0.3]	4 (0.4) [0.4]
*** Not coded ***	2 (0.3) [0.3]	3 (0.5) [0.5]	3 (0.3) [0.3]	4 (0.4) [0.4]
血液およびリンパ系障害	35 (5.5) [5.5]	67 (10.5) [10.5]	46 (5.1) [5.0]	80 (8.7) [8.7]
貧血	9 (1.4) [1.4]	16 (2.5) [2.5]	10 (1.1) [1.1]	19 (2.1) [2.1]
大球性貧血	1 (0.2) [0.2]	2 (0.3) [0.3]	2 (0.2) [0.2]	2 (0.2) [0.2]
好塩基球増加症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
失血性貧血	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
骨髄浮腫	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
血球減少症	0	0	0	2 (0.2) [0.2]
播種性血管内凝固	0	0	0	1 (0.1) [0.1]
好酸球増加症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
赤血球減少症	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
顆粒球減少症	0	1 (0.2) [0.2]	0	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
血液およびリンパ系障害 (Cont.)				
内出血発生の増加傾向	0	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
鉄欠乏性貧血	0	1 (0.2) [0.2]	0	2 (0.2) [0.2]
白血球増加症	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
白血球減少症	14 (2.2) [2.2]	19 (3.0) [3.0]	16 (1.8) [1.7]	22 (2.4) [2.4]
リンパ節炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
リンパ節症	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
リンパ球増加症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
リンパ組織過形成	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
リンパ球減少症	9 (1.4) [1.4]	17 (2.7) [2.7]	10 (1.1) [1.1]	18 (2.0) [2.0]
好中球減少症	9 (1.4) [1.4]	23 (3.6) [3.6]	13 (1.4) [1.4]	27 (2.9) [3.0]
好中球増加症	2 (0.3) [0.3]	2 (0.3) [0.3]	2 (0.2) [0.2]	2 (0.2) [0.2]
正色素性貧血	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
汎血球減少症	0	0	0	1 (0.1) [0.1]
血小板減少症	0	2 (0.3) [0.3]	1 (0.1) [0.1]	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
血液およびリンパ系障害 (Cont.)				
血小板増加症	0	3 (0.5) [0.5]	1 (0.1) [0.1]	3 (0.3) [0.3]
心臓障害	3 (0.5) [0.5]	1 (0.2) [0.2]	3 (0.3) [0.3]	4 (0.4) [0.4]
心房細動	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
房室ブロック	0	0	0	1 (0.1) [0.1]
心肺停止	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
動悸	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
洞性徐脈	0	0	0	1 (0.1) [0.1]
頻脈	0	0	0	1 (0.1) [0.1]
発作性頻脈	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
心室細動	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
先天性、家族性および遺伝性障害	0	0	1 (0.1) [0.1]	0
陰嚢水瘤	0	0	1 (0.1) [0.1]	0
耳および迷路障害	1 (0.2) [0.2]	0	3 (0.3) [0.3]	0
耳痛	0	0	1 (0.1) [0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
耳および迷路障害 (Cont.)				
回転性めまい	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
頭位性回転性めまい	0	0	1 (0.1) [0.1]	0
内分泌障害	2 (0.3) [0.3]	0	2 (0.2) [0.2]	0
アンドロゲン欠乏症	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
甲状腺腫	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
眼障害	3 (0.5) [0.5]	4 (0.6) [0.6]	3 (0.3) [0.3]	5 (0.5) [0.5]
一過性黒内障	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
眼瞼痙攣	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
霰粒腫	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
ドライアイ	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
眼痛	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
虹彩毛様体炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
瞼板腺炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
眼部不快感	0	0	0	1 (0.1) [0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
眼障害 (Cont.)				
霧視	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
視力障害	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
胃腸障害	50 (7.8) [7.8]	57 (8.9) [8.9]	58 (6.4) [6.4]	68 (7.4) [7.4]
腹部不快感	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	3 (0.3) [0.3]
腹部膨満	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
腹痛	5 (0.8) [0.8]	2 (0.3) [0.3]	7 (0.8) [0.8]	3 (0.3) [0.3]
上腹部痛	5 (0.8) [0.8]	8 (1.2) [1.3]	5 (0.6) [0.5]	8 (0.9) [0.9]
口角口唇炎	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
アフタ性潰瘍	1 (0.2) [0.2]	0	1 (0.1) [0.1]	1 (0.1) [0.1]
根尖肉芽腫	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
大腸炎	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
便秘	4 (0.6) [0.6]	2 (0.3) [0.3]	4 (0.4) [0.4]	2 (0.2) [0.2]
下痢	10 (1.6) [1.6]	12 (1.9) [1.9]	13 (1.4) [1.4]	14 (1.5) [1.5]
憩室	0	0	1 (0.1) [0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
胃腸障害 (Cont.)				
口内乾燥	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
十二指腸潰瘍	0	0	0	1 (0.1) [0.1]
消化不良	4 (0.6) [0.6]	3 (0.5) [0.5]	4 (0.4) [0.4]	4 (0.4) [0.4]
小腸炎	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
腸炎	0	0	0	1 (0.1) [0.1]
びらん性十二指腸炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
変色便	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
鼓腸	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]
食中毒	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
胃出血	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
胃炎	2 (0.3) [0.3]	4 (0.6) [0.6]	2 (0.2) [0.2]	4 (0.4) [0.4]
びらん性胃炎	3 (0.5) [0.5]	0	3 (0.3) [0.3]	0
胃十二指腸出血	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
胃十二指腸潰瘍	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
胃腸障害 (Cont.)				
消化器痛	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
胃食道逆流性疾患	2 (0.3) [0.3]	1 (0.2) [0.2]	3 (0.3) [0.3]	1 (0.1) [0.1]
潰瘍性歯肉炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
舌炎	0	0	1 (0.1) [0.1]	0
血便排泄	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
痔核	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
口腔内潰瘍形成	2 (0.3) [0.3]	3 (0.5) [0.5]	2 (0.2) [0.2]	3 (0.3) [0.3]
悪心	10 (1.6) [1.6]	10 (1.6) [1.6]	10 (1.1) [1.1]	11 (1.2) [1.2]
食道潰瘍	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
口腔障害	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
口腔粘膜水疱形成	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
膵脂肪変性	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
膵炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
歯周の炎症	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
胃腸障害 (Cont.)				
レッチング	0	0	1 (0.1) [0.1]	0
小腸出血	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
小腸潰瘍	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
口内炎	1 (0.2) [0.2]	2 (0.3) [0.3]	3 (0.3) [0.3]	3 (0.3) [0.3]
舌潰瘍	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
歯の障害	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
埋伏歯	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
歯痛	2 (0.3) [0.3]	1 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.1) [0.1]
上部消化管出血	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
嘔吐	0	7 (1.1) [1.1]	1 (0.1) [0.1]	7 (0.8) [0.8]
一般・全身障害および投与部位の状態	12 (1.9) [1.9]	26 (4.1) [4.1]	17 (1.9) [1.9]	33 (3.6) [3.6]
無力症	1 (0.2) [0.2]	3 (0.5) [0.5]	1 (0.1) [0.1]	3 (0.3) [0.3]
胸痛	1 (0.2) [0.2]	0	1 (0.1) [0.1]	1 (0.1) [0.1]
悪寒	1 (0.2) [0.2]	0	1 (0.1) [0.1]	1 (0.1) [0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
一般・全身障害および投与部位の状態 (Cont.)				
疲労	3 (0.5) [0.5]	4 (0.6) [0.6]	5 (0.6) [0.5]	8 (0.9) [0.9]
炎症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
インフルエンザ様疾患	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
注射部位疼痛	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
注射部位反応	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
倦怠感	2 (0.3) [0.3]	0	2 (0.2) [0.2]	0
非心臓性胸痛	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
末梢性浮腫	1 (0.2) [0.2]	0	2 (0.2) [0.2]	0
疼痛	0	1 (0.2) [0.2]	0	2 (0.2) [0.2]
末梢腫脹	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
発熱	2 (0.3) [0.3]	9 (1.4) [1.4]	4 (0.4) [0.4]	10 (1.1) [1.1]
腫脹	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
全身性炎症反応症候群	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
肝胆道系障害	10 (1.6) [1.6]	14 (2.2) [2.2]	14 (1.5) [1.5]	16 (1.7) [1.7]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
肝胆道系障害 (Cont.)				
薬物性肝障害	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
肝機能異常	5 (0.8) [0.8]	5 (0.8) [0.8]	8 (0.9) [0.9]	7 (0.8) [0.8]
肝腫瘤	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
脂肪肝	1 (0.2) [0.2]	3 (0.5) [0.5]	1 (0.1) [0.1]	3 (0.3) [0.3]
肝炎	0	0	1 (0.1) [0.1]	0
肝毒性	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
高ビリルビン血症	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
肝障害	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
肝損傷	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
非アルコール性脂肪性肝炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
脂肪性肝炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
免疫系障害	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
食物アレルギー	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
過敏症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
感染症および寄生虫症	205 (32.0) [32.0]	236 (36.8) [36.8]	262 (28.9) [28.9]	309 (33.6) [33.6]
腹部膿瘍	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
腹壁膿瘍	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
膿瘍	0	0	1 (0.1) [0.1]	0
四肢膿瘍	0	4 (0.6) [0.6]	0	5 (0.5) [0.5]
急性副鼻腔炎	1 (0.2) [0.2]	3 (0.5) [0.5]	2 (0.2) [0.2]	3 (0.3) [0.3]
肛門膿瘍	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
肛門直腸蜂巣炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
虫垂炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
異型肺炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
菌血症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
細菌感染	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
細菌性膣症	1 (0.2) [0.2]	0	1 (0.1) [0.1]	1 (0.1) [0.1]
体部白癬	2 (0.3) [0.3]	0	2 (0.2) [0.2]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
感染症および寄生虫症 (Cont.)				
細気管支炎	0	0	1 (0.1) [0.1]	0
気管支炎	22 (3.4) [3.4]	26 (4.1) [4.1]	29 (3.2) [3.2]	33 (3.6) [3.6]
細菌性気管支炎	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
蜂巣炎	4 (0.6) [0.6]	4 (0.6) [0.6]	5 (0.6) [0.6]	5 (0.5) [0.5]
コクシジオイデス症	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
結膜炎	2 (0.3) [0.3]	0	2 (0.2) [0.2]	0
ウイルス性結膜炎	2 (0.3) [0.3]	0	2 (0.2) [0.2]	0
コロナウイルス感染	0	2 (0.3) [0.3]	1 (0.1) [0.1]	3 (0.3) [0.3]
膀胱炎	4 (0.6) [0.6]	3 (0.5) [0.5]	4 (0.4) [0.4]	3 (0.3) [0.3]
大腸菌性膀胱炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
サイトメガロウイルス感染	0	1 (0.2) [0.2]	0	2 (0.2) [0.2]
毛嚢虫症	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
憩室炎	0	1 (0.2) [0.2]	0	2 (0.2) [0.2]
耳感染	1 (0.2) [0.2]	2 (0.3) [0.3]	2 (0.2) [0.2]	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
感染症および寄生虫症 (Cont.)				
精巣上体炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
丹毒	2 (0.3) [0.3]	1 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.1) [0.1]
大腸菌性尿路感染	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
眼感染	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
毛包炎	11 (1.7) [1.7]	4 (0.6) [0.6]	11 (1.2) [1.2]	7 (0.8) [0.8]
真菌感染	1 (0.2) [0.2]	0	2 (0.2) [0.2]	0
皮膚真菌感染	3 (0.5) [0.5]	6 (0.9) [0.9]	3 (0.3) [0.3]	8 (0.9) [0.9]
せつ	3 (0.5) [0.5]	1 (0.2) [0.2]	3 (0.3) [0.3]	1 (0.1) [0.1]
胃腸炎	6 (0.9) [0.9]	9 (1.4) [1.4]	8 (0.9) [0.9]	12 (1.3) [1.3]
ウイルス性胃腸炎	1 (0.2) [0.2]	4 (0.6) [0.6]	1 (0.1) [0.1]	6 (0.7) [0.7]
消化管感染	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
性器カンジダ症	0	0	0	1 (0.1) [0.1]
陰部ヘルペス	3 (0.5) [0.5]	1 (0.2) [0.2]	3 (0.3) [0.3]	1 (0.1) [0.1]
歯肉膿瘍	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
感染症および寄生虫症 (Cont.)				
歯肉炎	1 (0.2) [0.2]	2 (0.3) [0.3]	1 (0.1) [0.1]	2 (0.2) [0.2]
単径部膿瘍	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
H1N1インフルエンザ	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
B型肝炎	0	0	0	1 (0.1) [0.1]
B型肝炎再活性化	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
ヘルペス眼感染	0	0	0	1 (0.1) [0.1]
単純ヘルペス	3 (0.5) [0.5]	7 (1.1) [1.1]	3 (0.3) [0.3]	9 (1.0) [1.0]
ヘルペスウイルス感染	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
帯状疱疹	23 (3.6) [3.6]	43 (6.7) [6.7]	36 (4.0) [4.0]	60 (6.5) [6.5]
皮膚播種性帯状疱疹	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
神経合併症を伴う帯状疱疹感染	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
麦粒腫	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
膿痂疹	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
伝染性単核症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

	Upadacitinib			
System Organ Class MedDRA 22.0 Preferred Term	15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Any 15 mg QD (N = 907) n (%) [SSA%]	Any 30 mg QD (N = 921) n (%) [SSA%]
感染症および寄生虫症 (Cont.)				
インフルエンザ	13 (2.0) [2.0]	15 (2.3) [2.3]	17 (1.9) [1.9]	17 (1.8) [1.8]
注射部位感染	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
クレブシエラ感染	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
喉頭炎	0	1 (0.2) [0.2]	0	3 (0.3) [0.3]
潜伏結核	1 (0.2) [0.2]	1 (0.2) [0.2]	5 (0.6) [0.5]	3 (0.3) [0.3]
限局性感染	0	0	1 (0.1) [0.1]	0
下気道感染	4 (0.6) [0.6]	2 (0.3) [0.3]	4 (0.4) [0.4]	3 (0.3) [0.3]
肺感染	0	2 (0.3) [0.3]	1 (0.1) [0.1]	3 (0.3) [0.3]
リンパ管炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
髄膜炎	0	0	0	1 (0.1) [0.1]
ムンプス	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
爪感染	1 (0.2) [0.2]	3 (0.5) [0.5]	1 (0.1) [0.1]	4 (0.4) [0.4]
上咽頭炎	20 (3.1) [3.1]	21 (3.3) [3.3]	24 (2.6) [2.6]	28 (3.0) [3.0]
爪真菌症	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
感染症および寄生虫症 (Cont.)				
眼部単純ヘルペス	0	0	0	1 (0.1) [0.1]
口腔カンジダ症	2 (0.3) [0.3]	3 (0.5) [0.5]	2 (0.2) [0.2]	5 (0.5) [0.5]
口腔真菌感染	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
口腔ヘルペス	9 (1.4) [1.4]	26 (4.1) [4.1]	13 (1.4) [1.4]	30 (3.3) [3.3]
中咽頭カンジダ症	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
外耳炎	0	3 (0.5) [0.5]	0	3 (0.3) [0.3]
中耳炎	0	3 (0.5) [0.5]	0	3 (0.3) [0.3]
急性中耳炎	0	3 (0.5) [0.5]	0	3 (0.3) [0.3]
爪囲炎	2 (0.3) [0.3]	2 (0.3) [0.3]	2 (0.2) [0.2]	2 (0.2) [0.2]
歯周炎	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.1) [0.1]
咽頭炎	6 (0.9) [0.9]	3 (0.5) [0.5]	9 (1.0) [1.0]	5 (0.5) [0.5]
細菌性咽頭炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
レンサ球菌性咽頭炎	3 (0.5) [0.5]	2 (0.3) [0.3]	3 (0.3) [0.3]	2 (0.2) [0.2]
ニューモシスチス・イロベチイ肺炎	0	1 (0.2) [0.2]	0	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
感染症および寄生虫症 (Cont.)				
肺炎	7 (1.1) [1.1]	8 (1.2) [1.2]	7 (0.8) [0.8]	12 (1.3) [1.3]
細菌性肺炎	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
インフルエンザ性肺炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
レンサ球菌性肺炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
処置後感染	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
シュードモナス感染	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
歯髄炎	2 (0.3) [0.3]	0	2 (0.2) [0.2]	0
化膿性分泌物	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
腎盂腎炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
膿尿	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
膿疱性皮疹	0	2 (0.3) [0.3]	0	3 (0.3) [0.3]
気道感染	12 (1.9) [1.9]	12 (1.9) [1.9]	14 (1.5) [1.5]	13 (1.4) [1.4]
ウイルス性気道感染	1 (0.2) [0.2]	2 (0.3) [0.3]	2 (0.2) [0.2]	2 (0.2) [0.2]
鼻炎	1 (0.2) [0.2]	4 (0.6) [0.6]	1 (0.1) [0.1]	5 (0.5) [0.5]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
感染症および寄生虫症 (Cont.)				
卵管炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
敗血症	2 (0.3) [0.3]	0	2 (0.2) [0.2]	1 (0.1) [0.1]
副鼻腔炎	12 (1.9) [1.9]	16 (2.5) [2.5]	16 (1.8) [1.8]	17 (1.8) [1.8]
皮膚カンジダ	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
皮膚感染	1 (0.2) [0.2]	0	2 (0.2) [0.2]	0
ブドウ球菌性菌血症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
ブドウ球菌感染	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
ブドウ球菌性敗血症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
ブドウ球菌皮膚感染	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
皮下組織膿瘍	0	1 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.1) [0.1]
股部白癬	0	0	0	1 (0.1) [0.1]
白癬感染	1 (0.2) [0.2]	2 (0.3) [0.3]	1 (0.1) [0.1]	2 (0.2) [0.2]
手白癬	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
足部白癬	2 (0.3) [0.3]	3 (0.5) [0.5]	3 (0.3) [0.3]	3 (0.3) [0.3]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
感染症および寄生虫症 (Cont.)				
癜風	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.1) [0.1]
扁桃炎	4 (0.6) [0.6]	6 (0.9) [0.9]	5 (0.6) [0.5]	6 (0.7) [0.7]
細菌性扁桃炎	3 (0.5) [0.5]	1 (0.2) [0.2]	3 (0.3) [0.3]	1 (0.1) [0.1]
歯膿瘍	2 (0.3) [0.3]	1 (0.2) [0.2]	4 (0.4) [0.4]	1 (0.1) [0.1]
歯感染	1 (0.2) [0.2]	5 (0.8) [0.8]	1 (0.1) [0.1]	7 (0.8) [0.8]
気管炎	0	3 (0.5) [0.5]	1 (0.1) [0.1]	3 (0.3) [0.3]
気管気管支炎	2 (0.3) [0.3]	2 (0.3) [0.3]	2 (0.2) [0.2]	2 (0.2) [0.2]
細菌性気管気管支炎	0	0	0	1 (0.1) [0.1]
上気道感染	53 (8.3) [8.3]	61 (9.5) [9.5]	65 (7.2) [7.1]	73 (7.9) [7.9]
尿路感染	32 (5.0) [5.0]	25 (3.9) [3.9]	36 (4.0) [4.0]	34 (3.7) [3.7]
細菌性尿路感染	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
腸球菌性尿路感染	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
尿路性敗血症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
ウイルス感染	0	2 (0.3) [0.3]	0	4 (0.4) [0.4]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
感染症および寄生虫症 (Cont.)				
ウイルス性筋炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
ウイルス性咽頭炎	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
ウイルス性副鼻腔炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
ウイルス性気管炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
ウイルス性上気道感染	1 (0.2) [0.2]	1 (0.2) [0.2]	4 (0.4) [0.4]	2 (0.2) [0.2]
外陰部炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
外陰部腟カンジダ症	2 (0.3) [0.3]	2 (0.3) [0.3]	2 (0.2) [0.2]	2 (0.2) [0.2]
外陰腟真菌感染	1 (0.2) [0.2]	3 (0.5) [0.5]	1 (0.1) [0.1]	3 (0.3) [0.3]
外陰腟炎	0	0	0	1 (0.1) [0.1]
傷害、中毒および処置合併症	1 (0.2) [0.2]	5 (0.8) [0.8]	1 (0.1) [0.1]	6 (0.7) [0.7]
節足動物咬傷	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
挫傷	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
大腿骨骨折	0	0	0	1 (0.1) [0.1]
仙骨骨折	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
傷害、中毒および処置合併症 (Cont.)				
処置による疼痛	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
皮膚擦過傷	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
歯牙破折	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
臨床検査	91 (14.2) [14.2]	131 (20.4) [20.5]	117 (12.9) [12.9]	162 (17.6) [17.6]
アラニンアミノトランスフェラーゼ増加	32 (5.0) [5.0]	36 (5.6) [5.6]	38 (4.2) [4.2]	44 (4.8) [4.8]
αヒドロキシ酪酸脱水素酵素増加	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
アスパラギン酸アミノトランスフェラーゼ増加	24 (3.8) [3.7]	24 (3.7) [3.8]	28 (3.1) [3.1]	32 (3.5) [3.5]
血中アルカリホスファターゼ増加	1 (0.2) [0.2]	0	2 (0.2) [0.2]	0
血中ビリルビン増加	2 (0.3) [0.3]	1 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.1) [0.1]
血中コレステロール増加	4 (0.6) [0.6]	5 (0.8) [0.8]	5 (0.6) [0.6]	5 (0.5) [0.5]
血中クレアチン増加	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
血中クレアチンホスホキナーゼ増加	47 (7.3) [7.3]	70 (10.9) [10.9]	57 (6.3) [6.3]	87 (9.4) [9.5]
血中クレアチニン増加	2 (0.3) [0.3]	5 (0.8) [0.8]	5 (0.6) [0.6]	5 (0.5) [0.5]
血中ブドウ糖異常	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
臨床検査 (Cont.)				
血中ブドウ糖増加	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
血中乳酸脱水素酵素増加	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
血中リン減少	0	0	1 (0.1) [0.1]	0
血中カリウム増加	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
血圧上昇	2 (0.3) [0.3]	2 (0.3) [0.3]	2 (0.2) [0.2]	2 (0.2) [0.2]
血中甲状腺刺激ホルモン減少	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
血中トリグリセリド増加	0	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
血中尿素増加	0	2 (0.3) [0.3]	1 (0.1) [0.1]	2 (0.2) [0.2]
血中尿酸増加	1 (0.2) [0.2]	4 (0.6) [0.6]	1 (0.1) [0.1]	4 (0.4) [0.4]
体温上昇	0	0	1 (0.1) [0.1]	0
γ－グルタミルトランスフェラーゼ増加	0	0	1 (0.1) [0.1]	0
ヘマトクリット減少	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
ヘモグロビン減少	2 (0.3) [0.3]	5 (0.8) [0.8]	2 (0.2) [0.2]	7 (0.8) [0.8]
肝酵素上昇	1 (0.2) [0.2]	8 (1.2) [1.2]	2 (0.2) [0.2]	9 (1.0) [1.0]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
臨床検査 (Cont.)				
高比重リポ蛋白増加	2 (0.3) [0.3]	1 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.1) [0.1]
未熟顆粒球数増加	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
深吸気量減少	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
肝機能検査値上昇	4 (0.6) [0.6]	6 (0.9) [0.9]	4 (0.4) [0.4]	7 (0.8) [0.8]
低比重リポ蛋白増加	2 (0.3) [0.3]	3 (0.5) [0.5]	2 (0.2) [0.2]	3 (0.3) [0.3]
リンパ球数減少	5 (0.8) [0.8]	4 (0.6) [0.6]	5 (0.6) [0.6]	5 (0.5) [0.5]
リンパ球数増加	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
平均赤血球容積増加	3 (0.5) [0.5]	4 (0.6) [0.6]	3 (0.3) [0.3]	7 (0.8) [0.8]
筋酵素上昇	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
骨髄球存在	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
好中球数減少	2 (0.3) [0.3]	10 (1.6) [1.6]	2 (0.2) [0.2]	13 (1.4) [1.4]
血小板数増加	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
総蛋白増加	0	0	1 (0.1) [0.1]	0
赤血球数減少	1 (0.2) [0.2]	4 (0.6) [0.6]	1 (0.1) [0.1]	5 (0.5) [0.5]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
臨床検査 (Cont.)				
血沈亢進	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
ブドウ球菌検査陽性	0	0	0	1 (0.1) [0.1]
レンサ球菌検査陽性	0	0	0	1 (0.1) [0.1]
トランスアミナーゼ上昇	2 (0.3) [0.3]	5 (0.8) [0.8]	3 (0.3) [0.3]	7 (0.8) [0.8]
尿検査異常	0	0	0	1 (0.1) [0.1]
超低比重リポ蛋白増加	2 (0.3) [0.3]	4 (0.6) [0.6]	2 (0.2) [0.2]	4 (0.4) [0.4]
体重減少	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
体重増加	2 (0.3) [0.3]	3 (0.5) [0.5]	5 (0.6) [0.6]	4 (0.4) [0.4]
白血球数減少	4 (0.6) [0.6]	11 (1.7) [1.7]	5 (0.6) [0.6]	14 (1.5) [1.5]
代謝および栄養障害	15 (2.3) [2.3]	28 (4.4) [4.4]	20 (2.2) [2.2]	35 (3.8) [3.8]
脂質異常症	3 (0.5) [0.5]	8 (1.2) [1.3]	4 (0.4) [0.4]	8 (0.9) [0.9]
高カルシウム血症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
高コレステロール血症	1 (0.2) [0.2]	8 (1.2) [1.3]	3 (0.3) [0.3]	9 (1.0) [1.0]
高血糖	1 (0.2) [0.2]	2 (0.3) [0.3]	1 (0.1) [0.1]	3 (0.3) [0.3]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
代謝および栄養障害 (Cont.)				
高脂血症	4 (0.6) [0.6]	6 (0.9) [0.9]	5 (0.6) [0.6]	8 (0.9) [0.9]
高トリグリセリド血症	2 (0.3) [0.3]	1 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]
高尿酸血症	2 (0.3) [0.3]	1 (0.2) [0.2]	3 (0.3) [0.3]	2 (0.2) [0.2]
低血糖	0	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
低カリウム血症	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
低リン酸血症	1 (0.2) [0.2]	0	1 (0.1) [0.1]	1 (0.1) [0.1]
ビタミンD欠乏	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
筋骨格系および結合組織障害	18 (2.8) [2.8]	15 (2.3) [2.3]	22 (2.4) [2.4]	22 (2.4) [2.4]
関節痛	0	0	1 (0.1) [0.1]	0
関節炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
背部痛	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
軟骨疾患	0	0	0	1 (0.1) [0.1]
瘻孔	0	0	1 (0.1) [0.1]	0
側腹部痛	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
筋骨格系および結合組織障害 (Cont.)				
関節雑音	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
関節硬直	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
筋痙縮	3 (0.5) [0.5]	1 (0.2) [0.2]	3 (0.3) [0.3]	1 (0.1) [0.1]
筋力低下	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
筋骨格系胸痛	0	1 (0.2) [0.2]	0	2 (0.2) [0.2]
筋肉痛	3 (0.5) [0.5]	2 (0.3) [0.3]	3 (0.3) [0.3]	3 (0.3) [0.3]
ミオパチー	0	0	0	1 (0.1) [0.1]
変形性関節症	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
骨端症	0	0	1 (0.1) [0.1]	0
骨粗鬆症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
四肢痛	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
乾癬性関節症	5 (0.8) [0.8]	3 (0.5) [0.5]	7 (0.8) [0.8]	6 (0.7) [0.6]
急速進行性変形性関節症	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
脊椎痛	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	4 (0.6) [0.6]	12 (1.9) [1.9]	8 (0.9) [0.9]	14 (1.5) [1.5]
肛門性器疣贅	0	3 (0.5) [0.5]	0	3 (0.3) [0.3]
基底細胞癌	0	1 (0.2) [0.2]	0	2 (0.2) [0.2]
ボーエン病	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
乳癌	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
大腸腺腫	0	0	1 (0.1) [0.1]	0
遠隔転移を伴う肺癌	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
メラノサイト性母斑	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
形質細胞性骨髄腫	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
直腸腺癌	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
直腸癌	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
脂漏性角化症	0	0	1 (0.1) [0.1]	0
皮膚乳頭腫	0	4 (0.6) [0.6]	2 (0.2) [0.2]	4 (0.4) [0.4]
扁平上皮癌	0	0	0	1 (0.1) [0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

	Upadacitinib			
System Organ Class MedDRA 22.0 Preferred Term	15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Any 15 mg QD (N = 907) n (%) [SSA%]	Any 30 mg QD (N = 921) n (%) [SSA%]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
皮膚有棘細胞癌	2 (0.3) [0.3]	0	2 (0.2) [0.2]	0
神経系障害	17 (2.7) [2.7]	30 (4.7) [4.7]	21 (2.3) [2.3]	35 (3.8) [3.8]
異痛症	0	0	1 (0.1) [0.1]	0
灼熱感	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
手根管症候群	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
頚髄神経根障害	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
浮動性めまい	3 (0.5) [0.5]	3 (0.5) [0.5]	4 (0.4) [0.4]	4 (0.4) [0.4]
顔面麻痺	0	0	0	1 (0.1) [0.1]
頭痛	7 (1.1) [1.1]	13 (2.0) [2.0]	8 (0.9) [0.9]	13 (1.4) [1.4]
感覚鈍麻	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
ラクナ脳卒中	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
嗜眠	1 (0.2) [0.2]	0	1 (0.1) [0.1]	1 (0.1) [0.1]
記憶障害	0	1 (0.2) [0.2]	0	2 (0.2) [0.2]
片頭痛	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
神経系障害 (Cont.)				
神経痛	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
錯感覚	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
末梢性感覚ニューロパチー	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
ヘルペス後神経痛	1 (0.2) [0.2]	4 (0.6) [0.6]	2 (0.2) [0.2]	5 (0.5) [0.5]
失神寸前の状態	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
感覚障害	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
傾眠	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
失神	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
緊張性頭痛	0	0	1 (0.1) [0.1]	0
三叉神経障害	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
三叉神経痛	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
精神障害	5 (0.8) [0.8]	6 (0.9) [0.9]	6 (0.7) [0.7]	6 (0.7) [0.7]
感情不安定	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
不安	0	2 (0.3) [0.3]	1 (0.1) [0.1]	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
精神障害 (Cont.)				
うつ病	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
不眠症	3 (0.5) [0.5]	2 (0.3) [0.3]	3 (0.3) [0.3]	2 (0.2) [0.2]
睡眠障害	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
腎および尿路障害	6 (0.9) [0.9]	8 (1.2) [1.3]	7 (0.8) [0.8]	10 (1.1) [1.1]
急性腎障害	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
尿路結石	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
慢性腎臓病	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
腺性膀胱炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
糖尿病性腎症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
排尿困難	0	1 (0.2) [0.2]	0	2 (0.2) [0.2]
血尿	1 (0.2) [0.2]	3 (0.5) [0.5]	1 (0.1) [0.1]	4 (0.4) [0.4]
緊張性膀胱	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
白血球尿	2 (0.3) [0.3]	1 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.1) [0.1]
尿意切迫	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
腎および尿路障害 (Cont.)				
頻尿	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
蛋白尿	0	2 (0.3) [0.3]	1 (0.1) [0.1]	2 (0.2) [0.2]
生殖系および乳房障害	5 (0.8) [0.8]	3 (0.5) [0.5]	7 (0.8) [0.8]	5 (0.5) [0.5]
無月経	1 (0.2) [0.2]	0	1 (0.1) [0.1]	1 (0.1) [0.1]
乳房嚢胞	0	0	1 (0.1) [0.1]	0
前立腺結石	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
勃起不全	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
線維嚢胞性乳腺疾患	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
月経過多	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
不規則月経	2 (0.3) [0.3]	0	2 (0.2) [0.2]	0
不正子宮出血	0	0	0	1 (0.1) [0.1]
前立腺炎	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
陰嚢痛	0	0	1 (0.1) [0.1]	0
呼吸器、胸郭および縦隔障害	22 (3.4) [3.4]	31 (4.8) [4.9]	24 (2.6) [2.7]	39 (4.2) [4.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
呼吸器、胸郭および縦隔障害 (Cont.)				
急性呼吸不全	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
気管支反応性亢進	0	0	1 (0.1) [0.1]	0
カタル	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
咳嗽	4 (0.6) [0.6]	12 (1.9) [1.9]	4 (0.4) [0.4]	16 (1.7) [1.7]
発声障害	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
呼吸困難	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]
労作性呼吸困難	2 (0.3) [0.3]	0	2 (0.2) [0.2]	0
鼻出血	1 (0.2) [0.2]	1 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.1) [0.1]
間質性肺疾患	1 (0.2) [0.2]	2 (0.3) [0.3]	1 (0.1) [0.1]	3 (0.3) [0.3]
鼻閉	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
鼻部不快感	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
鼻の炎症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
鼻潰瘍	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
口腔咽頭痛	5 (0.8) [0.8]	4 (0.6) [0.6]	5 (0.6) [0.6]	5 (0.5) [0.5]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
呼吸器、胸郭および縦隔障害 (Cont.)				
咽頭の炎症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
胸膜炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
自然気胸	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
湿性咳嗽	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
肺塞栓症	3 (0.5) [0.5]	2 (0.3) [0.3]	3 (0.3) [0.3]	3 (0.3) [0.3]
肺線維症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
肺高血圧症	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
呼吸窮迫	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
アレルギー性鼻炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
鼻漏	2 (0.3) [0.3]	1 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.1) [0.1]
副鼻腔うっ血	1 (0.2) [0.2]	0	1 (0.1) [0.1]	1 (0.1) [0.1]
咽喉刺激感	0	3 (0.5) [0.5]	0	3 (0.3) [0.3]
上気道の炎症	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
皮膚および皮下組織障害	31 (4.8) [4.8]	35 (5.5) [5.5]	39 (4.3) [4.3]	41 (4.5) [4.5]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
皮膚および皮下組織障害 (Cont.)				
ざ瘡	4 (0.6) [0.6]	4 (0.6) [0.6]	4 (0.4) [0.4]	4 (0.4) [0.4]
光線性口唇炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
光線角化症	0	0	1 (0.1) [0.1]	0
脱毛症	2 (0.3) [0.3]	3 (0.5) [0.5]	2 (0.2) [0.2]	3 (0.3) [0.3]
水疱	1 (0.2) [0.2]	2 (0.3) [0.3]	1 (0.1) [0.1]	4 (0.4) [0.4]
肝斑	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
慢性特発性蕁麻疹	0	0	1 (0.1) [0.1]	0
皮膚嚢腫	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
皮膚炎	3 (0.5) [0.5]	1 (0.2) [0.2]	3 (0.3) [0.3]	1 (0.1) [0.1]
ざ瘡様皮膚炎	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
アレルギー性皮膚炎	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]
アトピー性皮膚炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
皮膚乾燥	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
異汗性湿疹	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
皮膚および皮下組織障害 (Cont.)				
斑状出血	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
湿疹	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
紅斑	0	2 (0.3) [0.3]	0	4 (0.4) [0.4]
毛髪成長異常	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
多汗症	2 (0.3) [0.3]	0	2 (0.2) [0.2]	0
間擦疹	3 (0.5) [0.5]	0	3 (0.3) [0.3]	0
爪郭の炎症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
爪成長異常	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
寝汗	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
爪破損	0	0	1 (0.1) [0.1]	0
爪甲剥離症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
丘疹	0	0	0	1 (0.1) [0.1]
そう痒症	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
全身性そう痒症	0	0	1 (0.1) [0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
皮膚および皮下組織障害 (Cont.)				
乾癬	7 (1.1) [1.1]	4 (0.6) [0.6]	8 (0.9) [0.9]	5 (0.5) [0.5]
膿疱性乾癬	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
発疹	4 (0.6) [0.6]	6 (0.9) [0.9]	5 (0.6) [0.6]	7 (0.8) [0.8]
毛孔性皮疹	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
全身性皮疹	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
斑状皮疹	1 (0.2) [0.2]	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
斑状丘疹状皮疹	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
酒さ	2 (0.3) [0.3]	1 (0.2) [0.2]	2 (0.2) [0.2]	1 (0.1) [0.1]
皮膚剥脱	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
皮膚刺激	0	1 (0.2) [0.2]	1 (0.1) [0.1]	1 (0.1) [0.1]
皮膚病変	2 (0.3) [0.3]	0	3 (0.3) [0.3]	0
皮膚壊死	0	0	1 (0.1) [0.1]	0
顔面腫脹	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
血管障害	14 (2.2) [2.2]	11 (1.7) [1.7]	14 (1.5) [1.5]	14 (1.5) [1.5]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 907) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 921) n (%) [SSA%]
血管障害 (Cont.)				
深部静脈血栓症	2 (0.3) [0.3]	0	2 (0.2) [0.2]	0
ほてり	3 (0.5) [0.5]	0	3 (0.3) [0.3]	0
高血圧	8 (1.3) [1.2]	8 (1.2) [1.3]	8 (0.9) [0.9]	11 (1.2) [1.2]
高血圧クリーゼ	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
低血圧	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
リンパ浮腫	0	1 (0.2) [0.2]	0	1 (0.1) [0.1]
血栓性静脈炎	1 (0.2) [0.2]	0	1 (0.1) [0.1]	0
表在性血栓性静脈炎	0	2 (0.3) [0.3]	0	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

表 2.7.4.7-92. 全ウパダシチニブ併合解析集団（20[redacted]年[redacted]月[redacted]日データカットオフ）の日本人部分集団の治験薬と関連ありの有害事象

TABLE 2.4__1.2.3.8_J

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 17) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 18) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 23) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 26) n (%) [SSA%]
Any adverse event	10 (58.8) [58.9]	15 (83.3) [83.5]	14 (60.9) [60.7]	20 (76.9) [76.9]
血液およびリンパ系障害	0	3 (16.7) [16.7]	0	5 (19.2) [19.1]
貧血	0	1 (5.6) [5.5]	0	1 (3.8) [3.9]
血球減少症	0	0	0	1 (3.8) [3.9]
播種性血管内凝固	0	0	0	1 (3.8) [3.9]
リンパ球減少症	0	1 (5.6) [5.5]	0	2 (7.7) [7.6]
好中球減少症	0	1 (5.6) [5.7]	0	1 (3.8) [3.7]
汎血球減少症	0	0	0	1 (3.8) [3.9]
耳および迷路障害	1 (5.9) [5.9]	0	1 (4.3) [4.3]	0
回転性めまい	1 (5.9) [5.9]	0	1 (4.3) [4.3]	0
胃腸障害	1 (5.9) [5.7]	3 (16.7) [16.5]	1 (4.3) [4.5]	5 (19.2) [19.4]
十二指腸潰瘍	0	0	0	1 (3.8) [3.9]
悪心	1 (5.9) [5.7]	0	1 (4.3) [4.5]	0
小腸潰瘍	0	1 (5.6) [5.5]	0	1 (3.8) [3.9]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8_J

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 17) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 18) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 23) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 26) n (%) [SSA%]
胃腸障害 (Cont.)				
口内炎	0	1 (5.6) [5.5]	0	2 (7.7) [7.8]
嘔吐	0	1 (5.6) [5.5]	0	1 (3.8) [3.9]
肝胆道系障害	0	3 (16.7) [16.5]	1 (4.3) [4.3]	3 (11.5) [11.6]
薬物性肝障害	0	1 (5.6) [5.5]	0	1 (3.8) [3.9]
肝機能異常	0	0	1 (4.3) [4.3]	0
肝損傷	0	2 (11.1) [11.0]	0	2 (7.7) [7.8]
感染症および寄生虫症	8 (47.1) [47.0]	12 (66.7) [66.7]	9 (39.1) [39.1]	17 (65.4) [65.4]
肛門膿瘍	0	1 (5.6) [5.5]	0	1 (3.8) [3.9]
肛門直腸蜂巣炎	0	1 (5.6) [5.5]	0	1 (3.8) [3.9]
細菌性膣症	1 (5.9) [5.9]	0	1 (4.3) [4.3]	1 (3.8) [3.9]
気管支炎	0	2 (11.1) [11.2]	0	2 (7.7) [7.6]
サイトメガロウイルス感染	0	0	0	1 (3.8) [3.9]
毛包炎	1 (5.9) [5.9]	0	1 (4.3) [4.3]	1 (3.8) [3.9]
胃腸炎	1 (5.9) [5.7]	0	1 (4.3) [4.5]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8_J

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 17) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 18) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 23) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 26) n (%) [SSA%]
感染症および寄生虫症 (Cont.)				
ウイルス性胃腸炎	1 (5.9) [5.9]	0	1 (4.3) [4.3]	1 (3.8) [3.9]
性器カンジダ症	0	0	0	1 (3.8) [3.9]
単純ヘルペス	0	1 (5.6) [5.5]	0	2 (7.7) [7.8]
帯状疱疹	3 (17.6) [17.8]	7 (38.9) [39.0]	3 (13.0) [12.9]	8 (30.8) [30.7]
インフルエンザ	0	1 (5.6) [5.7]	0	1 (3.8) [3.7]
上咽頭炎	3 (17.6) [17.6]	1 (5.6) [5.5]	3 (13.0) [13.1]	2 (7.7) [7.8]
眼部単純ヘルペス	0	0	0	1 (3.8) [3.9]
口腔カンジダ症	0	0	0	1 (3.8) [3.7]
口腔ヘルペス	1 (5.9) [5.9]	0	1 (4.3) [4.3]	2 (7.7) [7.8]
歯周炎	0	0	1 (4.3) [4.3]	0
咽頭炎	0	1 (5.6) [5.5]	1 (4.3) [4.3]	2 (7.7) [7.8]
ニューモシスチス・イロベチイ肺炎	0	0	0	1 (3.8) [3.9]
肺炎	0	2 (11.1) [11.0]	0	2 (7.7) [7.8]
シュードモナス感染	0	1 (5.6) [5.5]	0	1 (3.8) [3.9]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8_J

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 17) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 18) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 23) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 26) n (%) [SSA%]
感染症および寄生虫症 (Cont.)				
白癬感染	0	1 (5.6) [5.5]	0	1 (3.8) [3.9]
足部白癬	1 (5.9) [5.9]	1 (5.6) [5.5]	1 (4.3) [4.3]	1 (3.8) [3.9]
扁桃炎	0	1 (5.6) [5.5]	0	1 (3.8) [3.9]
上気道感染	0	1 (5.6) [5.7]	0	1 (3.8) [3.7]
尿路感染	0	1 (5.6) [5.5]	0	1 (3.8) [3.9]
臨床検査	2 (11.8) [11.6]	6 (33.3) [33.7]	4 (17.4) [17.4]	9 (34.6) [34.4]
アラニンアミノトランスフェラーゼ増加	0	0	0	1 (3.8) [3.9]
血中クレアチンホスホキナーゼ増加	0	4 (22.2) [22.2]	2 (8.7) [8.6]	4 (15.4) [15.4]
ヘモグロビン減少	0	0	0	1 (3.8) [3.9]
肝機能検査値上昇	1 (5.9) [5.7]	0	1 (4.3) [4.5]	0
リンパ球数減少	1 (5.9) [5.9]	1 (5.6) [5.7]	1 (4.3) [4.3]	2 (7.7) [7.5]
骨髄球存在	0	1 (5.6) [5.7]	0	1 (3.8) [3.7]
赤血球数減少	0	0	0	1 (3.8) [3.9]
体重増加	0	0	1 (4.3) [4.3]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8_J

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 17) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 18) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 23) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 26) n (%) [SSA%]
臨床検査 (Cont.)				
白血球数減少	0	2 (11.1) [11.4]	0	3 (11.5) [11.4]
代謝および栄養障害	2 (11.8) [11.9]	1 (5.6) [5.7]	2 (8.7) [8.6]	1 (3.8) [3.7]
脂質異常症	0	1 (5.6) [5.7]	0	1 (3.8) [3.7]
高脂血症	1 (5.9) [5.9]	0	1 (4.3) [4.3]	0
高トリグリセリド血症	1 (5.9) [5.9]	0	1 (4.3) [4.3]	0
筋骨格系および結合組織障害	2 (11.8) [11.9]	0	2 (8.7) [8.6]	0
筋肉痛	1 (5.9) [5.9]	0	1 (4.3) [4.3]	0
乾癬性関節症	1 (5.9) [5.9]	0	1 (4.3) [4.3]	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	2 (11.1) [11.0]	0	2 (7.7) [7.8]
肛門性器疣贅	0	2 (11.1) [11.0]	0	2 (7.7) [7.8]
神経系障害	0	1 (5.6) [5.5]	0	3 (11.5) [11.6]
浮動性めまい	0	0	0	1 (3.8) [3.9]
顔面麻痺	0	0	0	1 (3.8) [3.9]
ヘルペス後神経痛	0	1 (5.6) [5.5]	0	1 (3.8) [3.9]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.8_J

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
with Reasonable Possibility of Being Related to Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 17) n (%) [SSA%]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 18) n (%) [SSA%]	Upadacitinib Any 15 mg QD (N = 23) n (%) [SSA%]	Upadacitinib Any 30 mg QD (N = 26) n (%) [SSA%]
生殖系および乳房障害	0	0	1 (4.3) [4.3]	0
陰嚢痛	0	0	1 (4.3) [4.3]	0
呼吸器、胸郭および縦隔障害	1 (5.9) [5.7]	1 (5.6) [5.7]	1 (4.3) [4.5]	2 (7.7) [7.6]
間質性肺疾患	0	0	0	1 (3.8) [3.9]
上気道の炎症	1 (5.9) [5.7]	1 (5.6) [5.7]	1 (4.3) [4.5]	1 (3.8) [3.7]
皮膚および皮下組織障害	2 (11.8) [11.9]	1 (5.6) [5.7]	2 (8.7) [8.6]	1 (3.8) [3.7]
ざ瘡	1 (5.9) [5.9]	0	1 (4.3) [4.3]	0
水疱	0	1 (5.6) [5.7]	0	1 (3.8) [3.7]
発疹	1 (5.9) [5.9]	0	1 (4.3) [4.3]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.

Program Source Code: [redacted]

表 2.7.4.7-93. 全ウパダシチニブ併合解析集団（20[redacted]年[redacted]月[redacted]日データカットオフ）の Grade 3 以上の有害事象（100 人年あたりの発現件数）

TABLE 2.4__3.4

Treatment-Emergent Severe Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
Any Adverse Event	104 (10.9) [10.9]	145 (15.3) [15.3]	133 (10.7) [10.7]	195 (15.5) [15.5]
*** Not Coded ***	1 (0.1) [0.1]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
*** Not Coded ***	1 (0.1) [0.1]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
血液およびリンパ系障害	5 (0.5) [0.5]	10 (1.1) [1.1]	5 (0.4) [0.4]	14 (1.1) [1.1]
貧血	0	3 (0.3) [0.3]	0	3 (0.2) [0.2]
失血性貧血	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
血球減少症	0	0	0	1 (<0.1) [<0.1]
播種性血管内凝固	0	0	0	1 (<0.1) [<0.1]
鉄欠乏性貧血	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
リンパ節炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
リンパ組織過形成	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
リンパ球減少症	4 (0.4) [0.4]	3 (0.3) [0.3]	4 (0.3) [0.3]	4 (0.3) [0.3]
好中球減少症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
汎血球減少症	0	0	0	1 (<0.1) [<0.1]
心臓障害	9 (0.9) [0.9]	5 (0.5) [0.5]	10 (0.8) [0.8]	6 (0.5) [0.5]
狭心症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.4

Treatment-Emergent Severe Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
心臓障害 (Cont.)				
不安定狭心症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
大動脈弁狭窄	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
心房細動	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
心不全	1 (0.1) [0.1]	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]
うっ血性心不全	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
心肺停止	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
冠動脈狭窄	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
心筋梗塞	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
上室性頻脈	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
頻脈	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
心室細動	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
先天性、家族性および遺伝性障害	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
陰嚢水瘤	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
内分泌障害	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
甲状腺腫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
眼障害	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.4

Treatment-Emergent Severe Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
眼障害 (Cont.)				
白内障	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
後嚢部混濁	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
胃腸障害	9 (0.9) [0.9]	6 (0.6) [0.6]	10 (0.8) [0.8]	9 (0.7) [0.7]
腹部不快感	0	0	0	1 (<0.1) [<0.1]
痔瘻	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
大腸炎	0	0	1 (<0.1) [<0.1]	0
下痢	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
十二指腸潰瘍	0	0	0	1 (<0.1) [<0.1]
出血性十二指腸潰瘍	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
消化不良	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
穿孔性胃潰瘍	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
びらん性胃炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
胃腸出血	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
裂孔ヘルニア	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
大腸ポリープ	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
悪心	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.4

Treatment-Emergent Severe Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
胃腸障害 (Cont.)				
小腸潰瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
上部消化管出血	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
一般・全身障害および投与部位の状態	1 (0.1) [0.1]	4 (0.4) [0.4]	1 (<0.1) [<0.1]	5 (0.4) [0.4]
胸痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
浮腫	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
発熱	0	2 (0.2) [0.2]	0	3 (0.2) [0.2]
全身性炎症反応症候群	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肝胆道系障害	0	6 (0.6) [0.6]	1 (<0.1) [<0.1]	6 (0.5) [0.5]
胆管結石	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
胆石症	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
薬物性肝障害	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
胆嚢ポリープ	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肝損傷	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
感染症および寄生虫症	24 (2.5) [2.5]	49 (5.2) [5.2]	35 (2.8) [2.8]	69 (5.5) [5.5]
膿瘍	0	0	1 (<0.1) [<0.1]	0
四肢膿瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.4

Treatment-Emergent Severe Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
肛門膿瘍	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
虫垂炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
異型肺炎	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
菌血症	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
細気管支炎	0	0	1 (<0.1) [<0.1]	0
気管支炎	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	4 (0.3) [0.3]
気管支肺アスペルギルス症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
蜂巣炎	2 (0.2) [0.2]	2 (0.2) [0.2]	3 (0.2) [0.2]	3 (0.2) [0.2]
コロナウイルス感染	0	0	0	1 (<0.1) [<0.1]
サイトメガロウイルス感染	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
憩室炎	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
耳感染	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
丹毒	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
硬膜外膿瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
せつ	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
胃腸炎	3 (0.3) [0.3]	2 (0.2) [0.2]	3 (0.2) [0.2]	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.4

Treatment-Emergent Severe Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
ウイルス性胃腸炎	0	0	0	1 (<0.1) [<0.1]
歯肉炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
H1N1インフルエンザ	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
帯状疱疹	2 (0.2) [0.2]	6 (0.6) [0.6]	4 (0.3) [0.3]	10 (0.8) [0.8]
皮膚播種性帯状疱疹	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
インフルエンザ	0	0	2 (0.2) [0.2]	0
喉頭炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
下気道感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
肺感染	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
髄膜炎	0	0	0	1 (<0.1) [<0.1]
爪感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
上咽頭炎	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
外耳炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
中耳炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
咽頭炎	0	0	0	1 (<0.1) [<0.1]
ニューモシスチス・イロベチイ肺炎	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.4

Treatment-Emergent Severe Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
肺炎	3 (0.3) [0.3]	6 (0.6) [0.6]	3 (0.2) [0.2]	11 (0.9) [0.9]
細菌性肺炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
レンサ球菌性肺炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
卵管炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
敗血症	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	2 (0.2) [0.2]
副鼻腔炎	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
ブドウ球菌性菌血症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ブドウ球菌感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
ブドウ球菌性敗血症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
皮下組織膿瘍	0	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
足部白癬	0	0	1 (<0.1) [<0.1]	0
扁桃炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
上気道感染	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
尿路感染	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
傷害、中毒および処置合併症	9 (0.9) [0.9]	6 (0.6) [0.6]	11 (0.9) [0.9]	8 (0.6) [0.6]
足関節部骨折	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.4

Treatment-Emergent Severe Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
傷害、中毒および処置合併症 (Cont.)				
骨亀裂	0	0	1 (<0.1) [<0.1]	0
頚椎骨折	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
粉砕骨折	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
上腕骨骨折	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
靭帯捻挫	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
腰椎骨折	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
半月板損傷	0	0	0	1 (<0.1) [<0.1]
膝蓋骨骨折	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
交通事故	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
腱損傷	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
腱断裂	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
胸椎骨折	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
脛骨骨折	0	0	1 (<0.1) [<0.1]	0
外傷性血胸	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
上肢骨折	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
臨床検査	11 (1.2) [1.2]	12 (1.3) [1.3]	12 (1.0) [1.0]	16 (1.3) [1.3]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.4

Treatment-Emergent Severe Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
臨床検査 (Cont.)				
アラニンアミノトランスフェラーゼ増加	4 (0.4) [0.4]	3 (0.3) [0.3]	5 (0.4) [0.4]	3 (0.2) [0.2]
アスパラギン酸アミノトランスフェラーゼ増加	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]
血中クレアチンホスホキナーゼ増加	4 (0.4) [0.4]	5 (0.5) [0.5]	4 (0.3) [0.3]	6 (0.5) [0.5]
ヘモグロビン減少	0	0	0	1 (<0.1) [<0.1]
リンパ球数減少	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
前立腺特異性抗原	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
赤血球数減少	0	0	0	1 (<0.1) [<0.1]
白血球数減少	0	0	0	1 (<0.1) [<0.1]
代謝および栄養障害	1 (0.1) [0.1]	5 (0.5) [0.5]	2 (0.2) [0.2]	5 (0.4) [0.4]
脱水	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
糖尿病	0	0	1 (<0.1) [<0.1]	0
高トリグリセリド血症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
高尿酸血症	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
1型糖尿病	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
2型糖尿病	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
筋骨格系および結合組織障害	10 (1.1) [1.0]	8 (0.8) [0.8]	12 (1.0) [1.0]	14 (1.1) [1.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.4

Treatment-Emergent Severe Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
筋骨格系および結合組織障害 (Cont.)				
関節痛	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
背部痛	0	1 (0.1) [0.1]	0	5 (0.4) [0.4]
骨侵食	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
滑液包炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
瘻孔	0	0	1 (<0.1) [<0.1]	0
腰部脊柱管狭窄症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
筋骨格痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
変形性関節症	2 (0.2) [0.2]	2 (0.2) [0.2]	3 (0.2) [0.2]	4 (0.3) [0.3]
骨壊死	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
足底筋膜炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
乾癬性関節症	3 (0.3) [0.3]	0	3 (0.2) [0.2]	0
急速進行性変形性関節症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
腱炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	5 (0.5) [0.5]	5 (0.5) [0.5]	8 (0.6) [0.6]	6 (0.5) [0.5]
基底細胞癌	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
遠隔転移を伴う肺癌	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.4

Treatment-Emergent Severe Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
悪性黒色腫	0	0	1 (<0.1) [<0.1]	0
悪性黒色腫第3期	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
神経内分泌癌	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
中咽頭扁平上皮癌	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
卵巣癌	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
形質細胞性骨髄腫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
前立腺癌	1 (0.1) [0.1]	0	2 (0.2) [0.2]	0
直腸腺癌	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
直腸癌	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
腎癌	0	0	0	1 (<0.1) [<0.1]
神経系障害	3 (0.3) [0.3]	5 (0.5) [0.5]	4 (0.3) [0.3]	6 (0.5) [0.5]
頚髄神経根障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
糖尿病性ニューロパチー	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
顔面麻痺	0	0	0	1 (<0.1) [<0.1]
頭痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ラクナ脳卒中	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.4

Treatment-Emergent Severe Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
神経系障害 (Cont.)				
神経痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ヘルペス後神経痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
坐骨神経痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
失神	1 (0.1) [0.1]	0	2 (0.2) [0.2]	0
妊娠、産褥および周産期の状態	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
自然流産	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
異所性妊娠	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
精神障害	0	4 (0.4) [0.4]	1 (<0.1) [<0.1]	4 (0.3) [0.3]
不安	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
うつ病	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
腎および尿路障害	4 (0.4) [0.4]	1 (0.1) [0.1]	4 (0.3) [0.3]	1 (<0.1) [<0.1]
急性腎障害	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
腎結石症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
腎仙痛	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
生殖系および乳房障害	4 (0.4) [0.4]	0	4 (0.3) [0.3]	0
子宮頚部上皮異形成	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.4

Treatment-Emergent Severe Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
生殖系および乳房障害 (Cont.)				
卵管嚢胞	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
出血性卵巣嚢胞	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
前立腺炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
呼吸器、胸郭および縦隔障害	4 (0.4) [0.4]	7 (0.7) [0.7]	4 (0.3) [0.3]	12 (1.0) [1.0]
急性呼吸不全	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
慢性閉塞性肺疾患	0	2 (0.2) [0.2]	0	4 (0.3) [0.3]
間質性肺疾患	0	0	0	1 (<0.1) [<0.1]
気胸	0	0	0	1 (<0.1) [<0.1]
自然気胸	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肺塞栓症	3 (0.3) [0.3]	3 (0.3) [0.3]	3 (0.2) [0.2]	4 (0.3) [0.3]
肺線維症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
皮膚および皮下組織障害	1 (0.1) [0.1]	5 (0.5) [0.5]	4 (0.3) [0.3]	6 (0.5) [0.5]
血管浮腫	0	0	2 (0.2) [0.2]	0
乾癬	0	4 (0.4) [0.4]	0	5 (0.4) [0.4]
皮膚病変	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
皮膚壊死	0	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.4

Treatment-Emergent Severe Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
皮膚および皮下組織障害 (Cont.)				
蕁麻疹	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
血管障害	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	2 (0.2) [0.2]
深部静脈血栓症	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
高血圧	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
静脈瘤	0	0	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-94. 投与 56 週時データカットオフまでの Grade 3 以上の有害事象（100 人年あたりの発現件数，安全性解析対象集団）：M15-572 試験

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
Any adverse event	88 (10.5)	118 (14.0)	78 (12.4)
血液およびリンパ系障害	4 (0.5)	10 (1.2)	4 (0.6)
貧血	0	4 (0.5)	0
鉄欠乏性貧血	0	1 (0.1)	0
リンパ組織過形成	0	1 (0.1)	0
リンパ球減少症	4 (0.5)	3 (0.4)	0
好中球減少症	0	1 (0.1)	3 (0.5)
正色素性正球性貧血	0	0	1 (0.2)
心臓障害	2 (0.2)	2 (0.2)	3 (0.5)
急性心筋梗塞	0	0	1 (0.2)
冠動脈硬化症	0	0	1 (0.2)
心不全	1 (0.1)	0	0
うっ血性心不全	0	1 (0.1)	0
心筋梗塞	1 (0.1)	1 (0.1)	0
心膜炎	0	0	1 (0.2)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
先天性、家族性および遺伝性障害	0	1 (0.1)	0
陰嚢水瘤	0	1 (0.1)	0
耳および迷路障害	0	1 (0.1)	0
頭位性回転性めまい	0	1 (0.1)	0
眼障害	0	1 (0.1)	0
白内障	0	1 (0.1)	0
胃腸障害	7 (0.8)	3 (0.4)	5 (0.8)
痔瘻	0	1 (0.1)	0
大腸炎	1 (0.1)	0	0
下痢	0	0	2 (0.3)
十二指腸潰瘍	0	0	1 (0.2)
出血性十二指腸潰瘍	0	1 (0.1)	0
消化不良	1 (0.1)	0	0
小腸炎	0	0	1 (0.2)
穿孔性胃潰瘍	1 (0.1)	0	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
胃腸障害 (Cont.)			
胃腸出血	1 (0.1)	0	0
痔核	0	1 (0.1)	0
裂孔ヘルニア	1 (0.1)	0	0
大腸ポリープ	1 (0.1)	0	1 (0.2)
上部消化管出血	1 (0.1)	0	0
一般・全身障害および投与部位の状態	3 (0.4)	3 (0.4)	1 (0.2)
胸痛	0	1 (0.1)	0
疲労	1 (0.1)	0	0
浮腫	1 (0.1)	0	0
疼痛	0	1 (0.1)	0
発熱	1 (0.1)	1 (0.1)	1 (0.2)
肝胆道系障害	0	1 (0.1)	4 (0.6)
胆管結石	0	1 (0.1)	0
薬物性肝障害	0	0	1 (0.2)
黄疸	0	0	1 (0.2)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
肝胆道系障害 (Cont.)			
肝障害	0	0	1 (0.2)
門脈血栓症	0	0	1 (0.2)
免疫系障害	0	1 (0.1)	1 (0.2)
過敏症	0	0	1 (0.2)
免疫系障害	0	1 (0.1)	0
感染症および寄生虫症	31 (3.7)	40 (4.7)	15 (2.4)
四肢膿瘍	0	1 (0.1)	1 (0.2)
肛門膿瘍	0	1 (0.1)	0
虫垂炎	1 (0.1)	1 (0.1)	0
異型肺炎	0	2 (0.2)	0
菌血症	0	1 (0.1)	0
細菌性卵管炎	0	1 (0.1)	0
骨膿瘍	0	0	1 (0.2)
気管支炎	1 (0.1)	2 (0.2)	0
気管支肺アスペルギルス症	1 (0.1)	0	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
感染症および寄生虫症 (Cont.)			
蜂巣炎	2 (0.2)	1 (0.1)	3 (0.5)
コロナウイルス感染	2 (0.2)	2 (0.2)	1 (0.2)
憩室炎	1 (0.1)	0	0
耳感染	0	1 (0.1)	1 (0.2)
丹毒	1 (0.1)	0	1 (0.2)
胃腸炎	1 (0.1)	2 (0.2)	0
歯肉炎	0	1 (0.1)	0
H1N1インフルエンザ	1 (0.1)	0	0
帯状疱疹	5 (0.6)	6 (0.7)	0
皮膚播種性帯状疱疹	0	1 (0.1)	0
インフルエンザ	1 (0.1)	0	1 (0.2)
喉頭炎	1 (0.1)	0	0
潜伏結核	1 (0.1)	0	0
限局性感染	0	0	2 (0.3)
下気道感染	1 (0.1)	0	1 (0.2)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
感染症および寄生虫症 (Cont.)			
肺感染	0	1 (0.1)	0
上咽頭炎	0	1 (0.1)	0
腹膜炎	0	1 (0.1)	0
ニューモシスチス・イロベチイ肺炎	0	1 (0.1)	0
肺炎	4 (0.5)	6 (0.7)	2 (0.3)
細菌性肺炎	1 (0.1)	0	0
レンサ球菌性肺炎	0	1 (0.1)	0
卵管炎	0	1 (0.1)	0
敗血症	2 (0.2)	0	0
副鼻腔炎	0	1 (0.1)	0
ブドウ球菌性菌血症	0	1 (0.1)	0
ブドウ球菌感染	1 (0.1)	0	1 (0.2)
ブドウ球菌性敗血症	0	1 (0.1)	0
皮下組織膿瘍	0	1 (0.1)	0
足部白癬	1 (0.1)	0	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
感染症および寄生虫症 (Cont.)			
細菌性扁桃炎	1 (0.1)	0	0
上気道感染	1 (0.1)	0	0
尿路感染	0	1 (0.1)	0
傷害、中毒および処置合併症	2 (0.2)	4 (0.5)	4 (0.6)
足関節部骨折	1 (0.1)	1 (0.1)	0
粉砕骨折	0	1 (0.1)	0
上腕骨骨折	0	1 (0.1)	0
半月板損傷	0	1 (0.1)	0
多発性外傷	0	0	1 (0.2)
交通事故	0	0	1 (0.2)
腱断裂	0	0	1 (0.2)
脛骨骨折	1 (0.1)	0	0
創離開	0	0	1 (0.2)
臨床検査	11 (1.3)	18 (2.1)	14 (2.2)
アラニンアミノトランスフェラーゼ増加	6 (0.7)	3 (0.4)	4 (0.6)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
臨床検査 (Cont.)			
アスパラギン酸アミノトランスフェラーゼ増加	2 (0.2)	4 (0.5)	4 (0.6)
血中クレアチンホスホキナーゼ増加	3 (0.4)	9 (1.1)	4 (0.6)
血中ブドウ糖増加	0	0	1 (0.2)
肝酵素上昇	0	1 (0.1)	0
リンパ球数減少	0	1 (0.1)	0
トランスアミナーゼ上昇	0	0	1 (0.2)
代謝および栄養障害	0	3 (0.4)	1 (0.2)
高トリグリセリド血症	0	1 (0.1)	1 (0.2)
高尿酸血症	0	2 (0.2)	0
筋骨格系および結合組織障害	6 (0.7)	9 (1.1)	9 (1.4)
関節痛	2 (0.2)	0	0
背部痛	0	3 (0.4)	1 (0.2)
骨侵食	0	1 (0.1)	0
椎間板突出	0	0	3 (0.5)
腰部脊柱管狭窄症	1 (0.1)	0	1 (0.2)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
筋骨格系および結合組織障害 (Cont.)			
変形性関節症	2 (0.2)	3 (0.4)	2 (0.3)
骨壊死	0	2 (0.2)	0
足底筋膜炎	1 (0.1)	0	0
乾癬性関節症	0	0	1 (0.2)
脊椎すべり症	0	0	1 (0.2)
良性、悪性および詳細不明の新生物(嚢胞およびポリープを含む)	5 (0.6)	4 (0.5)	4 (0.6)
結腸腺癌	0	1 (0.1)	0
基底細胞癌	1 (0.1)	1 (0.1)	0
腎明細胞癌	0	1 (0.1)	0
遠隔転移を伴う結腸癌	0	0	1 (0.2)
肺腺癌	1 (0.1)	0	0
遠隔転移を伴う肺癌	1 (0.1)	0	0
悪性黒色腫	1 (0.1)	0	0
神経内分泌癌	1 (0.1)	0	0
卵巣癌	0	0	1 (0.2)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
良性、悪性および詳細不明の新生物(嚢胞およびポリープを含む) (Cont.)			
遠隔転移を伴う膵癌	0	0	1 (0.2)
形質細胞性骨髄腫	0	1 (0.1)	0
子宮癌	0	0	1 (0.2)
神経系障害	4 (0.5)	3 (0.4)	4 (0.6)
意識変容状態	1 (0.1)	0	0
頚髄神経根障害	1 (0.1)	0	0
糖尿病性ニューロパチー	0	1 (0.1)	0
顔面麻痺	0	0	1 (0.2)
肝性脳症	0	0	1 (0.2)
ラクナ脳卒中	1 (0.1)	0	0
腰髄神経根障害	0	1 (0.1)	0
神経痛	0	1 (0.1)	0
失神	1 (0.1)	0	1 (0.2)
一過性脳虚血発作	0	0	1 (0.2)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
精神障害	1 (0.1)	2 (0.2)	1 (0.2)
不安	0	1 (0.1)	1 (0.2)
うつ病	1 (0.1)	1 (0.1)	0
腎および尿路障害	1 (0.1)	0	2 (0.3)
腎結石症	0	0	1 (0.2)
腎仙痛	1 (0.1)	0	0
尿管結石症	0	0	1 (0.2)
生殖系および乳房障害	2 (0.2)	0	1 (0.2)
卵管嚢胞	1 (0.1)	0	0
出血性卵巣嚢胞	1 (0.1)	0	0
腟脱	0	0	1 (0.2)
呼吸器、胸郭および縦隔障害	4 (0.5)	7 (0.8)	2 (0.3)
慢性閉塞性肺疾患	0	2 (0.2)	0
咳嗽	1 (0.1)	0	0
呼吸困難	1 (0.1)	0	0
自然気胸	0	1 (0.1)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
呼吸器、胸郭および縦隔障害 (Cont.)			
肺塞栓症	2 (0.2)	3 (0.4)	0
肺線維症	0	1 (0.1)	0
扁桃出血	0	0	2 (0.3)
皮膚および皮下組織障害	3 (0.4)	3 (0.4)	3 (0.5)
脱毛症	0	0	1 (0.2)
血管浮腫	2 (0.2)	0	0
皮膚炎	0	0	1 (0.2)
乾癬	0	2 (0.2)	0
膿疱性乾癬	0	0	1 (0.2)
皮膚病変	1 (0.1)	0	0
蕁麻疹	0	1 (0.1)	0
血管障害	2 (0.2)	2 (0.2)	0
深部静脈血栓症	1 (0.1)	1 (0.1)	0
高血圧	1 (0.1)	0	0
静脈瘤	0	1 (0.1)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

表 2.7.4.7-95. 投与 56 週時データカットオフまでの Grade 3 以上の有害事象（100 人年あたりの発現件数，安全性解析対象集団）：M15-554 試験

[redacted]
ABT-494 (PSA)
STUDY M15-554 - WEEK 56 (DATA CUTOFF - [redacted]20[redacted])
R&D/20/0898 - CLINICAL/STATISTICAL

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 290) (PYs = 419.4) Events (E/100 PYs)	UPA 30 mg QD (N = 308) (PYs = 423.5) Events (E/100 PYs)
Any adverse event	54 (12.9)	86 (20.3)
血液およびリンパ系障害	1 (0.2)	5 (1.2)
失血性貧血	1 (0.2)	0
血球減少症	0	1 (0.2)
播種性血管内凝固	0	1 (0.2)
リンパ節炎	0	1 (0.2)
リンパ球減少症	0	1 (0.2)
汎血球減少症	0	1 (0.2)
心臓障害	8 (1.9)	4 (0.9)
狭心症	1 (0.2)	0
不安定狭心症	0	1 (0.2)
大動脈弁狭窄	1 (0.2)	0
心房細動	1 (0.2)	0
心不全	1 (0.2)	1 (0.2)
心肺停止	1 (0.2)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 290) (PYs = 419.4) Events (E/100 PYs)	UPA 30 mg QD (N = 308) (PYs = 423.5) Events (E/100 PYs)
心臓障害 (Cont.)		
冠動脈狭窄	0	1 (0.2)
心筋梗塞	1 (0.2)	0
上室性頻脈	0	1 (0.2)
頻脈	1 (0.2)	0
心室細動	1 (0.2)	0
内分泌障害	0	1 (0.2)
甲状腺腫	0	1 (0.2)
眼障害	1 (0.2)	0
後嚢部混濁	1 (0.2)	0
胃腸障害	3 (0.7)	7 (1.7)
腹部不快感	0	1 (0.2)
下痢	1 (0.2)	2 (0.5)
十二指腸潰瘍	0	1 (0.2)
出血性十二指腸潰瘍	1 (0.2)	0
びらん性胃炎	1 (0.2)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 290) (PYs = 419.4) Events (E/100 PYs)	UPA 30 mg QD (N = 308) (PYs = 423.5) Events (E/100 PYs)
胃腸障害 (Cont.)		
悪心	0	2 (0.5)
小腸潰瘍	0	1 (0.2)
一般・全身障害および投与部位の状態	0	3 (0.7)
発熱	0	2 (0.5)
全身性炎症反応症候群	0	1 (0.2)
肝胆道系障害	1 (0.2)	5 (1.2)
胆石症	1 (0.2)	2 (0.5)
薬物性肝障害	0	1 (0.2)
胆嚢ポリープ	0	1 (0.2)
肝損傷	0	1 (0.2)
感染症および寄生虫症	9 (2.1)	32 (7.6)
膿瘍	1 (0.2)	0
肛門膿瘍	0	1 (0.2)
菌血症	0	1 (0.2)
細気管支炎	1 (0.2)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 290) (PYs = 419.4) Events (E/100 PYs)	UPA 30 mg QD (N = 308) (PYs = 423.5) Events (E/100 PYs)
感染症および寄生虫症 (Cont.)		
気管支炎	0	2 (0.5)
蜂巣炎	1 (0.2)	2 (0.5)
サイトメガロウイルス感染	0	1 (0.2)
憩室炎	0	1 (0.2)
硬膜外膿瘍	0	1 (0.2)
せつ	0	1 (0.2)
胃腸炎	2 (0.5)	0
ウイルス性胃腸炎	0	1 (0.2)
帯状疱疹	0	5 (1.2)
インフルエンザ	1 (0.2)	0
肺感染	1 (0.2)	0
爪感染	1 (0.2)	0
上咽頭炎	0	1 (0.2)
外耳炎	0	1 (0.2)
中耳炎	0	1 (0.2)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 290) (PYs = 419.4) Events (E/100 PYs)	UPA 30 mg QD (N = 308) (PYs = 423.5) Events (E/100 PYs)
感染症および寄生虫症 (Cont.)		
咽頭炎	0	1 (0.2)
ニューモシスチス・イロベチイ肺炎	0	1 (0.2)
肺炎	1 (0.2)	6 (1.4)
敗血症	0	2 (0.5)
副鼻腔炎	0	1 (0.2)
上気道感染	0	1 (0.2)
尿路感染	0	1 (0.2)
傷害、中毒および処置合併症	9 (2.1)	4 (0.9)
足関節部骨折	0	1 (0.2)
骨亀裂	1 (0.2)	0
頚椎骨折	1 (0.2)	0
靭帯捻挫	1 (0.2)	0
腰椎骨折	1 (0.2)	0
膝蓋骨骨折	1 (0.2)	0
交通事故	1 (0.2)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 290) (PYs = 419.4) Events (E/100 PYs)	UPA 30 mg QD (N = 308) (PYs = 423.5) Events (E/100 PYs)
傷害、中毒および処置合併症 (Cont.)		
腱損傷	0	1 (0.2)
腱断裂	1 (0.2)	1 (0.2)
胸椎骨折	1 (0.2)	0
外傷性血胸	1 (0.2)	0
上肢骨折	0	1 (0.2)
臨床検査	1 (0.2)	4 (0.9)
アラニンアミノトランスフェラーゼ増加	0	1 (0.2)
ヘモグロビン減少	0	1 (0.2)
リンパ球数減少	1 (0.2)	0
赤血球数減少	0	1 (0.2)
白血球数減少	0	1 (0.2)
代謝および栄養障害	2 (0.5)	1 (0.2)
脱水	1 (0.2)	0
糖尿病	1 (0.2)	0
1型糖尿病	0	1 (0.2)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

[redacted]
ABT-494 (PSA)
STUDY M15-554 - WEEK 56 (DATA CUTOFF - [redacted]20[redacted])
R&D/20/0898 - CLINICAL/STATISTICAL

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 290) (PYs = 419.4) Events (E/100 PYs)	UPA 30 mg QD (N = 308) (PYs = 423.5) Events (E/100 PYs)
筋骨格系および結合組織障害	7 (1.7)	2 (0.5)
滑液包炎	0	1 (0.2)
変形性関節症	2 (0.5)	1 (0.2)
乾癬性関節症	3 (0.7)	0
急速進行性変形性関節症	1 (0.2)	0
腱炎	1 (0.2)	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	4 (1.0)	3 (0.7)
悪性黒色腫第3期	1 (0.2)	0
中咽頭扁平上皮癌	0	1 (0.2)
卵巣癌	0	1 (0.2)
前立腺癌	2 (0.5)	0
直腸腺癌	0	1 (0.2)
直腸癌	1 (0.2)	0
神経系障害	1 (0.2)	4 (0.9)
顔面麻痺	0	1 (0.2)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 290) (PYs = 419.4) Events (E/100 PYs)	UPA 30 mg QD (N = 308) (PYs = 423.5) Events (E/100 PYs)
神経系障害 (Cont.)		
頭痛	0	1 (0.2)
ヘルペス後神経痛	0	1 (0.2)
坐骨神経痛	0	1 (0.2)
失神	1 (0.2)	0
妊娠、産褥および周産期の状態	0	2 (0.5)
自然流産	0	1 (0.2)
異所性妊娠	0	1 (0.2)
精神障害	0	2 (0.5)
不安	0	1 (0.2)
うつ病	0	1 (0.2)
腎および尿路障害	3 (0.7)	1 (0.2)
急性腎障害	2 (0.5)	1 (0.2)
腎結石症	1 (0.2)	0
生殖系および乳房障害	2 (0.5)	0
子宮頚部上皮異形成	1 (0.2)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__1.4

Treatment-Emergent Severe Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 290) (PYs = 419.4) Events (E/100 PYs)	UPA 30 mg QD (N = 308) (PYs = 423.5) Events (E/100 PYs)
生殖系および乳房障害 (Cont.)		
前立腺炎	1 (0.2)	0
呼吸器、胸郭および縦隔障害	2 (0.5)	5 (1.2)
急性呼吸不全	1 (0.2)	0
慢性閉塞性肺疾患	0	2 (0.5)
間質性肺疾患	0	1 (0.2)
気胸	0	1 (0.2)
肺塞栓症	1 (0.2)	1 (0.2)
皮膚および皮下組織障害	0	1 (0.2)
乾癬	0	1 (0.2)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of UPA and up to 30 days after the last dose of UPA, if subject discontinued prematurely from the study.
Events with unknown toxicity grade or Grade 3 and above based on CTCAE v5.0 will be counted as severe.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

表 2.7.4.7-96. 全ウパダシチニブ併合解析集団（20[redacted]年[redacted]月[redacted]日データカットオフ）の発現時期別（3 ヵ月間隔）の有害事象の概要（100 人年あたりの発現状況）

TABLE 2.4__3.1

Overview of Treatment-Emergent Adverse Events in Exposure-Adjusted Rate per 100 Patient Years
by Onset of Adverse Events in 3-month Interval
(Any Upadacitinib Analysis Set)

	0 - < 3 Month Upadacitinib			
	15 mg QD (No Cross-Over from Placebo) (N = 640)	30 mg QD (No Cross-Over from Placebo) (N = 641)	Any 15 mg QD (N = 907)	Any 30 mg QD (N = 921)
Exposure-Adjusted Event Rate	(PYs = 155.6) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 155.6) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 221.3) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 224.0) Events (E/100 PYs) [SSA E/100 PYs]
Any adverse event (AE)	740 (475.6) [475.2]	957 (615.0) [615.0]	983 (444.2) [444.0]	1207 (538.8) [538.8]
Any serious AE	26 (16.7) [16.8]	27 (17.4) [17.3]	37 (16.7) [16.8]	34 (15.2) [15.2]
Any AE leading to discontinuation of study drug	22 (14.1) [14.2]	42 (27.0) [26.9]	29 (13.1) [13.1]	44 (19.6) [19.5]
Any severe AE	30 (19.3) [19.3]	30 (19.3) [19.3]	43 (19.4) [19.5]	38 (17.0) [17.0]
Any AE with reasonable possibility of being related to study drug$	295 (189.6) [189.1]	425 (273.1) [273.4]	386 (174.4) [173.8]	518 (231.3) [231.6]
Any AE leading to death	0	0	0	0
Exposure-Adjusted Incident Rate	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]
Deaths#	0/155.6	0/155.6	0/221.3	0/224.0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
E/100 PYs = Events per 100 patient-years. n/100 PYs = Number of subjects with at least one event per 100 patient-years.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or grade 3 and above based on CTCAE v5.0 will be counted as severe. Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
$ As assessed by investigator.
# Includes both treatment-emergent and non-treatment-emergent deaths.

Program Source Code: [redacted]

TABLE 2.4__3.1

Overview of Treatment-Emergent Adverse Events in Exposure-Adjusted Rate per 100 Patient Years
by Onset of Adverse Events in 3-month Interval
(Any Upadacitinib Analysis Set)

	>= 3 - < 6 Month			
	Upadacitinib			
	15 mg QD (No Cross-Over from Placebo) (N = 605)	30 mg QD (No Cross-Over from Placebo) (N = 603)	Any 15 mg QD (N = 858)	Any 30 mg QD (N = 862)
Exposure-Adjusted Event Rate	(PYs = 147.6) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 146.9) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 209.1) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 210.7) Events (E/100 PYs) [SSA E/100 PYs]
Any adverse event (AE)	597 (404.5) [403.8]	688 (468.3) [468.4]	729 (348.6) [348.5]	837 (397.2) [397.1]
Any serious AE	19 (12.9) [12.9]	27 (18.4) [18.3]	25 (12.0) [12.0]	34 (16.1) [16.1]
Any AE leading to discontinuation of study drug	21 (14.2) [14.5]	18 (12.3) [12.2]	26 (12.4) [12.6]	22 (10.4) [10.4]
Any severe AE	19 (12.9) [12.9]	38 (25.9) [25.8]	25 (12.0) [12.0]	44 (20.9) [20.8]
Any AE with reasonable possibility of being related to study drug$	215 (145.7) [145.2]	292 (198.8) [199.4]	252 (120.5) [120.4]	355 (168.5) [168.9]
Any AE leading to death	0	0	0	0
Exposure-Adjusted Incident Rate	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]
Deaths#	0/147.6	0/146.9	0/209.1	0/210.7

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
E/100 PYs = Events per 100 patient-years. n/100 PYs = Number of subjects with at least one event per 100 patient-years.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or grade 3 and above based on CTCAE v5.0 will be counted as severe. Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
$ As assessed by investigator.
# Includes both treatment-emergent and non-treatment-emergent deaths.

Program Source Code: [redacted]

TABLE 2.4__3.1

Overview of Treatment-Emergent Adverse Events in Exposure-Adjusted Rate per 100 Patient Years
by Onset of Adverse Events in 3-month Interval
(Any Upadacitinib Analysis Set)

	>= 6 - < 9 Month Upadacitinib			
	15 mg QD (No Cross-Over from Placebo) (N = 581)	30 mg QD (No Cross-Over from Placebo) (N = 571)	Any 15 mg QD (N = 821)	Any 30 mg QD (N = 822)
Exposure-Adjusted Event Rate	(PYs = 141.8) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 138.9) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 196.3) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 196.1) Events (E/100 PYs) [SSA E/100 PYs]
Any adverse event (AE)	495 (349.1) [349.0]	535 (385.2) [385.5]	600 (305.7) [305.5]	679 (346.3) [346.3]
Any serious AE	19 (13.4) [13.4]	17 (12.2) [12.3]	22 (11.2) [11.2]	25 (12.7) [12.8]
Any AE leading to discontinuation of study drug	9 (6.3) [6.3]	5 (3.6) [3.6]	13 (6.6) [6.6]	8 (4.1) [4.1]
Any severe AE	23 (16.2) [16.2]	14 (10.1) [10.1]	28 (14.3) [14.2]	28 (14.3) [14.2]
Any AE with reasonable possibility of being related to study drug$	171 (120.6) [120.4]	229 (164.9) [165.1]	201 (102.4) [102.2]	278 (141.8) [141.9]
Any AE leading to death	1 (0.7) [0.7]	0	1 (0.5) [0.5]	0
Exposure-Adjusted Incident Rate	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]
Deaths#	0/141.8	1/139.0(0.7) [0.7]	0/196.4	1/196.3(0.5) [0.5]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
E/100 PYs = Events per 100 patient-years. n/100 PYs = Number of subjects with at least one event per 100 patient-years.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or grade 3 and above based on CTCAE v5.0 will be counted as severe. Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
$ As assessed by investigator.
# Includes both treatment-emergent and non-treatment-emergent deaths.

Program Source Code: [redacted]

TABLE 2.4__3.1

Overview of Treatment-Emergent Adverse Events in Exposure-Adjusted Rate per 100 Patient Years
by Onset of Adverse Events in 3-month Interval
(Any Upadacitinib Analysis Set)

	>= 9 - < 12 Month Upadacitinib			
	15 mg QD (No Cross-Over from Placebo) (N = 550)	30 mg QD (No Cross-Over from Placebo) (N = 540)	Any 15 mg QD (N = 745)	Any 30 mg QD (N = 742)
Exposure-Adjusted Event Rate	(PYs = 134.1) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 132.0) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 174.4) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 174.1) Events (E/100 PYs) [SSA E/100 PYs]
Any adverse event (AE)	236 (176.0) [176.0]	331 (250.8) [250.8]	290 (166.3) [166.5]	423 (243.0) [242.8]
Any serious AE	8 (6.0) [6.0]	11 (8.3) [8.3]	12 (6.9) [6.9]	18 (10.3) [10.3]
Any AE leading to discontinuation of study drug	4 (3.0) [3.0]	7 (5.3) [5.3]	5 (2.9) [2.9]	12 (6.9) [6.9]
Any severe AE	7 (5.2) [5.2]	21 (15.9) [15.9]	8 (4.6) [4.6]	28 (16.1) [16.0]
Any AE with reasonable possibility of being related to study drug$	71 (52.9) [52.9]	110 (83.3) [83.4]	83 (47.6) [47.5]	138 (79.3) [79.2]
Any AE leading to death	1 (0.7) [0.7]	0	1 (0.6) [0.6]	0
Exposure-Adjusted Incident Rate	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]
Deaths#	2/134.1(1.5) [1.5]	0/132.0	2/174.4(1.1) [1.1]	0/174.1

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
E/100 PYs = Events per 100 patient-years. n/100 PYs = Number of subjects with at least one event per 100 patient-years.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or grade 3 and above based on CTCAE v5.0 will be counted as severe. Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
$ As assessed by investigator.
# Includes both treatment-emergent and non-treatment-emergent deaths.

Program Source Code: [redacted]

[redacted]

ABT-494 (PSA)
120-DAY SAFETY UPDATE
R&D/20/0773 - CLINICAL/STATISTICAL

TABLE 2.4__3.1

Overview of Treatment-Emergent Adverse Events in Exposure-Adjusted Rate per 100 Patient Years
by Onset of Adverse Events in 3-month Interval
(Any Upadacitinib Analysis Set)

	>= 12 - < 15 Month			
	Upadacitinib			
	15 mg QD (No Cross-Over from Placebo) (N = 527)	30 mg QD (No Cross-Over from Placebo) (N = 521)	Any 15 mg QD (N = 663)	Any 30 mg QD (N = 666)
Exposure-Adjusted Event Rate	(PYs = 116.9) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 115.7) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 145.8) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 147.3) Events (E/100 PYs) [SSA E/100 PYs]
Any adverse event (AE)	206 (176.2) [176.3]	274 (236.8) [236.6]	262 (179.7) [179.8]	326 (221.3) [221.5]
Any serious AE	6 (5.1) [5.1]	18 (15.6) [15.6]	8 (5.5) [5.5]	20 (13.6) [13.5]
Any AE leading to discontinuation of study drug	2 (1.7) [1.7]	4 (3.5) [3.5]	3 (2.1) [2.0]	4 (2.7) [2.7]
Any severe AE	4 (3.4) [3.4]	16 (13.8) [13.8]	5 (3.4) [3.4]	19 (12.9) [12.9]
Any AE with reasonable possibility of being related to study drug$	72 (61.6) [61.7]	98 (84.7) [84.6]	99 (67.9) [67.8]	114 (77.4) [77.5]
Any AE leading to death	0	0	0	0
Exposure-Adjusted Incident Rate	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]
Deaths#	0/116.8	0/115.7	0/145.7	0/147.3

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
E/100 PYs = Events per 100 patient-years. n/100 PYs = Number of subjects with at least one event per 100 patient-years.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or grade 3 and above based on CTCAE v5.0 will be counted as severe. Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
$ As assessed by investigator.
# Includes both treatment-emergent and non-treatment-emergent deaths.

Program Source Code: [redacted]

TABLE 2.4__3.1

Overview of Treatment-Emergent Adverse Events in Exposure-Adjusted Rate per 100 Patient Years
by Onset of Adverse Events in 3-month Interval
(Any Upadacitinib Analysis Set)

	>= 15 - < 18 Month Upadacitinib			
	15 mg QD (No Cross-Over from Placebo) (N = 414)	30 mg QD (No Cross-Over from Placebo) (N = 408)	Any 15 mg QD (N = 507)	Any 30 mg QD (N = 508)
Exposure-Adjusted Event Rate	(PYs = 88.4) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 88.2) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 107.3) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 108.6) Events (E/100 PYs) [SSA E/100 PYs]
Any adverse event (AE)	157 (177.6) [177.4]	190 (215.4) [215.4]	194 (180.8) [181.0]	244 (224.7) [224.7]
Any serious AE	14 (15.8) [15.8]	11 (12.5) [12.5]	14 (13.0) [13.1]	19 (17.5) [17.5]
Any AE leading to discontinuation of study drug	2 (2.3) [2.3]	1 (1.1) [1.1]	3 (2.8) [2.8]	3 (2.8) [2.8]
Any severe AE	13 (14.7) [14.7]	11 (12.5) [12.5]	15 (14.0) [14.0]	21 (19.3) [19.3]
Any AE with reasonable possibility of being related to study drug$	43 (48.6) [48.7]	57 (64.6) [64.6]	55 (51.3) [51.2]	76 (70.0) [70.0]
Any AE leading to death	0	0	0	1 (0.9) [0.9]
Exposure-Adjusted Incident Rate	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]
Deaths#	0/88.4	0/88.2	0/107.3	1/108.6(0.9) [0.9]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
E/100 PYs = Events per 100 patient-years. n/100 PYs = Number of subjects with at least one event per 100 patient-years.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or grade 3 and above based on CTCAE v5.0 will be counted as severe. Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
$ As assessed by investigator.
# Includes both treatment-emergent and non-treatment-emergent deaths.

Program Source Code: [redacted]

TABLE 2.4__3.1

Overview of Treatment-Emergent Adverse Events in Exposure-Adjusted Rate per 100 Patient Years
by Onset of Adverse Events in 3-month Interval
(Any Upadacitinib Analysis Set)

	>= 18 - < 21 Month			
	Upadacitinib			
	15 mg QD (No Cross-Over from Placebo) (N = 306)	30 mg QD (No Cross-Over from Placebo) (N = 313)	Any 15 mg QD (N = 366)	Any 30 mg QD (N = 382)
Exposure-Adjusted Event Rate	(PYs = 65.3) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 67.8) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 77.6) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 82.1) Events (E/100 PYs) [SSA E/100 PYs]
Any adverse event (AE)	71 (108.7) [108.5]	119 (175.5) [177.0]	88 (113.4) [113.3]	144 (175.4) [176.3]
Any serious AE	1 (1.5) [1.5]	5 (7.4) [7.3]	2 (2.6) [2.5]	6 (7.3) [7.2]
Any AE leading to discontinuation of study drug	1 (1.5) [1.5]	0	1 (1.3) [1.3]	1 (1.2) [1.2]
Any severe AE	1 (1.5) [1.6]	4 (5.9) [5.8]	1 (1.3) [1.3]	4 (4.9) [4.8]
Any AE with reasonable possibility of being related to study drug$	30 (45.9) [46.2]	33 (48.7) [48.9]	38 (49.0) [49.3]	42 (51.2) [51.2]
Any AE leading to death	0	0	0	0
Exposure-Adjusted Incident Rate	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]
Deaths#	0/65.3	0/67.8	0/77.6	0/82.1

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
E/100 PYs = Events per 100 patient-years. n/100 PYs = Number of subjects with at least one event per 100 patient-years.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or grade 3 and above based on CTCAE v5.0 will be counted as severe. Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
$ As assessed by investigator.
# Includes both treatment-emergent and non-treatment-emergent deaths.

Program Source Code: [redacted]

TABLE 2.4__3.1

Overview of Treatment-Emergent Adverse Events in Exposure-Adjusted Rate per 100 Patient Years
by Onset of Adverse Events in 3-month Interval
(Any Upadacitinib Analysis Set)

	>= 21 - < 24 Month			
	Upadacitinib			
	15 mg QD (No Cross-Over from Placebo) (N = 209)	30 mg QD (No Cross-Over from Placebo) (N = 225)	Any 15 mg QD (N = 248)	Any 30 mg QD (N = 273)
Exposure-Adjusted Event Rate	(PYs = 44.7) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 46.0) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 52.6) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 54.7) Events (E/100 PYs) [SSA E/100 PYs]
Any adverse event (AE)	59 (132.0) [131.1]	94 (204.3) [203.5]	66 (125.5) [124.9]	99 (181.0) [180.5]
Any serious AE	2 (4.5) [4.3]	5 (10.9) [10.4]	2 (3.8) [3.6]	5 (9.1) [8.7]
Any AE leading to discontinuation of study drug	1 (2.2) [2.1]	2 (4.3) [4.2]	1 (1.9) [1.8]	2 (3.7) [3.5]
Any severe AE	3 (6.7) [6.4]	5 (10.9) [10.6]	3 (5.7) [5.4]	5 (9.1) [8.9]
Any AE with reasonable possibility of being related to study drug$	17 (38.0) [38.4]	28 (60.9) [59.3]	18 (34.2) [34.7]	30 (54.8) [53.5]
Any AE leading to death	0	0	0	0
Exposure-Adjusted Incident Rate	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]
Deaths#	0/44.7	0/46.0	0/52.6	0/54.7

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
E/100 PYs = Events per 100 patient-years. n/100 PYs = Number of subjects with at least one event per 100 patient-years.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or grade 3 and above based on CTCAE v5.0 will be counted as severe. Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
$ As assessed by investigator.
# Includes both treatment-emergent and non-treatment-emergent deaths.

Program Source Code: [redacted]

TABLE 2.4__3.1

Overview of Treatment-Emergent Adverse Events in Exposure-Adjusted Rate per 100 Patient Years
by Onset of Adverse Events in 3-month Interval
(Any Upadacitinib Analysis Set)

	>= 24 Month Upadacitinib			
	15 mg QD (No Cross-Over from Placebo) (N = 152)	30 mg QD (No Cross-Over from Placebo) (N = 150)	Any 15 mg QD (N = 176)	Any 30 mg QD (N = 173)
Exposure-Adjusted Event Rate	(PYs = 57.2) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 54.3) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 62.9) Events (E/100 PYs) [SSA E/100 PYs]	(PYs = 59.8) Events (E/100 PYs) [SSA E/100 PYs]
Any adverse event (AE)	77 (134.6) [134.1]	75 (138.1) [139.8]	79 (125.6) [125.2]	84 (140.5) [141.8]
Any serious AE	6 (10.5) [10.6]	3 (5.5) [5.6]	7 (11.1) [11.4]	5 (8.4) [8.2]
Any AE leading to discontinuation of study drug	2 (3.5) [3.8]	1 (1.8) [1.9]	2 (3.2) [3.4]	2 (3.3) [3.3]
Any severe AE	4 (7.0) [7.1]	6 (11.0) [11.2]	5 (7.9) [8.1]	8 (13.4) [13.3]
Any AE with reasonable possibility of being related to study drug$	20 (35.0) [35.7]	31 (57.1) [58.0]	21 (33.4) [34.1]	38 (63.5) [64.0]
Any AE leading to death	0	0	0	1 (1.7) [1.6]
Exposure-Adjusted Incident Rate	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]	n/PYs (n/100 PYs) [SSA n/100 PYs]
Deaths#	0/57.2	0/54.3	0/62.9	1/59.6(1.7) [1.6]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
E/100 PYs = Events per 100 patient-years. n/100 PYs = Number of subjects with at least one event per 100 patient-years.
SSA = Study size adjusted.
Patients could be included in more than one treatment group.
Events with unknown toxicity grade or grade 3 and above based on CTCAE v5.0 will be counted as severe. Events with unknown relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
$ As assessed by investigator.
# Includes both treatment-emergent and non-treatment-emergent deaths.

Program Source Code: [redacted]

表 2.7.4.7-97. 全ウパダシチニブ併合解析集団（20[redacted]年[redacted]月[redacted]日データカットオフ）の重篤な有害事象（100 人年あたりの発現状況）

TABLE 2.4__3.3

Treatment-Emergent Serious Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
Any Adverse Event	101 (10.6) [10.6]	124 (13.1) [13.1]	129 (10.3) [10.3]	166 (13.2) [13.2]
*** Not Coded ***	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]
*** Not Coded ***	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]
血液およびリンパ系障害	1 (0.1) [0.1]	4 (0.4) [0.4]	1 (<0.1) [<0.1]	5 (0.4) [0.4]
貧血	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
失血性貧血	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
鉄欠乏性貧血	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
リンパ組織過形成	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
汎血球減少症	0	0	0	1 (<0.1) [<0.1]
心臓障害	7 (0.7) [0.7]	9 (1.0) [1.0]	8 (0.6) [0.6]	11 (0.9) [0.9]
急性心筋梗塞	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
狭心症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
不安定狭心症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
大動脈弁狭窄	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
心房細動	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
徐脈	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.3

Treatment-Emergent Serious Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
心臓障害 (Cont.)				
心不全	0	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
うっ血性心不全	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
心肺停止	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
冠動脈疾患	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
冠動脈狭窄	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
心筋梗塞	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]
上室性頻脈	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
心室細動	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
先天性、家族性および遺伝性障害	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
陰嚢水瘤	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
耳および迷路障害	0	0	1 (<0.1) [<0.1]	0
頭位性回転性めまい	0	0	1 (<0.1) [<0.1]	0
内分泌障害	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
甲状腺腫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
眼障害	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
白内障	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.3

Treatment-Emergent Serious Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
眼障害 (Cont.)				
複視	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
眼瞼下垂	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
胃腸障害	10 (1.1) [1.1]	8 (0.8) [0.8]	12 (1.0) [1.0]	12 (1.0) [1.0]
腹痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
痔瘻	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
大腸炎	0	0	1 (<0.1) [<0.1]	0
下痢	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
十二指腸潰瘍	0	0	0	1 (<0.1) [<0.1]
出血性十二指腸潰瘍	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
消化不良	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
糞塊	0	0	0	1 (<0.1) [<0.1]
穿孔性胃潰瘍	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
胃炎	0	0	1 (<0.1) [<0.1]	0
びらん性胃炎	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
胃十二指腸出血	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
胃腸出血	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.3

Treatment-Emergent Serious Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
胃腸障害 (Cont.)				
胃食道逆流性疾患	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
吐血	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
痔核	0	0	0	1 (<0.1) [<0.1]
裂孔ヘルニア	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
単径ヘルニア	0	0	0	1 (<0.1) [<0.1]
小腸潰瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
上部消化管出血	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
一般・全身障害および投与部位の状態	2 (0.2) [0.2]	4 (0.4) [0.4]	2 (0.2) [0.2]	5 (0.4) [0.4]
胸痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
疼痛	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
発熱	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
全身性炎症反応症候群	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肝胆道系障害	3 (0.3) [0.3]	1 (0.1) [0.1]	4 (0.3) [0.3]	1 (<0.1) [<0.1]
胆嚢炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
胆石症	2 (0.2) [0.2]	0	3 (0.2) [0.2]	0
薬物性肝障害	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.3

Treatment-Emergent Serious Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症	20 (2.1) [2.1]	45 (4.8) [4.8]	29 (2.3) [2.3]	64 (5.1) [5.1]
膿瘍	0	0	1 (<0.1) [<0.1]	0
四肢膿瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肛門膿瘍	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
虫垂炎	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
細菌性関節炎	0	0	1 (<0.1) [<0.1]	0
異型肺炎	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
菌血症	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
細気管支炎	0	0	1 (<0.1) [<0.1]	0
気管支炎	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	4 (0.3) [0.3]
蜂巣炎	2 (0.2) [0.2]	2 (0.2) [0.2]	3 (0.2) [0.2]	3 (0.2) [0.2]
コロナウイルス感染	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
サイトメガロウイルス感染	0	0	0	1 (<0.1) [<0.1]
憩室炎	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
丹毒	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
硬膜外膿瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.3

Treatment-Emergent Serious Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
胃腸炎	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
ウイルス性胃腸炎	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
H1N1インフルエンザ	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
帯状疱疹	1 (0.1) [0.1]	4 (0.4) [0.4]	2 (0.2) [0.2]	5 (0.4) [0.4]
皮膚播種性帯状疱疹	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
インフルエンザ	0	0	1 (<0.1) [<0.1]	0
喉頭炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
肝膿瘍	0	0	1 (<0.1) [<0.1]	0
肺感染	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
髄膜炎	0	0	0	1 (<0.1) [<0.1]
咽頭炎	0	0	0	1 (<0.1) [<0.1]
ニューモシスチス・イロベチイ肺炎	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
肺炎	6 (0.6) [0.6]	8 (0.8) [0.8]	6 (0.5) [0.5]	12 (1.0) [1.0]
細菌性肺炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
インフルエンザ性肺炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
レンサ球菌性肺炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.3

Treatment-Emergent Serious Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
腎盂腎炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
卵管炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
敗血症	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	2 (0.2) [0.2]
ブドウ球菌性菌血症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ブドウ球菌性敗血症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
皮下組織膿瘍	0	0	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
上気道感染	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
尿路感染	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
尿路性敗血症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
ウイルス感染	0	0	0	1 (<0.1) [<0.1]
ウイルス性上気道感染	0	0	0	1 (<0.1) [<0.1]
傷害、中毒および処置合併症	9 (0.9) [0.9]	7 (0.7) [0.7]	12 (1.0) [1.0]	8 (0.6) [0.6]
足関節部骨折	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
頚椎骨折	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
粉砕骨折	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
転倒	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.3

Treatment-Emergent Serious Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
傷害、中毒および処置合併症 (Cont.)				
大腿骨頚部骨折	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
足骨折	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
体内異物	0	0	1 (<0.1) [<0.1]	0
上腕骨骨折	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
関節脱臼	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
関節損傷	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
腰椎骨折	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
処置後胆汁漏出	0	0	1 (<0.1) [<0.1]	0
交通事故	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
腱断裂	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
胸椎骨折	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
脛骨骨折	0	0	1 (<0.1) [<0.1]	0
外傷性血胸	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
上肢骨折	0	0	0	1 (<0.1) [<0.1]
臨床検査	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
筋酵素上昇	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.3

Treatment-Emergent Serious Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
代謝および栄養障害	2 (0.2) [0.2]	1 (0.1) [0.1]	3 (0.2) [0.2]	1 (<0.1) [<0.1]
脱水	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
糖尿病	0	0	1 (<0.1) [<0.1]	0
低ナトリウム血症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
1型糖尿病	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
筋骨格系および結合組織障害	9 (0.9) [0.9]	10 (1.1) [1.1]	12 (1.0) [1.0]	12 (1.0) [1.0]
関節痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
背部痛	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
頚部脊柱管狭窄症	0	0	1 (<0.1) [<0.1]	0
瘻孔	0	0	1 (<0.1) [<0.1]	0
側腹部痛	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
椎間板変性症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
椎間板突出	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
腰部脊柱管狭窄症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
変形性関節症	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	4 (0.3) [0.3]
骨壊死	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.3

Treatment-Emergent Serious Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
筋骨格系および結合組織障害 (Cont.)				
乾癬性関節症	4 (0.4) [0.4]	1 (0.1) [0.1]	4 (0.3) [0.3]	1 (<0.1) [<0.1]
急速進行性変形性関節症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
脊椎後方すべり症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
全身性エリテマトーデス	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	8 (0.8) [0.8]	8 (0.8) [0.8]	8 (0.6) [0.6]	10 (0.8) [0.8]
肛門性器疣贅	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
乳癌	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
子宮内膜腺癌	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
肝臓血管腫	0	0	0	1 (<0.1) [<0.1]
肺腺癌	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
遠隔転移を伴う肺癌	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
悪性黒色腫第3期	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
神経内分泌癌	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
中咽頭扁平上皮癌	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
卵巣癌	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
良性副甲状腺腫瘍	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.3

Treatment-Emergent Serious Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
形質細胞性骨髄腫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
前立腺癌	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
直腸腺癌	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
直腸癌	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
腎癌	0	0	0	1 (<0.1) [<0.1]
子宮平滑筋腫	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
神経系障害	5 (0.5) [0.5]	3 (0.3) [0.3]	7 (0.6) [0.6]	4 (0.3) [0.3]
頚髄神経根障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
脱髄	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
糖尿病性ニューロパチー	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
浮動性めまい	1 (0.1) [0.1]	0	2 (0.2) [0.2]	0
顔面麻痺	0	0	0	1 (<0.1) [<0.1]
虚血性脳卒中	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
ラクナ脳卒中	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
会話障害	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
失神	0	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.3

Treatment-Emergent Serious Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
神経系障害 (Cont.)				
一過性全健忘	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
妊娠、産褥および周産期の状態	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
自然流産	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
異所性妊娠	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
精神障害	2 (0.2) [0.2]	0	3 (0.2) [0.2]	2 (0.2) [0.2]
うつ病	1 (0.1) [0.1]	0	2 (0.2) [0.2]	0
失見当識	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
精神状態変化	0	0	0	1 (<0.1) [<0.1]
自殺企図	0	0	0	1 (<0.1) [<0.1]
腎および尿路障害	5 (0.5) [0.5]	3 (0.3) [0.3]	5 (0.4) [0.4]	4 (0.3) [0.3]
急性腎障害	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]
腎結石症	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	2 (0.2) [0.2]
腎仙痛	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
生殖系および乳房障害	6 (0.6) [0.6]	2 (0.2) [0.2]	6 (0.5) [0.5]	2 (0.2) [0.2]
良性前立腺肥大症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
子宮頚部上皮異形成	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.3

Treatment-Emergent Serious Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
生殖系および乳房障害 (Cont.)				
子宮内膜増殖症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
卵管嚢胞	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
線維嚢胞性乳腺疾患	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
出血性卵巣嚢胞	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
子宮脱	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
呼吸器、胸郭および縦隔障害	6 (0.6) [0.6]	7 (0.7) [0.7]	6 (0.5) [0.5]	12 (1.0) [1.0]
急性呼吸不全	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
喘息	0	0	0	1 (<0.1) [<0.1]
慢性閉塞性肺疾患	0	1 (0.1) [0.1]	0	2 (0.2) [0.2]
間質性肺疾患	0	0	0	1 (<0.1) [<0.1]
気胸	0	0	0	1 (<0.1) [<0.1]
自然気胸	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肺塞栓症	3 (0.3) [0.3]	3 (0.3) [0.3]	3 (0.2) [0.2]	4 (0.3) [0.3]
肺線維症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
呼吸窮迫	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
睡眠時無呼吸症候群	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__3.3

Treatment-Emergent Serious Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 640) (PYs = 951.5) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 641) (PYs = 945.4) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 907) (PYs = 1247.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 921) (PYs = 1257.4) Events (E/100 PYs) [SSA E/100 PYs]
皮膚および皮下組織障害	2 (0.2) [0.2]	2 (0.2) [0.2]	5 (0.4) [0.4]	2 (0.2) [0.2]
血管浮腫	0	0	2 (0.2) [0.2]	0
接触皮膚炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
嵌入爪	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
乾癬	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
皮膚壊死	0	0	1 (<0.1) [<0.1]	0
血管障害	0	2 (0.2) [0.2]	0	3 (0.2) [0.2]
深部静脈血栓症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
表在性血栓性静脈炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
静脈瘤	0	0	0	1 (<0.1) [<0.1]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-98. 全ウパダシチニブ併合解析集団（20[redacted]年[redacted]月[redacted]日データカットオフ）の重篤な有害事象（100 人年あたりの発現状況，日本人部分集団）

TABLE 2.4__1.2.3.3_J

Treatment-Emergent Serious Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 17) (PYs = 26.7) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 18) (PYs = 29.3) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 23) (PYs = 35.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 26) (PYs = 40.1) Events (E/100 PYs) [SSA E/100 PYs]
Any Adverse Event	4 (15.0) [13.9]	11 (37.5) [38.7]	5 (14.2) [13.1]	21 (52.4) [55.2]
血液およびリンパ系障害	0	0	0	1 (2.5) [2.7]
汎血球減少症	0	0	0	1 (2.5) [2.7]
胃腸障害	0	1 (3.4) [3.7]	0	2 (5.0) [5.4]
十二指腸潰瘍	0	0	0	1 (2.5) [2.7]
小腸潰瘍	0	1 (3.4) [3.7]	0	1 (2.5) [2.7]
肝胆道系障害	0	1 (3.4) [3.7]	0	1 (2.5) [2.7]
薬物性肝障害	0	1 (3.4) [3.7]	0	1 (2.5) [2.7]
感染症および寄生虫症	1 (3.7) [3.5]	7 (23.9) [24.0]	1 (2.8) [2.6]	11 (27.4) [28.2]
肛門膿瘍	0	1 (3.4) [3.7]	0	1 (2.5) [2.7]
気管支炎	0	1 (3.4) [2.8]	0	1 (2.5) [2.0]
サイトメガロウイルス感染	0	0	0	1 (2.5) [2.7]
ウイルス性胃腸炎	1 (3.7) [3.5]	0	1 (2.8) [2.6]	1 (2.5) [2.7]
帯状疱疹	0	2 (6.8) [6.5]	0	2 (5.0) [4.7]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.3_J

Treatment-Emergent Serious Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 17) (PYs = 26.7) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 18) (PYs = 29.3) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 23) (PYs = 35.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 26) (PYs = 40.1) Events (E/100 PYs) [SSA E/100 PYs]
感染症および寄生虫症 (Cont.)				
咽頭炎	0	0	0	1 (2.5) [2.7]
ニューモシスチス・イロベチイ肺炎	0	0	0	1 (2.5) [2.7]
肺炎	0	2 (6.8) [7.4]	0	2 (5.0) [5.4]
尿路感染	0	1 (3.4) [3.7]	0	1 (2.5) [2.7]
傷害、中毒および処置合併症	1 (3.7) [3.5]	0	1 (2.8) [2.6]	0
腱断裂	1 (3.7) [3.5]	0	1 (2.8) [2.6]	0
代謝および栄養障害	0	0	1 (2.8) [2.6]	0
糖尿病	0	0	1 (2.8) [2.6]	0
筋骨格系および結合組織障害	2 (7.5) [6.9]	0	2 (5.7) [5.2]	0
乾癬性関節症	2 (7.5) [6.9]	0	2 (5.7) [5.2]	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	2 (6.8) [7.4]	0	2 (5.0) [5.4]
肛門性器疣贅	0	1 (3.4) [3.7]	0	1 (2.5) [2.7]
卵巣癌	0	1 (3.4) [3.7]	0	1 (2.5) [2.7]
神経系障害	0	0	0	1 (2.5) [2.7]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

TABLE 2.4__1.2.3.3_J

Treatment-Emergent Serious Adverse Events in Exposure-Adjusted Event Rate per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term
(Any Upadacitinib Analysis Set, Japanese Population)

System Organ Class MedDRA 22.0 Preferred Term	Upadacitinib 15 mg QD (No Cross-Over from Placebo) (N = 17) (PYs = 26.7) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib 30 mg QD (No Cross-Over from Placebo) (N = 18) (PYs = 29.3) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 15 mg QD (N = 23) (PYs = 35.2) Events (E/100 PYs) [SSA E/100 PYs]	Upadacitinib Any 30 mg QD (N = 26) (PYs = 40.1) Events (E/100 PYs) [SSA E/100 PYs]
神経系障害 (Cont.)				
顔面麻痺	0	0	0	1 (2.5) [2.7]
呼吸器、胸郭および縦隔障害	0	0	0	3 (7.5) [8.1]
喘息	0	0	0	1 (2.5) [2.7]
間質性肺疾患	0	0	0	1 (2.5) [2.7]
気胸	0	0	0	1 (2.5) [2.7]

Note: Treatment-emergent adverse event (TEAE) is defined as an adverse event with an onset date that is on or after the first dose of oral study drug, and no more than 30 days after the last dose of upadacitinib and placebo.
Patients could be included in more than one treatment group.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-99. 投与 56 週時データカットオフまでの重篤な有害事象（100 人年あたりの発現件数，安全性解析対象集団）：M15-572 試験

TABLE 14.3__2.1

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
Any adverse event	76 (9.1)	104 (12.3)	59 (9.3)
血液およびリンパ系障害	0	3 (0.4)	1 (0.2)
貧血	0	1 (0.1)	0
鉄欠乏性貧血	0	1 (0.1)	0
リンパ組織過形成	0	1 (0.1)	0
正色素性正球性貧血	0	0	1 (0.2)
心臓障害	1 (0.1)	4 (0.5)	5 (0.8)
急性心筋梗塞	0	0	1 (0.2)
冠動脈硬化症	0	0	1 (0.2)
心房細動	0	0	1 (0.2)
うっ血性心不全	0	1 (0.1)	0
冠動脈疾患	0	1 (0.1)	1 (0.2)
心筋梗塞	1 (0.1)	2 (0.2)	0
心膜炎	0	0	1 (0.2)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__2.1

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
先天性、家族性および遺伝性障害	1 (0.1)	1 (0.1)	0
陰嚢水瘤	1 (0.1)	1 (0.1)	0
耳および迷路障害	1 (0.1)	0	0
頭位性回転性めまい	1 (0.1)	0	0
眼障害	1 (0.1)	2 (0.2)	0
白内障	0	1 (0.1)	0
複視	0	1 (0.1)	0
眼瞼下垂	1 (0.1)	0	0
胃腸障害	10 (1.2)	5 (0.6)	4 (0.6)
痔瘻	0	1 (0.1)	0
大腸炎	1 (0.1)	0	0
十二指腸潰瘍	0	0	1 (0.2)
出血性十二指腸潰瘍	0	1 (0.1)	0
消化不良	1 (0.1)	0	0
小腸炎	0	0	1 (0.2)
腸膀胱瘻	1 (0.1)	0	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__2.1

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
胃腸障害 (Cont.)			
糞塊	0	1 (0.1)	0
穿孔性胃潰瘍	1 (0.1)	0	0
びらん性胃炎	1 (0.1)	0	0
胃十二指腸出血	1 (0.1)	0	0
胃腸出血	1 (0.1)	0	0
胃食道逆流性疾患	1 (0.1)	0	0
痔核	0	1 (0.1)	0
裂孔ヘルニア	1 (0.1)	0	0
大腸ポリープ	0	0	1 (0.2)
上部消化管出血	1 (0.1)	1 (0.1)	0
嘔吐	0	0	1 (0.2)
一般・全身障害および投与部位の状態	2 (0.2)	3 (0.4)	1 (0.2)
胸痛	0	1 (0.1)	0
疼痛	1 (0.1)	0	0
発熱	1 (0.1)	2 (0.2)	1 (0.2)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__2.1

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
肝胆道系障害	2 (0.2)	1 (0.1)	2 (0.3)
胆嚢炎	1 (0.1)	1 (0.1)	0
胆石症	1 (0.1)	0	0
黄疸	0	0	1 (0.2)
門脈血栓症	0	0	1 (0.2)
免疫系障害	0	1 (0.1)	0
免疫系障害	0	1 (0.1)	0
感染症および寄生虫症	24 (2.9)	40 (4.7)	8 (1.3)
四肢膿瘍	0	1 (0.1)	0
肛門膿瘍	0	1 (0.1)	0
虫垂炎	1 (0.1)	3 (0.4)	0
細菌性関節炎	1 (0.1)	0	0
異型肺炎	0	2 (0.2)	0
菌血症	0	1 (0.1)	0
骨膿瘍	0	0	1 (0.2)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__2.1

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
感染症および寄生虫症 (Cont.)			
気管支炎	1 (0.1)	3 (0.4)	0
蜂巣炎	1 (0.1)	1 (0.1)	3 (0.5)
コロナウイルス感染	2 (0.2)	2 (0.2)	1 (0.2)
憩室炎	2 (0.2)	0	0
丹毒	1 (0.1)	0	1 (0.2)
熱性感染症	1 (0.1)	0	0
胃腸炎	0	1 (0.1)	0
H1N1インフルエンザ	1 (0.1)	0	0
帯状疱疹	2 (0.2)	4 (0.5)	0
皮膚播種性帯状疱疹	0	1 (0.1)	0
インフルエンザ	1 (0.1)	0	0
喉頭炎	1 (0.1)	0	0
肺感染	0	1 (0.1)	0
腹膜炎	0	1 (0.1)	0
ニューモシスチス・イロベチイ肺炎	0	1 (0.1)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__2.1

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
感染症および寄生虫症 (Cont.)			
肺炎	6 (0.7)	8 (0.9)	1 (0.2)
細菌性肺炎	1 (0.1)	0	0
レンサ球菌性肺炎	0	1 (0.1)	0
腎盂腎炎	0	1 (0.1)	0
卵管炎	0	1 (0.1)	0
敗血症	2 (0.2)	0	0
ブドウ球菌性菌血症	0	1 (0.1)	0
ブドウ球菌感染	0	0	1 (0.2)
ブドウ球菌性敗血症	0	1 (0.1)	0
皮下組織膿瘍	0	1 (0.1)	0
尿路感染	0	1 (0.1)	0
尿路性敗血症	0	1 (0.1)	0
ウイルス感染	0	1 (0.1)	0
傷害、中毒および処置合併症	4 (0.5)	7 (0.8)	5 (0.8)
足関節部骨折	1 (0.1)	1 (0.1)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__2.1

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
傷害、中毒および処置合併症 (Cont.)			
粉砕骨折	0	1 (0.1)	0
足骨折	1 (0.1)	0	0
体内異物	1 (0.1)	0	0
上腕骨骨折	0	1 (0.1)	0
関節脱臼	0	1 (0.1)	0
半月板損傷	0	1 (0.1)	0
多発性外傷	0	0	1 (0.2)
橈骨骨折	0	0	1 (0.2)
交通事故	0	0	1 (0.2)
腱断裂	0	1 (0.1)	0
脛骨骨折	1 (0.1)	0	0
上肢骨折	0	1 (0.1)	1 (0.2)
創離開	0	0	1 (0.2)
臨床検査	1 (0.1)	0	1 (0.2)
筋酵素上昇	1 (0.1)	0	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__2.1

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
臨床検査 (Cont.)			
体重増加	0	0	1 (0.2)
筋骨格系および結合組織障害	3 (0.4)	11 (1.3)	8 (1.3)
後天性鉤爪趾	0	0	1 (0.2)
関節痛	0	1 (0.1)	0
背部痛	0	1 (0.1)	1 (0.2)
頚部脊柱管狭窄症	1 (0.1)	0	0
椎間板変性症	0	1 (0.1)	0
椎間板突出	0	1 (0.1)	1 (0.2)
腰部脊柱管狭窄症	1 (0.1)	0	0
変形性関節症	1 (0.1)	3 (0.4)	4 (0.6)
骨壊死	0	2 (0.2)	0
乾癬性関節症	0	1 (0.1)	0
脊椎後方すべり症	0	1 (0.1)	0
脊椎すべり症	0	0	1 (0.2)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__2.1

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
良性、悪性および詳細不明の新生物(嚢胞およびポリープを含む)	5 (0.6)	8 (0.9)	5 (0.8)
結腸腺癌	0	1 (0.1)	0
基底細胞癌	1 (0.1)	0	1 (0.2)
乳癌	0	1 (0.1)	0
腎明細胞癌	0	1 (0.1)	0
遠隔転移を伴う結腸癌	0	0	1 (0.2)
子宮内膜腺癌	1 (0.1)	0	0
肝臓血管腫	0	1 (0.1)	0
浸潤性乳癌	0	1 (0.1)	0
肺腺癌	1 (0.1)	1 (0.1)	0
遠隔転移を伴う肺癌	1 (0.1)	0	0
神経内分泌癌	1 (0.1)	0	0
卵巣癌	0	0	1 (0.2)
遠隔転移を伴う膵癌	0	0	1 (0.2)
形質細胞性骨髄腫	0	1 (0.1)	0
子宮癌	0	0	1 (0.2)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__2.1

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
良性、悪性および詳細不明の新生物(嚢胞およびポリープを含む) (Cont.)			
子宮平滑筋腫	0	1 (0.1)	0
神経系障害	5 (0.6)	3 (0.4)	6 (1.0)
意識変容状態	1 (0.1)	0	0
筋萎縮性側索硬化症	0	0	1 (0.2)
脳血管発作	0	0	2 (0.3)
頚髄神経根障害	1 (0.1)	0	0
脱髄	0	1 (0.1)	0
糖尿病性ニューロパチー	0	1 (0.1)	0
頭痛	0	0	1 (0.2)
肝性脳症	0	0	1 (0.2)
虚血性脳卒中	1 (0.1)	0	0
ラクナ脳卒中	1 (0.1)	0	0
腰髄神経根障害	0	1 (0.1)	0
失神	1 (0.1)	0	0
一過性脳虚血発作	0	0	1 (0.2)

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__2.1

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
精神障害	2 (0.2)	0	1 (0.2)
不安	0	0	1 (0.2)
うつ病	2 (0.2)	0	0
腎および尿路障害	1 (0.1)	4 (0.5)	2 (0.3)
急性腎障害	0	1 (0.1)	0
腎うっ血	0	1 (0.1)	0
腎結石症	0	2 (0.2)	1 (0.2)
腎仙痛	1 (0.1)	0	0
尿管結石症	0	0	1 (0.2)
生殖系および乳房障害	5 (0.6)	1 (0.1)	3 (0.5)
良性前立腺肥大症	0	0	1 (0.2)
子宮内膜増殖症	1 (0.1)	0	0
卵管嚢胞	1 (0.1)	0	0
線維嚢胞性乳腺疾患	0	1 (0.1)	0
出血性卵巣嚢胞	1 (0.1)	0	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__2.1

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
生殖系および乳房障害 (Cont.)			
卵巣嚢胞	0	0	1 (0.2)
子宮脱	2 (0.2)	0	0
腟脱	0	0	1 (0.2)
呼吸器、胸郭および縦隔障害	4 (0.5)	6 (0.7)	4 (0.6)
慢性閉塞性肺疾患	0	1 (0.1)	0
胸水	0	0	1 (0.2)
自然気胸	0	1 (0.1)	0
肺塞栓症	2 (0.2)	3 (0.4)	0
肺線維症	0	1 (0.1)	0
呼吸窮迫	1 (0.1)	0	0
睡眠時無呼吸症候群	1 (0.1)	0	1 (0.2)
扁桃出血	0	0	1 (0.2)
扁桃肥大	0	0	1 (0.2)
皮膚および皮下組織障害	4 (0.5)	1 (0.1)	2 (0.3)
血管浮腫	2 (0.2)	0	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]

TABLE 14.3__2.1

Treatment-Emergent Serious Adverse Events per 100 Patient Years
by Primary MedDRA System Organ Class and Preferred Term - Long Term
(Safety Analysis Set)

System Organ Class MedDRA 22.0 Preferred Term	UPA 15 mg QD (N = 617) (PYs = 839.1) Events (E/100 PYs)	UPA 30 mg QD (N = 613) (PYs = 842.8) Events (E/100 PYs)	ADA 40 mg EOW (N = 429) (PYs = 631.4) Events (E/100 PYs)
皮膚および皮下組織障害 (Cont.)			
皮膚炎	0	0	1 (0.2)
接触皮膚炎	1 (0.1)	0	0
嵌入爪	1 (0.1)	0	0
乾癬	0	1 (0.1)	0
膿疱性乾癬	0	0	1 (0.2)
血管障害	0	3 (0.4)	1 (0.2)
深部静脈血栓症	0	1 (0.1)	1 (0.2)
表在性血栓性静脈炎	0	1 (0.1)	0
静脈瘤	0	1 (0.1)	0

Note: Treatment-emergent AE (TEAE) is defined as an AE with an onset date that is on or after the first dose of study drug and up to 30 days after the last dose of UPA and up to 70 days for adalimumab, if subject discontinued prematurely from the study.
Subjects in UPA 15 mg QD/30 mg QD group include those who started UPA 15 mg QD/30 mg QD at the beginning of the study and those who switched to UPA 15 mg QD/30 mg QD at Week 24.
E/100 PYs = Events per 100 patient-years.

Program Source Code: [redacted]