表 2.7.4.7-100.　投与 56 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）：M15-572 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] 及び [redacted] である。

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:104.20 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:104.20 KG								
	BLIND	1 TO 6	6	6	6	R: LIMITED PNEUMOPHIBROSIS OF THE LOWER LOBE OF THE RIGHT LUNG. HYPERPLASIA OF MEDIASTINAL LYMPH NODES S: 血液およびリンパ系障害 P: リンパ組織過形成 L: Lymphoid tissue hyperplasia	O: YES	T: Severe R: Reasonable possibility A: DRUG WITHDRAWN O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:104.20 KG									
	BLIND	1 TO 6	6	6	6	R: LIMITED PNEUMOPHIBROSIS OF THE LOWER LOBE OF THE RIGHT LUNG. HYPERPLASIA OF MEDIASTINAL LYMPH NODES S: 呼吸器、胸郭および縦隔障害 P: 肺線維症 L: Pulmonary fibrosis	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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:104.20 KG

POST 7 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:45.30 KG								
	PRE	TO -1							
	BLIND	1 TO 386	122	122	122	R: FIBROCYSTIC MASTOPATHY OF THE LEFT BREAST S: 生殖系および乳房障害 P: 線維嚢胞性乳腺疾患 L: Fibrocystic breast disease	E: 129 L: 8 DAYS	T: Moderate R: Reasonable possibility A: DRUG INTERRUPTED O: LEFT BREAST' NEOPLASM SURGERY REMOVING	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	OL	387 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:102.06 KG								
	PRE	TO -1							
	BLIND	1 TO 399	77	77	77	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	E: 81 L: 5 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	400 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:90.72 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:7[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:90.72 KG					
	BLIND	1 TO 246	239	239	239	R: LUNG CANCER - LEFT KIDNEY & LIVER METASTASIZE S: 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） P: 遠隔転移を伴う肺癌 L: Lung cancer metastatic	E: 313 L: 75 DAYS	T: Life threatening R: Reasonable possibility A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Death of subject A: NO REASONABLE POSSIBILITY
	POST	247 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:76.60 KG

PRE TO -1

BLIND 1 TO 182

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:76.60 KG									
	POST	183 TO	7	189	189	R: MULTILOBAR PNEUMONIA(GRAM POSITIVE STREPTOCOCCUS) S: 感染症および寄生虫症 P: レンサ球菌性肺炎 L: Pneumonia due to Streptococcus	E: 198 L: 10 DAYS	T: Severe R: Reasonable possibility A: DOSE NOT CHANGED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,DISCONTINUED STUDY)	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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:133.81 KG

PRE TO -1

BLIND 1 TO 386

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:133.81 KG									
	OL	387 TO 452	66	452	452	R: CELLULITIS LEFT LEG S: 感染症および寄生虫症 P: 蜂巣炎 L: Cellulitis of leg	E: 506 L: 55 DAYS	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 E: NO

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:133.81 KG								
	POST	453 TO	7	459	459	R: DEEP VEIN THROMBOSIS LEFT LEG S: 血管障害 P: 深部静脈血栓症 L: Deep vein thrombosis leg	E: 560 L: 102 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: PROLONGED HOSPITALIZATION FOR CELLULITIS A: NO REASONABLE POSSIBILITY E: NO

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted]([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:107.00 KG

PRE TO -1

BLIND 1 TO 398

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:107.00 KG								
	OL	399 TO 350	748	748		R: STROKE S: 神経系障害 P: 脳血管発作 L: Stroke	E: 763 L: 16 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Persistent or significant disability, Important medical or surgical intervention O: ARTERIAL HYPERTENSION 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:125.60 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:125.60 KG								
		BLIND 1 TO 244	36	36	36	R: FEVER INTERMITTENT S: 一般・全身障害および投与部位の状態 P: 発熱 L: Intermittent fever	E: 252 L: 217 DAYS I: YES	T: Mild R: Reasonable possibility A: DRUG WITHDRAWN O: NONE	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY E: NO
		POST 245 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:90.00 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:90.00 KG								
	BLIND	1 TO 392	135	135	135	R: DEPRESSION EPISODE S: 精神障害 P: うつ病 L: Depression	E: 161 L: 27 DAYS	T: Moderate R: No reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: MOOD CHANGES DUE TO FAMILY PROBLEMS 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:107.77 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:107.77 KG								
		BLIND	1 TO 393	139	139	139	R: WORSENING OF OSTEOARTHRITIS S: 筋骨格系および結合組織障害 P: 変形性関節症 L: Osteoarthritis aggravated	E: 298 L: 160 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,LEFT TOTAL KNEE REPLACEMENT)	S: YES, Hospitalization or prolonged hospitalization O: OSTEOARTHRITIS 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

[redacted]AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:108.86 KG

PRE TO -1

BLIND 1 TO 394

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

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Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
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INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:108.86 KG								
	OL	395 TO	208	602	602	R: GASTROENTERITIS S: 感染症および寄生虫症 P: 胃腸炎 L: Gastroenteritis	E: 608 L: 7 DAYS	T: Severe R: Reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,CONCOMITANT MEDICATION OR THERAPY DISCONTINUED)	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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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INV: [redacted]([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:87.80 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 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.
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
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INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:87.80 KG									
	BLIND	1 TO 399	183	183	183	R: OBSTRUCTIVE SLEEP APNEA S: 呼吸器、胸郭および縦隔障害 P: 睡眠時無呼吸症候群 L: Obstructive sleep apnea syndrome	O: YES	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,CPAP [redacted] 20[redacted] CORRECTIVE SURGERY FOR OBSTRUCTIVE SLEEP APNEA)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: RESPIRATORY TRACT ANATOMIC ABNORMALITIES 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 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.
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# Subject prematurely discontinued.

Program Source Code: [redacted]

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INV: [redacted] ([redacted])									
TRT: ADA 40 mg EOW									
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:87.80 KG								
	BLIND	1 TO 399	369	369	369	R: SURGICAL WOUND OPENING S: 傷害、中毒および処置合併症 P: 創離開 L: Wound dehiscence	E: 369 L: 1 DAY	T: Severe R: No reasonable possibility A: DOSE NOT CHANGED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,SURGICAL INTERVENTION)	S: YES, Hospitalization or prolonged hospitalization O: SURGICAL INTERVENTION FOR OBSTRUCTIVE SLEEP APNEA A: NO REASONABLE POSSIBILITY
	OL	400 TO 631							
	POST	632 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 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.
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: UPA 15 mg QD

[redacted]AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:82.50 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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INV: [redacted]([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:82.50 KG								
	BLIND	1 TO 390	257	257	257	R: WORSENING OF HERPES ZOSTER S: 感染症および寄生虫症 P: 帯状疱疹 L: Herpes zoster	E: 285 L: 29 DAYS	T: Severe R: Reasonable possibility A: DOSE NOT CHANGED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,METHOTREXATE INTERRUPTED)	S: YES, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY
	OL	391 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

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

[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:79.83 KG

PRE TO -1

BLIND 1 TO 395

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.
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: UPA 15 mg QD									
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:79.83 KG									
	OL	396 TO 563	136	531	531	R: WORSENING OF LUMBOSACRAL SPINAL STENOSIS S: 筋骨格系および結合組織障害 P: 腰部脊柱管狭窄症 L: Lumbosacral spinal stenosis	E: 568 L: 38 DAYS	T: Severe R: No reasonable possibility A: DRUG WITHDRAWN O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,L4-L5 AND L5-S1 LAMINECTOMY,DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: LUMBAR-RADICULOPATHY DUE TO H/O OF LUMBAR SACRAL SPINAL STENOSIS 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 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.
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# Subject prematurely discontinued.

Program Source Code: [redacted]

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

[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:79.83 KG

POST 564 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 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.
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: UPA 30 mg QD

[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.04 KG

PRE TO -1

BLIND 1 TO 393

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.
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: UPA 30 mg QD									
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.04 KG								
	OL	394 TO 712	284	677	677	R: MULTIPLE MYELOMA S: 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） P: 形質細胞性骨髄腫 L: Multiple myeloma	O: YES	T: Life threatening R: Reasonable possibility A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: YES, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY
	POST	713 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 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.
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: UPA 30 mg QD

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.40 KG

PRE TO -1

BLIND 1 TO 43

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.
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: UPA 30 mg QD									
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.40 KG									
	POST	44 TO	4	47	47	R: ATYPICAL PNEUMONIA S: 感染症および寄生虫症 P: 異型肺炎 L: Atypical pneumonia	E: 63 L: 17 DAYS	T: Severe R: Reasonable possibility A: DOSE NOT CHANGED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,OXYGEN THERAPY,DISCONTINUED STUDY)	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 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.
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

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

[redacted]AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:99.10 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

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INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:99.10 KG								
	BLIND	1 TO 399	71	71	71	R: FRACTURE RIGHT ANKLE S: 傷害、中毒および処置合併症 P: 足関節部骨折 L: Ankle fracture	E: 400 L: 330 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,SURGERY, PHYSIOTHERAPY)	S: YES, Hospitalization or prolonged hospitalization O: 'THE PATIENT SLIPPED ON THE STAIRS A: NO REASONABLE POSSIBILITY
	OL	400 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:75.40 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] [redacted]									
TRT: Placebo to UPA 15 mg QD									
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:75.40 KG								
		BLIND	1 TO 394	175	175	7	R: FRACTURE TIBIA-LEFT S: 傷害、中毒および処置合併症 P: 脛骨骨折 L: Tibia fracture	E: 274 L: 100 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: DURING PLAYING VOLLEYBALL SUBJECT FELL AND BROKE HIS LEG. A: NO REASONABLE POSSIBILITY E: NO
		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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

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INV: [redacted]([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:64.50 KG

PRE TO -1

BLIND 1 TO 127

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted]	AGE:6[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:64.50 KG					
	POST	128 TO	18	145	145	R: OVARIAN CANCER S: 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) P: 卵巣癌 L: Ovarian cancer	O: YES	T: Severe R: No reasonable possibility A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: YES, Important medical or surgical intervention O: THERE ARE NO MEDICAL CONDITION IN MEDICAL HISTORY THAT ARE IN RELATIONSHIP WITH AE. SUBJECT DONE UNSCHEDULED CT SCAN WERE SUSPECTED OVARIAN CANCER WAS FOUND AFTER IT WAS CONFIRMED BY GYNECOLOGIST. 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted]([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:106.50 KG

PRE TO -1

BLIND 1 TO 394

OL 395 TO 463

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:106.50 KG									
	POST	464 TO 60	523	523		R: POLYTRAUMA DUE TO TRAFFIC ACCIDENT S: 傷害、中毒および処置合併症 P: 多発性外傷 L: Polytraumatism	E: 523 L: 1 DAY	T: Death R: No reasonable possibility A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: YES, Death of subject O: CAR ACCIDENT 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] [redacted] TRT: ADA 40 mg EOW									
[redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:106.50 KG									
	POST	464 TO	60	523	523	R: POLYTRAUMA DUE TO TRAFFIC ACCIDENT S: 傷害、中毒および処置合併症 P: 交通事故 L: Traffic accident	E: 523 L: 1 DAY	T: Death R: No reasonable possibility A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: YES, Death of subject O: CAR ACCIDENT 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted]([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:68.70 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: ADA 40 mg EOW									
[redacted]	AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:68.70 KG								
	BLIND	1 TO 392	370	370	370	R: FEVER OF UNKNOWN ORIGIN S: 一般・全身障害および投与部位の状態 P: 発熱 L: Fever of unknown origin	E: 372 L: 3 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: THIS SAE HAS NO REASONABLE POSSIBILITY OF BEING CAUSED BY STUDY IP--PATIENT WORKS IN A CAFE ENVIRONMENT AND IS AT RISK OF CONTRACTING VIRAL INFECTIONS FROM CUSTOMERS AND STAFF A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:68.70 KG

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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:97.10 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:6[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:97.10 KG					
	BLIND	1 TO 394	157	157 &	157	R: WORSENING OF OSTEOARTHRITIS RIGHT HIP S: 筋骨格系および結合組織障害 P: 変形性関節症 L: Osteoarthritis aggravated	E: 458 L: 302 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,RIGHT HIP REPLACEMENT SCHEDULED FOR [redacted])	S: YES, Hospitalization or prolonged hospitalization O: SEVERE OSTEOARTHRITIS AND SHE HAS FAILED SEVERAL ATTEMPTS AT CONSERVATIVE TREATMENT. A: NO REASONABLE POSSIBILITY E: NO
	OL	395 TO 712							

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.
& Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:97.10 KG									
	POST	713 TO #	1	713	713	R: PULMONARY EMBOLISM BILATERAL S: 呼吸器、胸郭および縦隔障害 P: 肺塞栓症 L: Pulmonary embolism	E: 715 L: 3 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 E: NO

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:105.00 KG

PRE TO -1

BLIND 1 TO 267

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.
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

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(Safety Analysis Set)

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INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:105.00 KG									
	POST	268 TO	1	268	268	R: LACUNAR CEREBRAL VASCULAR ACCIDENT S: 神経系障害 P: ラクナ脳卒中 L: Lacunar stroke	E: 276 L: 9 DAYS	T: Severe R: Reasonable possibility A: MULTIPLE:(DRUG INTERRUPTED, DRUG WITHDRAWN) O: CONCOMITANT MEDICATION OR THERAPY STARTED	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 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.
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

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

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INV: [redacted] TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:97.20 KG					
	PRE	TO -1							
	BLIND	1 TO 396							
	OL	397 TO 699	303	699	699	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	O: YES	T: Severe R: Reasonable possibility A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: YES

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:97.20 KG

POST 700 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 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.
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

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
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INV: [redacted] ([redacted])
TRT: Placebo to UPA 15 mg QD

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:100.00 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo to UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:100.00 KG								
		BLIND 1 TO 334	329	329	161	R: ARTHRITIS PURULENTA OF THE RIGHT GLENOHUMERAL JOINT S: 感染症および寄生虫症 P: 細菌性関節炎 L: Purulent arthritis	E: 372 L: 44 DAYS	T: Moderate R: No reasonable possibility A: DRUG WITHDRAWN O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,MTX IS INTERRUPTED,DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization O: MECHANICAL TRAUMA-SUBJET WAS DRIVING TRACTOR FEW DAYS BEFORE ONSET OF AE A: NO REASONABLE POSSIBILITY
		POST 335 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted]([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:83.50 KG

PRE TO -1

BLIND 1 TO 392

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:83.50 KG								
	OL	393 TO	403	795	795	R: ATHEROSCLEROSIS OF CORONARY ARTERIES S: 心臓障害 P: 冠動脈硬化症 L: Coronary atherosclerosis		T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CORONARY ARTERY BYPASS GRAFT SURGERY PERFORMED ON [redacted]20[redacted]. METHOTREXATE AND FOLIC ACID INTERRUPTED FROM [redacted]20[redacted] TO [redacted]20[redacted]	S: YES, Hospitalization or prolonged hospitalization O: ANGINA PECTORIS, HYPERTENSION, OBESITY, ISCHEMIC HEART DISEASE, HYPERLIPIDEMIA A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:109.50 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:109.50 KG								
	BLIND	1 TO 391	227	227	227	R: HABITUAL LUXATION OF THE LEFT SHOULDER S: 傷害、中毒および処置合併症 P: 関節脱臼 L: Subluxation shoulder	E: 310 L: 84 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,ARTHROSCOPY OF LEFT SHOULDER)	S: YES, Hospitalization or prolonged hospitalization O: TRAUMATIC DISLOCATION OF THE LEFT SHOULDER IN 20[redacted] A: NO REASONABLE POSSIBILITY
	OL	392 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:131.50 KG								
	PRE	TO -1							
	BLIND	1 TO 391	276	276	276	R: RENAL CALCULI S: 腎および尿路障害 P: 腎結石症 L: Renal calculi	E: 277 L: 2 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:131.50 KG

OL 392 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:71.00 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:71.00 KG								
	BLIND	1 TO 388	209	209	209	R: FRACTURE OF LEFT FOOT S: 傷害、中毒および処置合併症 P: 足骨折 L: Foot fracture	E: 389 L: 181 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,PATIENT TO HAVE SURGERY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: TWISTED ANKLE AND FELL OVER. A: NO REASONABLE POSSIBILITY
	OL	389 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:124.70 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted] TRT: ADA 40 mg EOW									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:124.70 KG								
	BLIND	1 TO 391	112	112	112	R: THROMBOSIS IN THE LEFT SUPERFICIAL FEMORAL AND POPLITEAL VEINS S: 血管障害 P: 深部静脈血栓症 L: Deep vein thrombosis		T: Mild R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: OBESITY LESS MOVEMENT A: NO REASONABLE POSSIBILITY
	OL	392 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:60.10 KG

PRE TO -1

BLIND 1 TO 127

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:60.10 KG									
	POST	128 TO	6	133	133	R: PORTAL VEIN THROMBOSIS S: 肝胆道系障害 P: 門脈血栓症 L: Portal vein thrombosis	E: 142 L: 10 DAYS	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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo to UPA 30 mg QD									
[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:69.70 KG									
	PRE	TO -1							
	BLIND	1 TO 327	233	233	60	R: FECAL IMPACTION S: 胃腸障害 P: 糞塊 L: Fecal impaction	E: 234 L: 2 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:69.70 KG

POST 328 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted]([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:89.40 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted] TRT: ADA 40 mg EOW									
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:89.40 KG								
	BLIND	1 TO 406	267	267	267	R: WORSENING OF CERVICAL DISCUS PROLAPS C7/C8 S: 筋骨格系および結合組織障害 P: 椎間板突出 L: Prolapsed cervical disc	E: 271 L: 5 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: PROGRESSION OF A UNDERLYING DISEASE 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:89.40 KG								
	BLIND	1 TO 406	302	302	302	R: DUODENAL ULCER (FORREST II A) S: 胃腸障害 P: 十二指腸潰瘍 L: Duodenal ulcer	E: 306 L: 5 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,CONCOMITANT MEDICATION OR THERAPY DISCONTINUED)	S: YES, Hospitalization or prolonged hospitalization O: BIG DOSES OF IBUPROFEN DUE TO SURGERY ON [redacted]-20[redacted] (SEE AE#3), BUT WITHOUT GASTRIC PROTECTION(DUE TO PATIENT) 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:89.40 KG								
	BLIND	1 TO 406	342	342	342	R: NORMOCHROMIC-NORMOCYTIC ANEMIA S: 血液およびリンパ系障害 P: 正色素性正球性貧血 L: Normochromic normocytic anemia	E: 345 L: 4 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	407 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:82.30 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:82.30 KG									
[redacted]	BLIND	1 TO 385	54	54	54	R: CONTACT ALLERGY DUE TO SLEEP APNEA MASK S: 呼吸器、胸郭および縦隔障害 P: 睡眠時無呼吸症候群 L: Sleep apnea	E: 133 L: 80 DAYS I: YES	T: Moderate R: No reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: ALLERGIC REACTION 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:82.30 KG								
	BLIND	1 TO 385	54	54	54	R: CONTACT ALLERGY DUE TO SLEEP APNEA MASK S: 皮膚および皮下組織障害 P: 接触皮膚炎 L: Allergic contact dermatitis	E: 133 L: 80 DAYS I: YES	T: Moderate R: No reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: ALLERGIC REACTION 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:82.30 KG								
	BLIND	1 TO 385	166	166	166	R: HAEMORRHAGIC EROSIVE GASTRODUODENOPATHY AND DISTAL EROSIVE REFLUX DISEASE S: 胃腸障害 P: びらん性胃炎 L: Erosive gastroduodenitis	E: 167 L: 2 DAYS	T: Moderate R: Reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:82.30 KG								
	BLIND	1 TO 385	166	166	166	R: HAEMORRHAGIC EROSIVE GASTRODUODENOPATHY AND DISTAL EROSIVE REFLUX DISEASE S: 胃腸障害 P: 胃十二指腸出血 L: Gastroduodenal haemorrhage	E: 167 L: 2 DAYS	T: Moderate R: Reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:82.30 KG								
	BLIND	1 TO 385	166	166	166	R: HAEMORRHAGIC EROSIVE GASTRODUODENOPATHY AND DISTAL EROSIVE REFLUX DISEASE S: 胃腸障害 P: 胃食道逆流性疾患 L: Gastrooesophageal reflux disease	E: 167 L: 2 DAYS	T: Moderate R: Reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:82.30 KG								
	BLIND	1 TO 385	208	208	208	R: CHRONIC WHOLE BODY PAIN S: 一般・全身障害および投与部位の状態 P: 疼痛 L: General body pain	E: 223 L: 16 DAYS	T: Moderate R: No reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: DEPRESSION, PSORIASIS ARTHRITIS 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:109.00 KG								
	PRE	TO -1							
	BLIND	1 TO 390	241	241	241	R: MYOCARDIAL INFARCTION S: 心臓障害 P: 心筋梗塞 L: Myocardial infarction	E: 272 L: 32 DAYS	T: Mild R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: HYPERTENSION A: NO REASONABLE POSSIBILITY
	OL	391 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:73.20 KG								
	PRE	TO -1							
	BLIND	1 TO 392							
	OL	393 TO	4	396	396	R: KIDNEY CONGESTION LEFT S: 腎および尿路障害 P: 腎うっ血 L: Kidney congestion		T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: KIDNEY STONE DISEASE IN MEDICAL HISTORY 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:73.20 KG								
	OL	393 TO 4	396	396		R: KIDNEY STONE LEFT S: 腎および尿路障害 P: 腎結石症 L: Kidney stone		T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: KIDNEY STONE DISEASE IN MEDICAL HISTORY A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted]([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:140.40 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted] TRT: ADA 40 mg EOW									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:140.40 KG								
	BLIND	1 TO 389	64	64	64	R: 3MM URETERAL CALCULUS S: 腎および尿路障害 P: 尿管結石症 L: Ureteral calculus	E: 66 L: 3 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,HOSPITALIZED)	S: YES, Hospitalization or prolonged hospitalization O: HYPERCALCEMIA A: NO REASONABLE POSSIBILITY E: NO
	OL	390 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:99.70 KG								
	PRE	TO -1							
	BLIND	1 TO 392	6	6	6	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	E: 16 L: 11 DAYS	T: Mild 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:99.70 KG								
	BLIND	1 TO 392	223	223	223	R: WORSENING UTERINE FIBROIDS S: 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） P: 子宮平滑筋腫 L: Uterine fibroids aggravated	E: 232 L: 10 DAYS I: YES	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: THE PATIENT UNDERWENT SURGICAL TREATMENT. ADDITIONAL INFORMATION WILL BE RECEIVED AFTER DISCHARGE.	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: INFORMATION WILL BE PROVIDED AFTER DISCHARGE 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:89.00 KG

PRE TO -1

BLIND 1 TO 392

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: Placebo to UPA 30 mg QD									
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:89.00 KG								
	OL	393 TO 120	512	344		R: ACUTE APPENDICITIS S: 感染症および寄生虫症 P: 虫垂炎 L: Acute appendicitis	E: 513 L: 2 DAYS	T: Moderate R: No reasonable possibility A: DOSE NOT CHANGED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,APPENDECTOMY ON [redacted]20[redacted])	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: CAUSE IS UNKNOWN A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted]
TRT: UPA 15 mg QD

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:109.54 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:109.54 KG					
	BLIND	1 TO 263	186	186	186	R: UPPER RESPIRATORY DISTRESS S: 呼吸器、胸郭および縦隔障害 P: 呼吸窮迫 L: Respiratory distress	E: 194 L: 9 DAYS	T: Moderate R: Reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	POST	264 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:78.10 KG

PRE TO -1

BLIND 1 TO 397

OL 398 TO 429

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.
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

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

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INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:78.10 KG									
	POST	430 TO	19	448	448	R: OTHER DISORDERS INVOLVING IMMUNOLOGICAL MECHANISMS S: 免疫系障害 P: 免疫系障害 L: Immune system disorder	E: 458 L: 11 DAYS	T: Severe 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 A: NO REASONABLE POSSIBILITY E: NO

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:81.00 KG

PRE TO -1

BLIND 1 TO 397

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted] TRT: ADA 40 mg EOW									
[redacted]	AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:81.00 KG								
	OL	398 TO 164	561	561		R: HAEMORRHAGED TONSIL BED S: 呼吸器、胸郭および縦隔障害 P: 扁桃出血 L: Tonsillar haemorrhage	E: 565 L: 5 DAYS I: YES	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,POST-OP SECONDARY BLEED FROM TONSILLECTOMY AND ADENOIDECTOMY ON [redacted]. INTRAVENOUS TRANSEXAMIC ACID IV IN EMERGENCY DEPARTMENT AND ADMITTED OVERNIGHT TO HOSPITAL)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: POST OP BLEED UE TO TONSILLECTOMY ON [redacted] A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

[redacted]AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:98.00 KG

PRE TO -1

BLIND 1 TO 392

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:98.00 KG								
	OL	393 TO 434	826	826		R: WORSENING RIGHT KNEE OSTEOARTHRITIS S: 筋骨格系および結合組織障害 P: 変形性関節症 L: Osteoarthritis knee	E: 848 L: 23 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,RIGHT TOTAL KNEE REPLACEMENT)	S: YES, Hospitalization or prolonged hospitalization O: FURTHER DETERIORATION OF OSTEOARTHRITIS RIGHT KNEE A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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(Safety Analysis Set)

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

[redacted]AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:70.50 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted] TRT: Placebo to UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:70.50 KG								
		BLIND	1 TO 399	399	399	233	R: BASAL CELL CARCINOMA OF THE SKIN S: 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） P: 基底細胞癌 L: Basal cell carcinoma		T: Moderate R: Reasonable possibility A: DRUG INTERRUPTED O: EXCISIONAL BIOPSY (ELECTRODESSICATION AND CURETTAGE-BACK) DONE BY DERMATOLOGIST	S: YES, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY E: NO
		OL	400 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

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INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:102.90 KG								
		PRE	TO -1						
		BLIND	1 TO 399						
		OL	400 TO 448	48	447	447	R: ACUTE RENAL FAILURE S: 腎および尿路障害 P: 急性腎障害 L: Acute renal failure	O: YES	T: Moderate R: Reasonable possibility A: DRUG INTERRUPTED O: MEDICATION TREATMENT UNKNOWN	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: NO

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.
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

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

[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:102.90 KG

POST 449 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 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.
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 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:92.08 KG								
	PRE	TO -1							
	BLIND	1 TO 392							
	OL	393 TO	547	939	771	R: SHINGLES S: 感染症および寄生虫症 P: 帯状疱疹 L: Shingles	E: 950 L: 12 DAYS	T: Severe R: Reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

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INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:83.00 KG

PRE TO -1

BLIND 1 TO 392

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

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

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INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:83.00 KG								
	OL	393 TO	64	456	456	R: INJURY: END OF RADIUS FRACTURE - EXTENSION TYPE, LEFT HAND S: 傷害、中毒および処置合併症 P: 橈骨骨折 L: Radius fracture	E: 484 L: 29 DAYS	T: Mild R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,SURGERY-OSTEOSYNTHESIS, DUE TO FRACTURE OF RADIUS, PLANNED HOSPITALIZATION FROM [redacted])	S: YES, Important medical or surgical intervention O: DUE TO AE FRACTURE OF RADIUS THERE WAS BAD HEALING OF THE FRACTURE SUBJECT WAS INVITED TO PLANNED HOSPITALIZATION [redacted] 20[redacted] 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

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INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:5[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:52.00 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 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.
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	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:5[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:52.00 KG									
		BLIND	1 TO 183	32	32 & 32	R: CANCER SARCOMA (UTERINE) S: 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） P: 子宮癌 L: Carcinosarcoma uterus	E: 263 L: 232 DAYS	T: Severe R: No reasonable possibility A: DRUG WITHDRAWN O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY DISCONTINUED,ABDOMINAL TYPE EXTENSIVE HYSTERECTOMY ADNEXECTOMY(BOTH) LYMPH NODEDISSECTION(PELVIC) PARA-AORTIC LYMPH NODES BIOPSY BILATERAL URETERAL STENT PLACEMENT)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: CONSISTENT WITH GENERAL RISK FACTORS SUCH AS AGE, FEMALE, MENOPAUSE, FIRST BIRTH, AND LESS CHILDBIRTH EXPERIENCE. 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.
& Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:5[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:52.00 KG

POST 184 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:74.30 KG

PRE TO -1

BLIND 1 TO 392

OL 393 TO 561

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.
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

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(Safety Analysis Set)

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INV: [redacted] ([redacted])									
TRT: Placebo to UPA 15 mg QD									
[redacted]	AGE:6[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:74.30 KG					
	POST	562 TO 1	562	392		R: POSTURAL VERTIGO S: 耳および迷路障害 P: 頭位性回転性めまい L: Vertigo positional	O: YES	T: Moderate 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.00 KG

PRE TO -1

BLIND 1 TO 391

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.00 KG								
	OL	392 TO 264	655	655		R: UPPER GASTROINTESTINAL BLEEDING S: 胃腸障害 P: 上部消化管出血 L: Upper gastrointestinal hemorrhage	E: 661 L: 7 DAYS	T: Moderate R: Reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:76.80 KG								
	PRE	TO -1							
	BLIND	1 TO 395	234	234	234	R: LEFT PYELONEPHRITIS S: 感染症および寄生虫症 P: 腎盂腎炎 L: Pyelonephritis	E: 241 L: 8 DAYS I: YES	T: Moderate R: Reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:72.50 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: ADA 40 mg EOW									
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:72.50 KG								
	BLIND	1 TO 388	275	275	275	R: GONARTHROSIS OF THE RIGHT KNEE S: 筋骨格系および結合組織障害 P: 変形性関節症 L: Gonarthrosis	E: 282 L: 8 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: WORSENING OF GONARTHROSIS A: NO REASONABLE POSSIBILITY
	OL	389 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:69.90 KG

PRE TO -1

BLIND 1 TO 391

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:69.90 KG								
	OL	392 TO	161	552	552	R: INVASIVE LEFT BREAST CANCER NST S: 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） P: 浸潤性乳癌 L: Breast cancer invasive NOS		T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: NONE	S: YES, Important medical or surgical intervention O: RISK FACTORS (CYSTS ON THE LEFT BREAST) A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:61.42 KG

PRE TO -1

BLIND 1 TO 221

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: Placebo to UPA 15 mg QD									
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:61.42 KG									
	POST	222 TO	12	233	64	R: INFLUENZA B S: 感染症および寄生虫症 P: インフルエンザ L: Influenza B virus infection	E: 235 L: 3 DAYS	T: Severe R: Reasonable possibility A: SUBJECT ALREADY DISCONTINUED OFF IP [redacted]20[redacted]. NO OTHER ACTION TAKEN WITH STUDY DRUG O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: NO

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted]([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:56.70 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: ADA 40 mg EOW									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:56.70 KG								
	BLIND	1 TO 392	303	303	303	R: HYPERTROPHY OF TONSILS S: 呼吸器、胸郭および縦隔障害 P: 扁桃肥大 L: Tonsillar hypertrophy	E: 304 L: 2 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,SURGERY)	S: YES, Hospitalization or prolonged hospitalization O: INFLAMMATION OF TONSILS 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:78.50 KG

PRE TO -1

BLIND 1 TO 392

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
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INV: [redacted]([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:78.50 KG								
	OL	393 TO 63	455	455		R: RIGHT MENISCUS KNEE JOINT DAMAGE S: 傷害、中毒および処置合併症 P: 半月板損傷 L: Meniscus injury	E: 456 L: 2 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: OLD INJURY OF RIGHT MENISCUS KNEE JOINT 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

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INV: [redacted] ([redacted]) TRT: Placebo to UPA 30 mg QD									
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:92.00 KG								
	PRE	TO -1							
	BLIND	1 TO 394							
	OL	395 TO	198	592	416	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	E: 602 L: 11 DAYS	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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: ADA 40 mg EOW									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.90 KG								
	PRE	TO -1							
	BLIND	1 TO 393	179	179	179	R: DUODENAL MUCOSITIS S: 胃腸障害 P: 小腸炎 L: Small intestinal mucositis	E: 182 L: 4 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.90 KG

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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:7[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:87.09 KG					
	PRE	TO -1							
	BLIND	1 TO 393	306	306	306	R: ISCHEMIC CEREBRAL VASCULAR ACCIDENT S: 神経系障害 P: 虚血性脳卒中 L: Ischemic stroke	E: 344 L: 39 DAYS I: YES	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: CORONARY ARTERY DISEASE 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted] TRT: UPA 15 mg QD									
[redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:87.09 KG									
	OL	394 TO 682	67	460	460	R: BRONCHITIS S: 感染症および寄生虫症 P: 気管支炎 L: Bronchitis	E: 481 L: 22 DAYS	T: Moderate R: No reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: SUBJECT WAS OUT OF THE COUNTRY AND BY AGE HE WAS MAY LIABLE TO DIFFERENT TYPES OF BACTERIAL 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:87.09 KG

POST 683 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 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.
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

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
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INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:107.50 KG								
	PRE	TO -1							
	BLIND	1 TO 391	226	226	226	R: RIGHT FALLOPIN TUBE CYST. S: 生殖系および乳房障害 P: 卵管嚢胞 L: Fallopian tube cyst	E: 226 L: 1 DAY	T: Severe R: No reasonable possibility A: DOSE NOT CHANGED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY DISCONTINUED,UTERUS WITH CERVIX HYSTRECTOMY)	S: YES, Hospitalization or prolonged hospitalization O: DYSMENORRHEA A: NO REASONABLE POSSIBILITY E: NO

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.
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Program Source Code: [redacted]

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INV: [redacted] ([redacted] TRT: UPA 15 mg QD									
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:107.50 KG								
	BLIND	1 TO 391	226	226	226	R: RIGHT OVARY HEMORRHAGIC CYST. S: 生殖系および乳房障害 P: 出血性卵巣嚢胞 L: Hemorrhagic ovarian cyst	E: 226 L: 1 DAY	T: Severe R: No reasonable possibility A: DOSE NOT CHANGED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY DISCONTINUED,UTERUS WITH CERVIX HYSTRECTOMY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: DYSMENORRHEA A: NO REASONABLE POSSIBILITY
	OL	392 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

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INV: [redacted]([redacted]
TRT: ADA 40 mg EOW

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:71.90 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 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.
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

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INV: [redacted] ([redacted])									
TRT: ADA 40 mg EOW									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:71.90 KG								
		BLIND 1 TO 43	21	21	21	R: AMYOTROPHIC LATERAL SCLEROSIS S: 神経系障害 P: 筋萎縮性側索硬化症 L: Amyotrophic lateral sclerosis	O: YES	T: Moderate R: No reasonable possibility A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: YES, Important medical or surgical intervention O: UNKNOWN ETIOLOGY A: NO REASONABLE POSSIBILITY
		POST 44 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 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.
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: UPA 15 mg QD

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:124.70 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

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INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:124.70 KG								
	BLIND	1 TO 391	143	143	143	R: LEFT LEG ERYSIPELAS S: 感染症および寄生虫症 P: 丹毒 L: Erysipelas	E: 195 L: 53 DAYS	T: Severe R: Reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,REFER TO HOSPITAL)	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	OL	392 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

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

[redacted]AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:92.00 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

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

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INV: [redacted]([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:92.00 KG								
	BLIND	1 TO 392	301	301	301	R: COMMUNITY-ACQUIRED RIGHT-SIDED PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Community acquired pneumonia	E: 311 L: 11 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: SEQUELA ACUTE RESPIRATORY VIRAL INFECTION A: NO REASONABLE POSSIBILITY E: NO
	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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

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

[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.50 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 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.
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: UPA 30 mg QD									
[redacted]	AGE:7[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:68.50 KG					
	BLIND	1 TO 296	251	251	251	R: EXACERBATION OF PSORIASIS S: 皮膚および皮下組織障害 P: 乾癬 L: Exacerbation of psoriasis	E: 272 L: 22 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: EXACERBATION OF DIABETES MELLITUS A: NO REASONABLE POSSIBILITY E: NO
	POST	297 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 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.
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: UPA 15 mg QD

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:81.30 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 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.
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: UPA 15 mg QD									
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:81.30 KG									
	BLIND	1 TO 205	205	205	205	R: H1N1 INFLUENZA S: 感染症および寄生虫症 P: H1N1インフルエンザ L: H1N1 influenza	O: 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, Persistent or significant disability, 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
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Program Source Code: [redacted]

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INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:81.30 KG									
	POST	206 TO	4	209	209	R: GASTRO INTESTINAL BLEEDING S: 胃腸障害 P: 胃腸出血 L: Gastro intestinal bleeding	E: 211 L: 3 DAYS I: YES	T: Life threatening R: No reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Life threatening O: CONCOMMITENT MEDICATION 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 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.
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Program Source Code: [redacted]

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INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:81.30 KG									
	POST	206 TO	8	213	213	R: PULMONARY EMBOLISM S: 呼吸器、胸郭および縦隔障害 P: 肺塞栓症 L: Pulmonary embolism	O: YES I: YES	T: Life threatening R: Reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, 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 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.
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: UPA 30 mg QD									
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:90.10 KG								
	PRE	TO -1							
	BLIND	1 TO 57	57	57	57	R:ATYPICAL PNEUMONIA ON BOTH SIDES S: 感染症および寄生虫症 P: 異型肺炎 L: Atypical pneumonia	E: 85 L: 29 DAYS	T: Severe R: No reasonable possibility A: DRUG WITHDRAWN O: MULTIPLE:(HOSPITALISATION,DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization O: ENVIRONMENT 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
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Program Source Code: [redacted]

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

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:90.10 KG

POST 58 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 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.
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: UPA 30 mg QD

[redacted]AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:96.00 KG

PRE TO -1

BLIND 1 TO 390

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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(Safety Analysis Set)

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:96.00 KG								
	OL	391 TO 114	504	504		R: DEGENERATIVE DISC DISEASE WITH RETROLISTHESIS S: 筋骨格系および結合組織障害 P: 椎間板変性症 L: Degenerative disc disease	E: 507 L: 4 DAYS	T: Moderate R: No reasonable possibility A: DOSE NOT CHANGED O: L5-S1 TRANSFORAMINAL LUMBAR INTERBODY FUSION	S: YES, Hospitalization or prolonged hospitalization O: LIFESTYLE A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:96.00 KG								
	OL	391 TO 114	504	504		R: DEGENERATIVE DISC DISEASE WITH RETROLISTHESIS S: 筋骨格系および結合組織障害 P: 脊椎後方すべり症 L: Retrospondylolisthesis	E: 507 L: 4 DAYS	T: Moderate R: No reasonable possibility A: DOSE NOT CHANGED O: L5-S1 TRANSFORAMINAL LUMBAR INTERBODY FUSION	S: YES, Hospitalization or prolonged hospitalization O: LIFESTYLE A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:91.20 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: ADA 40 mg EOW									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:91.20 KG								
	BLIND	1 TO 396	396	396 &	396	R: LEFT THIGH BASAL CELL CARCINOMA S: 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） P: 基底細胞癌 L: Basal cell carcinoma	E: 446 L: 51 DAYS	T: Moderate R: Reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Important medical or surgical intervention 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
& Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:ASIAN WEIGHT:53.10 KG

PRE TO -1

BLIND 1 TO 391

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:6[redacted] SEX:MALE RACE:ASIAN WEIGHT:53.10 KG								
	OL	392 TO	137	528	528	R: HERPES ZOSTER(RIGHT SIDE CHEST WALL)(RIGHT T4-T6 DERMATOME) S: 感染症および寄生虫症 P: 帯状疱疹 L: Herpes zoster	E: 553 L: 26 DAYS	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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:55.50 KG								
	PRE	TO -1							
	BLIND	1 TO 399	52	52	52	R: ACUTE PNEUMOIA S: 感染症および寄生虫症 P: 肺炎 L: Acute pneumonia	E: 92 L: 41 DAYS	T: Moderate 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:55.50 KG								
	BLIND	1 TO 399	336	336	336	R: DUODENAL ULCER WITH BLEEDING S: 胃腸障害 P: 出血性十二指腸潰瘍 L: Duodenal ulcer bleeding	E: 342 L: 7 DAYS	T: Life threatening R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: PEPTIC ULCERS A: NO REASONABLE POSSIBILITY
	OL	400 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:123.83 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo to UPA 15 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:123.83 KG								
	BLIND	1 TO 390	318	318	150	R: CERVICAL STENOSIS S: 筋骨格系および結合組織障害 P: 頚部脊柱管狭窄症 L: Cervical spinal stenosis	E: 321 L: 4 DAYS	T: Mild R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,CERVICAL STENOSIS SURGERY)	S: YES, Hospitalization or prolonged hospitalization O: CERVICAL SPONDYLOSIS WITH MYELOPATHY A: NO REASONABLE POSSIBILITY
	OL	391 TO 1069							
	POST	1070 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:113.40 KG

PRE TO -1

BLIND 1 TO 389

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: Placebo to UPA 30 mg QD									
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:113.40 KG									
	OL	390 TO 956	567	956	788	R: COVID-19 INFECTION S: 感染症および寄生虫症 P: コロナウイルス感染 L: Corona virus infection	E: 975 L: 20 DAYS	T: Death R: Reasonable possibility A: DRUG WITHDRAWN O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Persistent or significant disability, Important medical or surgical intervention, Life threatening, Death of subject E: YES

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: Placebo to UPA 30 mg QD									
[redacted]	AGE:4[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:113.40 KG					
	OL	390 TO 956	567	956	788	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	E: 975 L: 20 DAYS	T: Death R: Reasonable possibility A: DOSE NOT CHANGED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Persistent or significant disability, Life threatening A: NO REASONABLE POSSIBILITY E: YES
	POST	957 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:95.10 KG								
	PRE	TO -1							
	BLIND	1 TO 397	172	172	172	R: DIPLOPIA S: 眼障害 P: 複視 L: Diplopia	E: 177 L: 6 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: CORONARY ARTERY DISEASE 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:95.10 KG

OL 398 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:74.00 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted] AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:74.00 KG									
	BLIND	1 TO 283	135	135	135	R: MIDDLE AND LOWER COMMINUTED FRACTURE OF THE RIGHT TIBIA (AO43-A1 TYPE), MIDDLE RIGHT UPPER HUMERUS FRACTURE (AO 41-A1 TYPE) S: 傷害、中毒および処置合併症 P: 粉砕骨折 L: Comminuted fracture	E: 228 L: 94 DAYS	T: Severe R: No reasonable possibility A: DOSE NOT CHANGED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,GYPSUM TO HOLD FIXEDLY TO TREAT)	S: YES, Hospitalization or prolonged hospitalization O: FELL DOWN THE LOWER STEP 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted] AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:74.00 KG									
	BLIND	1 TO 283	135	135	135	R: MIDDLE AND LOWER COMMINUTED FRACTURE OF THE RIGHT TIBIA (AO43-A1 TYPE), MIDDLE RIGHT UPPER HUMERUS FRACTURE (AO 41-A1 TYPE) S: 傷害、中毒および処置合併症 P: 上腕骨骨折 L: Humerus fracture	E: 228 L: 94 DAYS	T: Severe R: No reasonable possibility A: DOSE NOT CHANGED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,GYPSUM TO HOLD FIXEDLY TO TREAT)	S: YES, Hospitalization or prolonged hospitalization O: FELL DOWN THE LOWER STEP 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted] TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:74.00 KG								
	BLIND	1 TO 283	282	282	282	R: FEVER S: 一般・全身障害および投与部位の状態 P: 発熱 L: Fever	O: YES	T: Life threatening R: Reasonable possibility A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	POST	284 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:4[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:75.20 KG

PRE TO -1

BLIND 1 TO 391

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV:[redacted]([redacted]) TRT: Placebo to UPA 30 mg QD									
[redacted] AGE:4[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:75.20 KG									
	OL	392 TO	129	520	352	R: HEPATIC CAVERNOUS HEMANGIOMA S: 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） P: 肝臓血管腫 L: Hemangioma of liver		T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: MAY BE RELATED TO ESTROGEN LEVELS IN THE BODY A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:56.00 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:56.00 KG								
	BLIND	1 TO 414	311	311	311	R: LEFT SPONTANEOUS PNEUMOTHORAX S: 呼吸器、胸郭および縦隔障害 P: 自然気胸 L: Pneumothorax spontaneous	E: 457 L: 147 DAYS	T: Severe R: Reasonable possibility A: DRUG INTERRUPTED O: OXYGEN CURE	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	OL	415 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:4[redacted]	SEX:MALE	RACE:ASIAN	WEIGHT:67.00 KG					
	PRE	TO -1							
	BLIND	1 TO 251	206	206	206	R: URINARY TRACT INFECTION S: 感染症および寄生虫症 P: 尿路感染 L: Urinary tract infection	E: 359 L: 154 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
	POST	252 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:70.00 KG								
		PRE	TO -1						
		BLIND	1 TO 58						
		POST	59 TO	8	66	66	R: PULMONARY INFECTION S: 感染症および寄生虫症 P: 肺感染 L: Lung infection	O: YES	T: Severe R: Reasonable possibility A: MULTIPLE:(DRUG INTERRUPTED, DRUG WITHDRAWN) O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY DISCONTINUED,DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Life threatening

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:108.80 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:108.80 KG									
	BLIND	1 TO 36	16	16	16	R: DEMYELINATING DISEASE FLARE S: 神経系障害 P: 脱髄 L: Demyelination disorder NOS	E: 20 L: 5 DAYS	T: Moderate R: No reasonable possibility A: DOSE NOT CHANGED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization O: [redacted]20[redacted]SHE HAD WORKUP FOR WEAKNESS A: NO REASONABLE POSSIBILITY
	POST	37 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted]([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:139.30 KG

PRE TO -1

BLIND 1 TO 404

OL 405

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted] TRT: ADA 40 mg EOW									
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:139.30 KG									
	POST	406 TO	25	430	430	R: CELLULITIS- LEFT GROIN S: 感染症および寄生虫症 P: 蜂巣炎 L: Cellulitis	E: 448 L: 19 DAYS	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 E: NO

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:139.30 KG									
	POST	406 TO	32	437	437	R: WORSENING VAGINAL PROLAPSE S: 生殖系および乳房障害 P: 膣脱 L: Vaginal prolapse	E: 438 L: 2 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: WEIGHT, PREGNANCIES A: NO REASONABLE POSSIBILITY E: NO

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:89.70 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo to UPA 15 mg QD									
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:89.70 KG									
		BLIND 1 TO 393	223	223	54	R: METAL FOREING BODY IN SUBCUTTIS OF FOREHEAD S: 傷害、中毒および処置合併症 P: 体内異物 L: Foreign body	E: 287 L: 65 DAYS	T: Mild R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,SURGICAL EXTRACTION)	S: YES, Hospitalization or prolonged hospitalization O: REPEATED TRAUMA OF HEAD IN CHILDHOOD A: NO REASONABLE POSSIBILITY E: NO
		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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

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Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
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Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: Placebo to UPA 30 mg QD									
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:60.80 KG								
	PRE	TO -1							
	BLIND	1 TO 393	338	338	170	R: HERPES ZOSTER THORACIS LOCALIZED S: 感染症および寄生虫症 P: 帯状疱疹 L: Herpes zoster	E: 417 L: 80 DAYS	T: Moderate R: Reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:84.10 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:7[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:84.10 KG					
	BLIND	1 TO 258	257	257	257	R: STAPHYLOCOCCUS AUREUS SEPSIS S: 感染症および寄生虫症 P: ブドウ球菌性敗血症 L: Staphylococcus aureus septicemia	E: 642 L: 386 DAYS	T: Life threatening R: Reasonable possibility A: DRUG WITHDRAWN O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,CONCOMITANT MEDICATION OR THERAPY DISCONTINUED)	S: YES, Hospitalization or prolonged hospitalization, Life threatening A: NO REASONABLE POSSIBILITY
	POST	259 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: ADA 40 mg EOW									
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:130.00 KG								
	PRE	TO -1							
	BLIND	1 TO 392	134	134	134	R: RIGHT LOWER LEG ERYSIPELAS S: 感染症および寄生虫症 P: 丹毒 L: Erysipelas	E: 146 L: 13 DAYS	T: Severe R: Reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:118.60 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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INV: [redacted]([redacted] TRT: Placebo to UPA 30 mg QD									
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:118.60 KG								
		BLIND	1 TO 393	198	198	31	R: WORSENED OSTEOARTHRITIS LEFT KNEE S: 筋骨格系および結合組織障害 P: 変形性関節症 L: Osteoarthritis aggravated	E: 533 L: 336 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,LEFT TOTAL KNEE ARTHROSCOPY)	S: YES, Hospitalization or prolonged hospitalization O: PROGRESSION OF PRE-EXISTING DISEASE, AGE, OBESITY 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 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.
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Program Source Code: [redacted]

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INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:73.90 KG

PRE TO -1

BLIND 1 TO 392

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.
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Program Source Code: [redacted]

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INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:73.90 KG									
	OL	393 TO	261	653	653	R: PERICARDITIS S: 心臓障害 P: 心膜炎 L: Pericarditis	E: 662 L: 10 DAYS	T: Life threatening 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: LONG TERM SMOKER, PSORIATIC ARTHRITIS 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 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.
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Program Source Code: [redacted]

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

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.80 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 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.
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Program Source Code: [redacted]

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INV: [redacted]([redacted]) TRT: Placebo to UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.80 KG								
		BLIND 1 TO 393	231	231	58	R: WORSENING OF MEDICAL CONDITION (COLITIS) S: 胃腸障害 P: 大腸炎 L: Colitis aggravated	E: 237 L: 7 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: WORSENING OF MEDICAL CONDITION (COLITIS) 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 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.
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Program Source Code: [redacted]

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INV: [redacted]([redacted]) TRT: Placebo to UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.80 KG								
	BLIND	1 TO 393	359	359	186	R: SYNCOPE, ALTERED LEVEL OF CONSCIOUSNESS S: 神経系障害 P: 意識変容状態 L: Altered state of consciousness	E: 360 L: 2 DAYS	T: Severe R: No reasonable possibility A: DOSE NOT CHANGED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: SITE RECEIVED MEDICAL RECORDS.MEDICAL RECORDS REPORT THAT SUDDEN ONSET OF BRIEF LOSS OF CONSCIOUSNESS IN PATIENT ARE OF UNCLEAR ETIOLOGY. A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

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INV: [redacted] ([redacted]) TRT: Placebo to UPA 15 mg QD									
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	BLIND	1 TO 393	359	359	186	R: SYNCOPE, ALTERED LEVEL OF CONSCIOUSNESS S: 神経系障害 P: 失神 L: Syncope	E: 360 L: 2 DAYS	T: Severe R: No reasonable possibility A: DOSE NOT CHANGED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: SITE RECEIVED MEDICAL RECORDS.MEDICAL RECORDS REPORT THAT SUDDEN ONSET OF BRIEF LOSS OF CONSCIOUSNESS IN PATIENT ARE OF UNCLEAR ETIOLOGY. A: NO REASONABLE POSSIBILITY E: NO

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.
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Program Source Code: [redacted]

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

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.80 KG

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 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.
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INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:108.30 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 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.
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INV: [redacted] ([redacted])									
TRT: ADA 40 mg EOW									
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:108.30 KG								
	BLIND	1 TO 392	121	121	121	R: TRANSIENT ISCHEMIC ATTACK S: 神経系障害 P: 一過性脳虚血発作 L: Transient ischaemic attack	E: 123 L: 3 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: PATIENT TREATED FOR ATRIAL FIBRILLATION 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 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.
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INV: [redacted] ([redacted])
TRT: UPA 15 mg QD

[redacted]AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:79.70 KG

PRE TO -1

BLIND 1 TO 394

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.
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INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:79.70 KG									
	OL	395 TO 383	777	777		R: BILATERAL POLYSEGMENTAL PNEUMONIA, MODERATE S: 感染症および寄生虫症 P: 肺炎 L: Bilateral pneumonia	E: 798 L: 22 DAYS	T: Moderate R: No reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: ACUTE RESPIRATORY DISEASE, ETIOLOGICAL AGENT NOT DETERMINED A: REASONABLE POSSIBILITY E: NO

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

[redacted]AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:90.70 KG

PRE TO -1

BLIND 1 TO 389

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.
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INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:90.70 KG								
	OL	390 TO	408	797	797	R: BILATERAL POLYSEGMENTAL PNEUMONIA OF MODERATE SEVERE COURSE S: 感染症および寄生虫症 P: 肺炎 L: Bilateral pneumonia	E: 821 L: 25 DAYS I: YES	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,CONCOMITANT MEDICATION OR THERAPY DISCONTINUED)	S: YES, Hospitalization or prolonged hospitalization O: COVID-19 A: NO REASONABLE POSSIBILITY E: YES

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.
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Program Source Code: [redacted]

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INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:90.70 KG								
	OL	390 TO 408		797	797	R: COVID-19 INFECTION S: 感染症および寄生虫症 P: コロナウイルス感染 L: Corona virus infection	E: 821 L: 25 DAYS I: YES	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: ACUTE RESPIRATORY DISEASE E: YES

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

[redacted]AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:85.20 KG

PRE TO -1

BLIND 1 TO 398

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

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INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:85.20 KG								
	OL	399 TO 52	450	450		R: L5 LUMBAR RADICULOPATHY ON THE LEFT SIDE S: 神経系障害 P: 腰髄神経根障害 L: Lumbar radiculopathy	E: 492 L: 43 DAYS	T: Severe R: No reasonable possibility A: DOSE NOT CHANGED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,SURGERY- L4/5 LAMINECTOMY AND DISCECTOMY ON [redacted]20[redacted])	S: YES, Hospitalization or prolonged hospitalization O: PADDLING E: NO

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.
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INV: [redacted]([redacted])									
TRT: ADA 40 mg EOW									
[redacted]	AGE:4[redacted] SEX:MALE RACE:AMERICAN INDIAN OR ALASKA NATIVE WEIGHT:113.60 KG								
	PRE	TO -1							
	BLIND	1 TO 392	224	224	224	R: CELLULITIS RIGHT LOWER LEG S: 感染症および寄生虫症 P: 蜂巣炎 L: Cellulitis of leg	E: 232 L: 9 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	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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:5[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:102.90 KG					
	PRE	TO -1							
	BLIND	1 TO 63	55	55	55	R: ACUTE SEPSIS S: 感染症および寄生虫症 P: 敗血症 L: Sepsis	O: YES	T: Life threatening 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:102.90 KG

POST 64 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted]([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:96.93 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: ADA 40 mg EOW									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:96.93 KG								
		BLIND	1 TO 156	94	94	94	R: HEPATIC ENCEPHALOPATHY S: 神経系障害 P: 肝性脳症 L: Hepatic encephalopathy	E: 254 L: 161 DAYS I: YES	T: Severe R: Reasonable possibility A: MULTIPLE:(DRUG INTERRUPTED, DRUG WITHDRAWN) O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY DISCONTINUED,MONITORING AMMONIA LEVELS)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY
		POST	157 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted]([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:4[redacted] SEX:MALE RACE:MULTIPLE WEIGHT:90.20 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:4[redacted] SEX:MALE RACE:MULTIPLE WEIGHT:90.20 KG									
	BLIND	1 TO 389	132	132	132	R: ACUTE ANTEROSEPTAL MYOCARDIAL INFARCTION S: 心臓障害 P: 急性心筋梗塞 L: Acute myocardial infarction	E: 136 L: 5 DAYS	T: Severe R: No reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Life threatening O: LIFESTYLE OF THE PATIENT, OBESITY, HIGH CHOLESTEROL AND TRYGLICERIDE LEVELS, GENETIC INHERITANCE 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:4[redacted] SEX:MALE RACE:MULTIPLE WEIGHT:90.20 KG

OL 390 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:132.45 KG

PRE TO -1

BLIND 1 TO 385

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:132.45 KG								
	OL	386 TO 304	689	689		R: WORSENING LOW BACK PAIN S: 筋骨格系および結合組織障害 P: 背部痛 L: Back pain aggravated	E: 761 L: 73 DAYS	T: Mild R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,PHYSICAL THERAPY STARTING [redacted])	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: LOW BACK PAIN 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:77.00 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:4[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:77.00 KG					
	BLIND	1 TO 191	191	191	191	R: ACUTE BRONCHITIS S: 感染症および寄生虫症 P: 気管支炎 L: Acute bronchitis	E: 217 L: 27 DAYS	T: Severe R: Reasonable possibility A: DRUG WITHDRAWN O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,HOSPITALIZATION)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: REASONABLE POSSIBILITY
	POST	192 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:100.00 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:100.00 KG								
	BLIND	1 TO 395	156	156	156	R: RIGHT ACHILLES TENDON TEAR S: 傷害、中毒および処置合併症 P: 腱断裂 L: Tendon rupture		T: Moderate R: No reasonable possibility A: DOSE NOT CHANGED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: PROLONGED AND INTENSIVE MECHANICAL ACTIVITY 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:109.00 KG

PRE TO -1

BLIND 1 TO 389

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.
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

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

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INV: [redacted] ([redacted]) TRT: Placebo to UPA 30 mg QD									
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:109.00 KG									
	OL	390 TO 520	131	520	353	R: MODERATE TO LOW DIFFERENTIATED LIGHTCELL CARCINOMA OF THE LEFT KIDNEY S: 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） P: 腎明細胞癌 L: Clear cell renal cell carcinoma	E: 544 L: 25 DAYS	T: Severe R: No reasonable possibility A: DRUG WITHDRAWN O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY DISCONTINUED,DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: NOT KNOWN RISK FACTORS BY PATIENT HYSTORY A: NO REASONABLE POSSIBILITY E: NO

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:109.00 KG

POST 521 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:110.00 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: Placebo to UPA 30 mg QD									
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:110.00 KG								
		BLIND	1 TO 382	381	381	213	R: SKIN ABSCESS OF THE LEFT ZYGOMATIC REGION. S: 感染症および寄生虫症 P: 皮下組織膿瘍 L: Abscesses of skin	E: 393 L: 13 DAYS	T: Severe R: No 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 O: DIABETES MELLITUS A: NO REASONABLE POSSIBILITY E: NO
		POST	383 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:108.00 KG

PRE TO -1

BLIND 1 TO 391

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:108.00 KG									
	OL	392 TO 497	83	474	474	R: PRIMARY METASTATIC PANCREAS NEOPLASIA S: 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） P: 遠隔転移を伴う膵癌 L: Pancreatic carcinoma metastatic	O: YES	T: Severe R: Reasonable possibility A: DRUG WITHDRAWN O: LIVER AND PANCREATIC BIOPSY AND ONCOLOGY APPOINTMENT	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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:108.00 KG									
	POST	498 TO	17	514	514	R: JAUNDICE S: 肝胆道系障害 P: 黄疸 L: Jaundice	O: YES	T: Severe R: Reasonable possibility A: DOSE NOT CHANGED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,ABDOMINAL CT TO EXCLUDE BILE DUCT OCCLUSION AND RENAL, ABDOMINAL, BLADDER AND PELVIC ULTRASOUND SCANS)	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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:3[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:89.00 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted]AGE:3[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:89.00 KG									
	BLIND	1 TO 385	240	240	240	R: HEADACHE WITH VOMITING S: 胃腸障害 P: 嘔吐 L: Vomiting	E: 250 L: 11 DAYS	T: Moderate R: Reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,ADMITTED TO HOSPITAL)	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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: ADA 40 mg EOW									
[redacted]	AGE:3[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:89.00 KG								
	BLIND	1 TO 385	240	240	240	R: HEADACHE WITH VOMITING S: 神経系障害 P: 頭痛 L: Headache	E: 250 L: 11 DAYS	T: Moderate R: Reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,ADMITTED TO HOSPITAL)	S: YES, Hospitalization or prolonged hospitalization 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: Placebo to UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:69.10 KG								
	PRE	TO -1							
	BLIND	1 TO 391	215	215	47	R: ACUTE OBSTRUCTIVE BRONCHITIS S: 感染症および寄生虫症 P: 気管支炎 L: Obstructive bronchitis	E: 233 L: 19 DAYS	T: Moderate R: Reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	OL	392 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: ADA 40 mg EOW									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:116.00 KG								
	PRE	TO -1							
	BLIND	1 TO 239	216	216	216	R: RAISED BODY MASS S: 臨床検査 P: 体重増加 L: Weight increased	E: 217 L: 2 DAYS I: YES	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: BARIATRIC SURGERY FOR RAISED BODY MASS INDEX	S: YES, Hospitalization or prolonged hospitalization O: LARGE BODY MASS INDEX 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted]([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:116.00 KG

POST 240 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:106.20 KG

PRE TO -1

BLIND 1 TO 392

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:106.20 KG									
	OL	393 TO 43		435	435	R: RECURRENCE SUPERFICIAL THROMBOPHLEBITIS LEFT LEG S: 血管障害 P: 表在性血栓性静脈炎 L: Superficial thrombophlebitis of leg	E: 458 L: 24 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,SURGICAL LIGATION)	S: YES, Hospitalization or prolonged hospitalization O: MASSIVE DILATED VARICOSE VEIN 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:92.00 KG

PRE TO -1

BLIND 1 TO 392

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:92.00 KG								
	OL	393 TO 98	490	490		R: EXACERBATION OF CALCULOUS CHOLECYSTITIS S: 肝胆道系障害 P: 胆嚢炎 L: Calculous cholecystitis	E: 499 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: EXACERBATION OF A CHRONIC DISEASE A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:92.50 KG

PRE TO -1

BLIND 1 TO 155

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:92.50 KG									
	POST	156 TO	22	177	177	R: LEFT LAMINAR PLEURAL EFFUSION S: 呼吸器、胸郭および縦隔障害 P: 胸水 L: Pleural effusion	E: 196 L: 20 DAYS	T: Moderate R: No reasonable possibility A: DOSE NOT CHANGED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: CAUSE IS PROBABLY VERTEBRAL ABSSCESS

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:92.50 KG									
	POST	156 TO	22	177	177	R: VERTEBRAL ABSCESS S: 感染症および寄生虫症 P: 骨膿瘍 L: Vertebral abscess	E: 510 L: 334 DAYS	T: Severe R: Reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: NO

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:92.50 KG									
	POST	156 TO	23	178	178	R: CEREBROVASCULAR ACCIDENT S: 神経系障害 P: 脳血管発作 L: Cerebrovascular accident	E: 205 L: 28 DAYS	T: Moderate R: No reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: CAUSE PROBABLY IS DIABETES.

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:92.50 KG									
	POST	156 TO	41	196	196	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	E: 253 L: 58 DAYS	T: Moderate R: Reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:66.00 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:66.00 KG								
		BLIND	1 TO 401	124	124	124	R: PERIANAL ABSCESS S: 感染症および寄生虫症 P: 肛門膿瘍 L: Perianal abscess	E: 127 L: 4 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: ANAL FISSURA 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:66.00 KG								
		BLIND	1 TO 401	255	255	255	R: ANAL FISTULA S: 胃腸障害 P: 痔瘻 L: Anal fistula	E: 309 L: 55 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,ELECTIV ANALFISTULAECTOMIA [redacted]20[redacted])	S: YES, Hospitalization or prolonged hospitalization O: ANAL FISTULA WAS REASON FOR ANAL FISTULECTOMIA (PI'S DECISION) A: NO REASONABLE POSSIBILITY E: NO
		OL	402 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:67.20 KG

PRE TO -1

BLIND 1 TO 392

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:67.20 KG									
	OL	393 TO	232	624	624	R: COVID 19 INFECTION S: 感染症および寄生虫症 P: コロナウイルス感染 L: Corona virus infection		T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: RELATIVES POSITIVE FOR COVID 19 INFECTION E: YES

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted] TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:67.20 KG								
	OL	393 TO	232	624	624	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia		T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: COVID 19 A: NO REASONABLE POSSIBILITY E: YES

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:99.00 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:99.00 KG									
	BLIND	1 TO 322	289	289	289	R: GASTRIC ULCER PERFORATION. S: 胃腸障害 P: 穿孔性胃潰瘍 L: Gastric ulcer perforation	E: 309 L: 21 DAYS	T: Severe R: No reasonable possibility A: MULTIPLE:(DRUG INTERRUPTED, DRUG WITHDRAWN) O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,CONCOMITANT MEDICATION OR THERAPY DISCONTINUED)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: MORE LIKELY CAUSE IS CONCOMITANT THERAPY - NON STEROID ANTI INFLAMMATORY DRUGS AND METHOTREXATE USAGE. 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:99.00 KG

POST 323 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:115.00 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted])									
TRT: UPA 30 mg QD									
[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:115.00 KG									
	BLIND	1 TO 174	153	153	153	R: BRONCHOPNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Bronchopneumonia	E: 162 L: 10 DAYS	T: Life threatening R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,CONCOMITANT MEDICATION OR THERAPY DISCONTINUED)	S: YES, Hospitalization or prolonged hospitalization, Persistent or significant disability, Important medical or surgical intervention, Life threatening O: DIABETES DISEASE. 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:115.00 KG

POST 175 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: Placebo to UPA 30 mg QD									
[redacted]	AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:87.00 KG								
	PRE	TO -1							
	BLIND	1 TO 398	370	370	194	R: HEMORRHOIDS S: 胃腸障害 P: 痔核 L: Hemorrhoids	E: 382 L: 13 DAYS I: YES	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: CONSTIPATION A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:87.00 KG

OL 399 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:113.40 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:113.40 KG									
	BLIND	1 TO 392	79	79	79	R: GASTRIC INDIGESTION S: 胃腸障害 P: 消化不良 L: Indigestion	E: 80 L: 2 DAYS	T: Severe R: No reasonable possibility A: DOSE NOT CHANGED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: SUBJECT HAD EATEN HEAVY MEAL CONSISTING OF PIZZA AND THEREAFTER COMPLAINED OF LEFT LOWER CHEST PAIN. 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:113.40 KG

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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:86.18 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: Placebo to UPA 30 mg QD									
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:86.18 KG								
		BLIND	1 TO 386	320	320	152	R: KIDNEY STONE S: 腎および尿路障害 P: 腎結石症 L: Kidney stone	E: 327 L: 8 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,CT SCAN)	S: YES, Hospitalization or prolonged hospitalization O: NATURALLY PREDISPOSED TO KIDNEY STONE DEVELOPMENT A: NO REASONABLE POSSIBILITY
		OL	387 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:85.27 KG

PRE TO -1

BLIND 1 TO 393

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:85.27 KG								
	OL	394 TO 90	483	483		R: COLOVESICAL FISTULA S: 胃腸障害 P: 腸膀胱瘻 L: Colovesical fistula	E: 515 L: 33 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: DIVERTICULOSIS A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:85.05 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:85.05 KG								
	BLIND	1 TO 392	313	313	313	R: COLLAPSED AVASCULAR NECROSIS OF THE LEFT HUMERAL HEAD WITHOUT OBVIOUS GLENOID INVOLVEMENT. S: 筋骨格系および結合組織障害 P: 骨壊死 L: Avascular necrosis	E: 369 L: 57 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,SURGICAL REPAIR)	S: YES, Hospitalization or prolonged hospitalization O: HEMIARTHROPLASTY OF L SHOULDER 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:85.05 KG

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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:84.00 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:84.00 KG								
	BLIND	1 TO 391	260	260	260	R: MYOCARDIAL INFARCTION S: 心臓障害 P: 心筋梗塞 L: Myocardial infarction	E: 264 L: 5 DAYS	T: Life threatening R: No reasonable possibility A: DOSE NOT CHANGED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: THE FIRST MANIFESTATION OF CORONARY HEART DISEASE A: NO REASONABLE POSSIBILITY
	OL	392 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: Placebo to UPA 30 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:105.00 KG								
	PRE	TO -1							
	BLIND	1 TO 389	370	370	203	R: VIRAL INFECTION S: 感染症および寄生虫症 P: ウイルス感染 L: Viral infection	E: 373 L: 4 DAYS I: YES	T: Moderate R: No reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: VIRUS 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:105.00 KG

OL 390 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:74.00 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]									
TRT: Placebo to UPA 15 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:74.00 KG								
	BLIND	1 TO 244	243	243	76	R: PHLEGMON S: 感染症および寄生虫症 P: 蜂巣炎 L: Phlegmon	E: 291 L: 49 DAYS	T: Severe R: Reasonable possibility A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: REASONABLE POSSIBILITY
	POST	245 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:82.50 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:82.50 KG								
	BLIND	1 TO 392	110	110	110	R: WORSENING OF PROLAPSE OF THE UTERUS S: 生殖系および乳房障害 P: 子宮脱 L: Uterine prolapse	E: 110 L: 1 DAY	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,TRANSVAGINAL ULTRASOUND, VAGINAL COLPOSCOPY, UTERUS ULTRASOUND)	S: YES, Hospitalization or prolonged hospitalization 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:82.50 KG								
		BLIND 1 TO 392	154	154	154	R: WORSENING OF PROLAPSE OF THE UTERUS S: 生殖系および乳房障害 P: 子宮脱 L: Uterine prolapse	E: 166 L: 13 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,HOSPITALIZATION)	S: YES, Hospitalization or prolonged hospitalization O: [redacted]20[redacted]FOLLOW UP-OTHER ETIOLOGY-AFTER BIRTH OF CHILDREN [redacted]20[redacted]: OTHER SUSPECTED CAUSES ARE UNKNOWN- NO INFORMATION ON DISCHARGED SUMMARY REPORT OTHER SUSPECTED CAUSES ARE 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

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INV: [redacted]([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:82.50 KG								
	BLIND	1 TO 392	209	209	209	R: DROOPING EYELIDS S: 眼障害 P: 眼瞼下垂 L: Eyelid ptosis	E: 209 L: 1 DAY	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: DUE TO AGE 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

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

[redacted]AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:95.10 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:95.10 KG								
	BLIND	1 TO 392	174	174	174	R: HOSPITALIZATION DUE TO PSORIATIC ARTHRITIS ACTIVITY ASSESSMENT S: 筋骨格系および結合組織障害 P: 乾癬性関節症 L: Psoriatic arthritis	E: 180 L: 7 DAYS	T: Moderate R: No reasonable possibility A: DOSE NOT CHANGED O: BLOOD EXAMINATION, ABDOMINAL ULTRASOUND	S: YES, Hospitalization or prolonged hospitalization O: PSORIATIC ARTHRITIS 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted] TRT: UPA 15 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:74.00 KG								
	PRE	TO -1							
	BLIND	1 TO 393							
	OL	394 TO 782	389	782	782	R: DIVERTICULITIS S: 感染症および寄生虫症 P: 憩室炎 L: Diverticulitis	O: YES	T: Moderate R: Reasonable possibility A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: NO

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:74.00 KG

POST 783 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:8[redacted] SEX:MALE RACE:WHITE WEIGHT:82.00 KG

PRE TO -1

BLIND 1 TO 46

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:8[redacted] SEX:MALE RACE:WHITE WEIGHT:82.00 KG								
	POST	47 TO	1	47	47	R: UROSEPSIS S: 感染症および寄生虫症 P: 尿路性敗血症 L: Urosepsis	E: 66 L: 20 DAYS	T: Mild 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:7[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:72.00 KG					
	PRE	TO -1							
	BLIND	1 TO 59	50	50	50	R: PNEUMOCYSTOSIS S: 感染症および寄生虫症 P: ニューモシスチス・イロベチイ肺炎 L: Pneumocystosis	O: YES	T: Life threatening R: Reasonable possibility A: DOSE NOT CHANGED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY
	POST	60 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:60.10 KG

PRE TO -1

BLIND 1 TO 211

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:60.10 KG									
	POST	212 TO 48		259	259	R: OVARIAN CYST S: 生殖系および乳房障害 P: 卵巣嚢胞 L: Ovarian cyst	E: 259 L: 1 DAY	T: Mild R: No reasonable possibility A: DOSE NOT CHANGED O: CYSTECTOMIA OVARII	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: POSTMENOPAUSE 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:74.40 KG								
		PRE	TO -1						
		BLIND	1 TO 396	303	303	303	R: APENDICITIS S: 感染症および寄生虫症 P: 虫垂炎 L: Appendicitis	E: 306 L: 4 DAYS I: YES	T: Severe R: No reasonable possibility A: DOSE NOT CHANGED O: APENDETOMY	S: YES, Hospitalization or prolonged hospitalization O: INFECTION 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:66.00 KG

PRE TO -1

BLIND 1 TO 392

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:66.00 KG								
	OL	393 TO 134	526	526		R: COVID-19 INFECTION S: 感染症および寄生虫症 P: コロナウイルス感染 L: Corona virus infection		T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: COVID PANDEMIC E: YES

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:66.00 KG								
	OL	393 TO 134	526	526		R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia		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: COVID-19 VIRUS A: NO REASONABLE POSSIBILITY E: YES

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:131.09 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:131.09 KG					
	BLIND	1 TO 221	177	177	177	R: UPPER GI BLEED S: 胃腸障害 P: 上部消化管出血 L: Upper gastrointestinal hemorrhage	E: 178 L: 2 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,CONCOMITANT MEDICATION OR THERAPY DISCONTINUED)	S: YES, Hospitalization or prolonged hospitalization O: BLEEDING ULCERS 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:131.09 KG					
	POST	222 TO	17	238	238	R: DIVERTICULITIS S: 感染症および寄生虫症 P: 憩室炎 L: Diverticulitis	E: 253 L: 16 DAYS I: YES	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: DIVERTICULOSIS 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:8[redacted] SEX:MALE RACE:WHITE WEIGHT:73.50 KG								
	PRE	TO -1							
	BLIND	1 TO 392							
	OL	393 TO	459	851	851	R: BACTERIAL PNEMONIA S: 感染症および寄生虫症 P: 細菌性肺炎 L: Pneumonia bacterial	E: 878 L: 28 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 E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:72.60 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo to UPA 15 mg QD									
[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:72.60 KG									
	BLIND	1 TO 252	179	179	11	R: QUINKE'S EDEMA S: 皮膚および皮下組織障害 P: 血管浮腫 L: Quincke's edema	E: 182 L: 4 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Life threatening O: ALLERGIC REACTION BECAUSE OF MEDICATION KLOFAN(CLOTRIMAZOL) 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo to UPA 15 mg QD									
[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:72.60 KG									
	POST	253 TO #	17	269	101	R: QUINCKE'S EDEMA S: 皮膚および皮下組織障害 P: 血管浮腫 L: Quincke's edema	E: 294 L: 26 DAYS	T: Severe R: No reasonable possibility A: DRUG WITHDRAWN O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,PLASMOPHERESIS)	S: YES, Hospitalization or prolonged hospitalization O: ALLERGIC REACTION BECAUSE OF DEEP RELIEF(IBUPROFEN, LEVOMENTHOL) A: NO REASONABLE POSSIBILITY E: NO

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.70 KG

PRE TO -1

BLIND 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.70 KG									
	POST	2 TO	5	6	6	R: CECUM CANCER WITH METASTASIS IN RIGHT HEPATIC LOBE. S: 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） P: 遠隔転移を伴う結腸癌 L: Metastatic colon cancer	O: YES	T: Severe R: No reasonable possibility A: DRUG WITHDRAWN O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY DISCONTINUED,DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: PATIENT DOES NOT HAVE ANY NEW SYMPTOMS, RISK FACTORS ARE ABSENT, PATIENT THOUGHT THAT IT REFERS TO GALLSTONE DISEASE. THE CAUSE OF CECUM CANCER 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:71.00 KG

PRE TO -1

BLIND 1 TO 396

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:71.00 KG								
	OL	397 TO 651	231	627	627	R: LEFT BREAST CANCER S: 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） P: 乳癌 L: Breast cancer	O: YES	T: Mild R: Reasonable possibility A: DRUG WITHDRAWN O: THE SUBJECT WAS ASSESSED BY THE ONCOLOGIST AND CURRENTLY IS WAITING FOR THE SURGERY	S: YES, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY E: NO
	POST	652 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:55.00 KG									
	PRE	TO -1							
	BLIND	1 TO 138	138	138	138	R: PULMONARY EMBOLISM S: 呼吸器、胸郭および縦隔障害 P: 肺塞栓症 L: Pulmonary embolism	E: 371 L: 234 DAYS	T: Life threatening R: Reasonable possibility A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:55.00 KG

POST 139 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:3[redacted] SEX:FEMALE RACE:MULTIPLE WEIGHT:88.00 KG

PRE TO -1

BLIND 1 TO 385

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo to UPA 30 mg QD									
[redacted] AGE:3[redacted] SEX:FEMALE RACE:MULTIPLE WEIGHT:88.00 KG									
	OL	386 TO 141	526	360		R: WORSENING OF VERICOSE VEINS BOTH LEGS S: 血管障害 P: 静脈瘤 L: Varicose veins of lower extremities	E: 532 L: 7 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: BILATERAL VARICOSE VEIN STRIPPING	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: SHE IS A NURSE AND STANDS A LOT 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:2[redacted] SEX:FEMALE RACE:MULTIPLE WEIGHT:69.00 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted] TRT: UPA 15 mg QD									
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:MULTIPLE WEIGHT:69.00 KG								
	BLIND	1 TO 393	165	165	165	R: HIATIS HERNIA S: 胃腸障害 P: 裂孔ヘルニア L: Hiatal hernia	E: 182 L: 18 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: DECREASED TONE OF THE LOWER OESOPHAGEAL SPHINCTER 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:85.00 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:85.00 KG								
		BLIND	1 TO 393	233	233 & 233	R: ATYPICAL CHEST PAIN S: 一般・全身障害および投与部位の状態 P: 胸痛 L: Chest pain	E: 328 L: 96 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: OCCASIONAL DIZZINESS AND ON ONE OCCASION HAD AN EPISODE OF PRESYNCOPE. 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
& Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:3[redacted] SEX:FEMALE RACE:MULTIPLE WEIGHT:96.50 KG								
	PRE	TO -1							
	BLIND	1 TO 393							
	OL	394 TO	36	429	429	R: HERPES ZOSTER OF UPPER LEG, BUTTOCK AND LOWER BACK S: 感染症および寄生虫症 P: 帯状疱疹 L: Herpes zoster	E: 446 L: 18 DAYS	T: Moderate 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:104.00 KG

PRE TO -1

BLIND 1 TO 393

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted]AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:104.00 KG									
	OL	394 TO	144	537	537	R: PULMONARY EMBOLI S: 呼吸器、胸郭および縦隔障害 P: 肺塞栓症 L: Pulmonary embolism	E: 645 L: 109 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: ACCORDING TO PHYSICIAN LETTER: REFERRED FOR INVESTIGATION OF CHRONIC COUGH EXCESS ETOH IF HE GETS UP OR PERFORMS ANY ACTIVITIES HE DEVELOPS TACHYCARDIA. A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted]([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:147.30 KG

PRE TO -1

BLIND 1 TO 16

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:147.30 KG									
	POST	17 TO	17	33	33	R: POSSIBLE STAPH INFECTION S: 感染症および寄生虫症 P: ブドウ球菌感染 L: Staphylococcal infection	O: YES	A: DOSE NOT CHANGED O: HOSPITALIZATION	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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:76.40 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:76.40 KG								
	BLIND	1 TO 394	21	21	21	R: ACUTE APPENDICITIS S: 感染症および寄生虫症 P: 虫垂炎 L: Acute appendicitis	E: 22 L: 2 DAYS	T: Mild 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
	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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.00 KG

PRE TO -1

BLIND 1 TO 387

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.00 KG								
	OL	388 TO	147	534	534	R: LEFT EXTERNAL ANKLE FRACTURE S: 傷害、中毒および処置合併症 P: 足関節部骨折 L: Ankle fracture	O: YES	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: KARMIC PLATE OSTEOSYNTHESIS,PLASTER FIXATION	S: YES, Hospitalization or prolonged hospitalization O: INSTABILITY 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:93.00 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:93.00 KG								
	BLIND	1 TO 398	51	51	51	R: CHRONIC LARYNGITIS S: 感染症および寄生虫症 P: 喉頭炎 L: Chronic laryngitis	E: 52 L: 2 DAYS I: YES	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: BECAUSE OF RETURNING HOARSENESS THAT HAS EXISTED FOR YEARS LARYNGOSCOPY AND OESOPHAGOSCOPY WAS PERFORMED.THE RESULT IS CHRONIC MUCOUS INFLAMMATION. 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:93.00 KG

OL 399 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:98.00 KG

PRE TO -1

BLIND 1 TO 387

OL 388 TO 581

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:98.00 KG									
	POST	582 TO	4	585	585	R: ADENOCARCINOMA OF CAECUM S: 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） P: 結腸腺癌 L: Adenocarcinoma of colon	O: YES I: YES	T: Severe R: Reasonable possibility A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: NO

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:90.20 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: Placebo to UPA 30 mg QD									
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:90.20 KG								
	BLIND	1 TO 398	300	300	131	R: WORSENING LEFT UPPER ARM FRACTURE S: 傷害、中毒および処置合併症 P: 上肢骨折 L: Arm fracture	E: 308 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, Important medical or surgical intervention O: UPPER ARM FRACTURE AS A RESULT OF MOTORCYCLE ACCIDENT ON [redacted]20[redacted]. A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:90.20 KG

OL 399 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:113.00 KG

PRE TO -1

BLIND 1 TO 385

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo to UPA 15 mg QD									
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:113.00 KG									
	OL	386 TO	50	435	267	R: HYDROCELE TESTIS S: 先天性、家族性および遺伝性障害 P: 陰嚢水瘤 L: Hydrocele	E: 443 L: 9 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: HYDROCELE TESTIS REMOVAL SURGERY	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: PROBABLE CAUSE OF THE EVENT IS VARICOSE VEINS OF THE SPERMATIC CORDS AND EPIDIDYMIS CYSTS. 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:86.50 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: ADA 40 mg EOW									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:86.50 KG								
	BLIND	1 TO 389	189	189	189	R: VERTEBRAE L/S SPONDYLOLISTHESIS EXACERBATION S: 筋骨格系および結合組織障害 P: 脊椎すべり症 L: Spondylolisthesis	E: 196 L: 8 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,SURGERY OF LUMBOSACRAL SPINE)	S: YES, Hospitalization or prolonged hospitalization O: VERTEBRAE L5/S1 SLIPPAGE A: NO REASONABLE POSSIBILITY
	OL	390 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- RX Day	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:101.40 KG

PRE TO -1

BLIND 1 TO 385

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] [redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:5[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:101.40 KG					
	OL	386 TO 479	67	452	452	R: ENDOMETRIAL HYPERPLASIA S: 生殖系および乳房障害 P: 子宮内膜増殖症 L: Endometrial hyperplasia	E: 452 L: 1 DAY	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: GLANDULAR HYPERPLASIA OF THE ENDOMETRIUM 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:101.40 KG									
	OL	386 TO 479	67	452	452	R: METASTATIC SQUAMOUS FOCAL ENDOMETRIAL ADENOCARCINOMA G-2 S: 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） P: 子宮内膜腺癌 L: Endometrial adenocarcinoma metastatic	O: YES	T: Moderate R: No reasonable possibility A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: PROBABLY OBESITY, NO BIRTH GIVING, HYPERTENSION 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:101.40 KG

POST 480 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.00 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.00 KG									
	BLIND	1 TO 112	19	19	19	R: LEFT EYE CATARACT S: 眼障害 P: 白内障 L: Left cataract	E: 19 L: 1 DAY	T: Severe R: No reasonable possibility A: DOSE NOT CHANGED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,SURGERY FOR EYE CATARACT WAS PERFORMED.)	S: YES, Hospitalization or prolonged hospitalization O: MEDICAL HISTORY - CATARACT SINCE 20[redacted]. A: NO REASONABLE POSSIBILITY
	POST	113 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:83.30 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: Placebo to UPA 15 mg QD									
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:83.30 KG								
	BLIND	1 TO 391	309	309	141	R: RECURRING DEPRESSIVE DISORDER S: 精神障害 P: うつ病 L: Recurrent depressive disorder		T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,REFERRED TO PSYCHIATRIST WHO PRESCRIBED CONMEDS)	S: YES, Hospitalization or prolonged hospitalization O: PERSONAL ISSUES A: NO REASONABLE POSSIBILITY
	OL	392 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:112.00 KG								
	PRE	TO -1							
	BLIND	1 TO 392	378	378 &	378	R: BACK PAIN S: 筋骨格系および結合組織障害 P: 背部痛 L: Back pain	E: 527 L: 150 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: PREVIOUS SPINAL SURGERY A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
& Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:112.00 KG								
	OL	393 TO 260	652	652		R: CLAW TOE LEFT FOOT SECOND DIGIT S: 筋骨格系および結合組織障害 P: 後天性鉤爪趾 L: Claw toe (acquired)	E: 725 L: 74 DAYS	T: Mild R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: PSORIATIC ARTHRITIS E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:82.50 KG								
	PRE	TO -1							
	BLIND	1 TO 392	86	86	86	R: WORSENING OSTEOARTHRITIS LEFT KNEE S: 筋骨格系および結合組織障害 P: 変形性関節症 L: Osteoarthritis aggravated	E: 453 L: 368 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CONSULTATION WITH ORTHOPAEDIC SURGEON	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: OSTEOARTHRITIS 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV:[redacted] ([redacted] TRT: ADA 40 mg EOW									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:82.50 KG								
	BLIND	1 TO 392	307	307	307	R: WORSENING OSTEOARTHRITIS RIGHT KNEE S: 筋骨格系および結合組織障害 P: 変形性関節症 L: Osteoarthritis aggravated		T: Severe R: No reasonable possibility A: DOSE NOT CHANGED O: CONSULTATION WITH ORTHOPAEDIC SURGEON	S: YES, Hospitalization or prolonged hospitalization O: OSTEOARTHRITIS
	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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:112.20 KG								
	PRE	TO -1							
	BLIND	1 TO 393	15	15	15	R: RAISED MUSCLE ENZYMES S: 臨床検査 P: 筋酵素上昇 L: Muscle enzyme increased		T: Mild R: Reasonable possibility A: DRUG INTERRUPTED O: NONE	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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:112.20 KG								
		BLIND 1 TO 393	254	254	254	R: RIGHT RENAL COLIC S: 腎および尿路障害 P: 腎仙痛 L: Renal colic	E: 254 L: 1 DAY I: YES	T: Severe R: No reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: SUSPECTED RENAL STONES. CONFIRMED THROUGH SCAN, NO STONES 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:111.00 KG								
	PRE	TO -1							
	BLIND	1 TO 391	3	3	3	R: C7 RADICULOPATHY S: 神経系障害 P: 頚髄神経根障害 L: Cervical radiculopathy	E: 49 L: 47 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: SHOULDER PAIN A: NO REASONABLE POSSIBILITY
	OL	392 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo to UPA 30 mg QD									
[redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:105.00 KG									
	PRE	TO -1							
	BLIND	1 TO 367	260	260	89	R: WORSENING OF PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia aggravated	E: 267 L: 8 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: LOW IMMUNE RESPONSE, DIABETES 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:105.00 KG

POST 368 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted]([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.00 KG

PRE TO -1

BLIND 1 TO 392

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.00 KG									
	OL	393 TO	24	416	416	R: RIGHT LOWER ARM FRACTURE S: 傷害、中毒および処置合併症 P: 上肢骨折 L: Arm fracture	E: 468 L: 53 DAYS	T: Moderate R: No reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: PATIENT FELL DURING CLIMBING. 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:60.00 KG

PRE TO -1

BLIND 1 TO 393

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:60.00 KG								
	OL	394 TO 146	539	539		R: WORSENING OF HYDROCELE S: 先天性、家族性および遺伝性障害 P: 陰嚢水瘤 L: Hydrocele aggravated	E: 549 L: 11 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: YES, Hospitalization or prolonged hospitalization O: HERNIA 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:104.00 KG								
	PRE	TO -1							
	BLIND	1 TO 392							
	OL	393 TO	65	457	457	R: WORSENING OF DIABETIC POLYNEUROPATHY S: 神経系障害 P: 糖尿病性ニューロパチー L: Diabetic polyneuropathy	E: 470 L: 14 DAYS	T: Severe R: No reasonable possibility A: DOSE NOT CHANGED O: REHABILITATION	S: YES, Hospitalization or prolonged hospitalization O: DIABETIC POLYNEUROPATHY 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:104.00 KG								
	OL	393 TO	66	458	458	R: ANEMIA S: 血液およびリンパ系障害 P: 貧血 L: Anemia	E: 567 L: 110 DAYS	T: Moderate R: No reasonable possibility A: DOSE NOT CHANGED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY DISCONTINUED,STOPPED TAKING METHOTREXAT)	S: YES, Hospitalization or prolonged hospitalization O: POSSIBLY DUE TO METHOTREXAT TREATMENT 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:74.40 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:74.40 KG								
	BLIND	1 TO 392	143	143	143	R: JOINT PAIN S: 筋骨格系および結合組織障害 P: 関節痛 L: Joint pain	E: 157 L: 15 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: PATIENT HAS GENERAL JOINT PAIN DUE TO WORK-RELATED FATIGUE 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:71.20 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:6[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:71.20 KG					
	BLIND	1 TO 83	64	64	64	R: FEVER OF UNKNOWN ORIGIN S: 一般・全身障害および投与部位の状態 P: 発熱 L: Fever of unknown origin	E: 90 L: 27 DAYS I: YES	T: Moderate 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	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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: ADA 40 mg EOW									
[redacted]	AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:61.30 KG								
	PRE	TO -1							
	BLIND	1 TO 392							
	OL	393 TO	161	553	553	R: CORONARY ARTERY DISEASE S: 心臓障害 P: 冠動脈疾患 L: Coronary artery disease		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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:64.90 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted] AGE:6[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:64.90 KG									
	BLIND	1 TO 392	157	157	157	R: CORONARY ARTERIAL DISEASE S: 心臓障害 P: 冠動脈疾患 L: Coronary artery disease		T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED, STOP IMP SINCE [redacted]20[redacted]. O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: IN THE JUDGMENT OF THE PRINCIPAL INVESTIGATOR, THE EVENT WAS NOT RELATED TO THE STUDY DRUG AND ANGIOGRAPHY IS A PROCEDURE AND NOT A SURGERY BECAUSE NO INCISION AND SUTURE WAS NEEDED. 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted] AGE:6[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:64.90 KG									
		BLIND 1 TO 392	378	378	378	R: AVASCULAR NECROSIS OF BILATERAL HIP JOINTS S: 筋骨格系および結合組織障害 P: 骨壊死 L: Avascular necrosis of bone	E: 493 L: 116 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: SMOKING AND RECEIVING LOCAL TRIAMCINOLONE INJECTION WERE CONSIDERED AS CAUSE OF THE EVENT. 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:65.20 KG								
	PRE	TO -1							
	BLIND	1 TO 392							
	OL	393 TO	151	543	543	R: BRONCHITIS S: 感染症および寄生虫症 P: 気管支炎 L: Bronchitis	E: 568 L: 26 DAYS I: YES	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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:65.20 KG								
	OL	393 TO 222	614	614		R: HERPES ZOSTER S: 感染症および寄生虫症 P: 帯状疱疹 L: Herpes zoster	E: 729 L: 116 DAYS I: YES	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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.00 KG

PRE TO -1

BLIND 1 TO 195

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.00 KG									
	POST	196 TO	1	196	196	R: DISSEMINATED PUSTULAR PSORIASIS S: 皮膚および皮下組織障害 P: 膿疱性乾癬 L: Pustular psoriasis	E: 203 L: 8 DAYS	T: Severe R: No reasonable possibility A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: IMMUNOSUPPRESSION 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: ADA 40 mg EOW									
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:81.00 KG								
	PRE	TO -1							
	BLIND	1 TO 391	34	34	34	R: ATRIAL FIBRILLATION PAROXYSMIC S: 心臓障害 P: 心房細動 L: Paroxysmal atrial fibrillation	E: 37 L: 4 DAYS	T: Moderate R: Reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	OL	392 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:78.00 KG

PRE TO -1

BLIND 1 TO 393

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted] TRT: UPA 15 mg QD									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:78.00 KG								
	OL	394 TO 49	442	442		R: GALLSTONE WITH CHOLECYSTITIS S: 肝胆道系障害 P: 胆嚢炎 L: Cholecystitis	E: 446 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: CHOLELITHIASIS A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:78.00 KG								
	OL	394 TO 49	442	442		R: GALLSTONE WITH CHOLECYSTITIS S: 肝胆道系障害 P: 胆石症 L: Gallstones	E: 446 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: CHOLELITHIASIS A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: Placebo to UPA 30 mg QD									
[redacted]	AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:72.30 KG								
	PRE	TO -1							
	BLIND	1 TO 392	199	199	31	R: APPENDICITIS S: 感染症および寄生虫症 P: 虫垂炎 L: Appendicitis	E: 200 L: 2 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: PHLAGMONOUS, GANGRENOUS APPENDIX 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:72.30 KG

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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted]([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:80.80 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:80.80 KG									
		BLIND	1 TO 225	225	225	225	R: WORSENING HYPERTROPHY PROSTATE S: 生殖系および乳房障害 P: 良性前立腺肥大症 L: Prostatic hypertrophy	E: 254 L: 30 DAYS	T: Moderate R: No reasonable possibility A: DRUG WITHDRAWN O: TRANSURETHRAL RESECTION OF THE PROSTATE	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: INSUFFICIENT WORKING OFF TAMSULOSINE A: NO REASONABLE POSSIBILITY
		POST	226 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:84.40 KG								
	PRE	TO -1							
	BLIND	1 TO 393							
	OL	394 TO	68	461	461	R: COVID-19 POSITIVE INFECTION S: 感染症および寄生虫症 P: コロナウイルス感染 L: Corona virus infection	E: 475 L: 15 DAYS	T: Life threatening R: No reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: VIRAL INFECTION E: YES

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:102.20 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

[redacted]
ABT-494 (PSA)
STUDY M15-572 - WEEK 56 (DATA CUTOFF - [redacted]20[redacted])
R&D/20/1009 - CLINICAL/STATISTICAL

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted] TRT: UPA 15 mg QD									
[redacted]	AGE:7[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:102.20 KG					
	BLIND	1 TO 58	37	37	37	R: NEURO-ENDOCRIENE CARCINOMA OF UNKNOWN PRIMARY SITE S: 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） P: 神経内分泌癌 L: Neuroendocrine carcinoma	O: YES	T: Severe R: No reasonable possibility A: DRUG WITHDRAWN O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,PET SCAN,DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: AGE 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:102.20 KG

POST 59 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:88.00 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: ADA 40 mg EOW									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:88.00 KG								
	BLIND	1 TO 391	343	343	343	R: WORSENING OF OSTEOARTHRITIS OF LEFT KNEE S: 筋骨格系および結合組織障害 P: 変形性関節症 L: Osteoarthritis knee	E: 359 L: 17 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,LEFT TOTAL KNEE REPLACEMENT)	S: YES, Hospitalization or prolonged hospitalization O: DISEASE PROGRESSION A: NO REASONABLE POSSIBILITY E: NO
	OL	392 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:112.00 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:112.00 KG								
		BLIND 1 TO 392	256	256	256	R: MYOCARDIAL INFARCTION S: 心臓障害 P: 心筋梗塞 L: Myocardial infarction	E: 260 L: 5 DAYS	T: Life threatening 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: SUBJECT HAS SMOKING HX AND HYPERTENSION. 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- RX Day	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:77.40 KG

PRE TO -1

BLIND 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: ADA 40 mg EOW									
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:77.40 KG									
	POST	2 TO	14	15	15	R: DERMATITIS WORSENING S: 皮膚および皮下組織障害 P: 皮膚炎 L: Dermatitis NOS aggravated	E: 23 L: 9 DAYS	T: Severe R: Reasonable possibility A: DOSE NOT CHANGED 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:83.00 KG									
	PRE	TO -1							
	BLIND	1 TO 399	79	79	79	R: TOENAILS INGROWN WORSENING S: 皮膚および皮下組織障害 P: 嵌入爪 L: Ingrown toe nail	E: 232 L: 154 DAYS	T: Moderate R: No reasonable possibility A: DRUG INTERRUPTED O: PARTIAL SURGICAL REMOVAL OF THE BOTH TOENAILS	S: YES, Hospitalization or prolonged hospitalization O: REPETITIVE PRESSURE TO THE FEET 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:83.00 KG

OL 400 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
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INV: [redacted]([redacted])
TRT: UPA 30 mg QD

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:74.00 KG

PRE TO -1

BLIND 1 TO 72

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.
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

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

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INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:74.00 KG									
	POST	73 TO	18	90	90	R: IRON DEFICIENT ANAEMIA S: 血液およびリンパ系障害 P: 鉄欠乏性貧血 L: Iron deficiency anaemia	E: 143 L: 54 DAYS	T: Severe R: Reasonable possibility A: DOSE NOT CHANGED O: HOSPITALIZED FOR FURTHER INVESTIGATION	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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:89.90 KG

PRE TO -1

BLIND 1 TO 385

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.
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

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

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INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:89.90 KG					
	OL	386 TO 812	423	808	808	R: PULMONARY EMBOLISM S: 呼吸器、胸郭および縦隔障害 P: 肺塞栓症 L: Pulmonary embolism	E: 819 L: 12 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, Life threatening A: NO REASONABLE POSSIBILITY
	POST	813 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 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.
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: UPA 30 mg QD

[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:79.50 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.
# Subject prematurely discontinued.

Program Source Code: [redacted]

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(Safety Analysis Set)

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INV: [redacted]([redacted])									
TRT: UPA 30 mg QD									
[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:79.50 KG									
	BLIND	1 TO 217	34	34	34	R: EXACERBATION OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE S: 呼吸器、胸郭および縦隔障害 P: 慢性閉塞性肺疾患 L: Chronic obstructive airways disease exacerbated	E: 45 L: 12 DAYS	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,NEBULIZATION)	S: YES, Hospitalization or prolonged hospitalization O: EXACERBATION OF EXISTING CONDITION 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:79.50 KG									
	POST	218 TO	1	218	218	R: BACTEREMIA STAPHYLOCOCCUS EPIDERMIDIS S: 感染症および寄生虫症 P: ブドウ球菌性菌血症 L: Staphylococcal bacteremia	E: 234 L: 17 DAYS I: YES	T: Severe 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 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:7[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:79.50 KG					
	POST	218 TO	3	220	220	R: CONGESTIVE HEART FAILURE-WORSENING S: 心臓障害 P: うっ血性心不全 L: Congestive cardiac failure aggravated	E: 234 L: 15 DAYS	T: Severe R: No reasonable possibility A: DOSE NOT CHANGED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: UPPER RESPIRATORY 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: ADA 40 mg EOW									
[redacted]	AGE:6[redacted] SEX:MALE RACE:ASIAN WEIGHT:49.00 KG								
	PRE	TO -1							
	BLIND	1 TO 392							
	OL	393 TO	45	437	437	R: LEFT DORSAL CELLULITIS S: 感染症および寄生虫症 P: 蜂巣炎 L: Cellulitis	E: 455 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: ADA 40 mg EOW									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:84.00 KG								
	PRE	TO -1							
	BLIND	1 TO 399	350	350	350	R: COLON POLYPS S: 胃腸障害 P: 大腸ポリープ L: Colonic polyp	E: 350 L: 1 DAY	T: Severe R: No reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: YES, Hospitalization or prolonged hospitalization O: IT IS ASSOCIATED WITH CHRONIC INTESTINAL INFLAMMATION, LIFESTYLE AND AGE FACTORS A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted]
TRT: ADA 40 mg EOW

[redacted]AGE:6[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:84.00 KG

OL 400 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:78.00 KG								
	PRE	TO -1							
	BLIND	1 TO 392							
	OL	393 TO	87	479	479	R: INFECTIOUS FEVER S: 感染症および寄生虫症 P: 熱性感染症 L: Febrile infection	E: 481 L: 3 DAYS	T: Moderate R: Reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

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INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:78.00 KG								
	OL	393 TO	87	479	479	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	E: 490 L: 12 DAYS	T: Moderate R: Reasonable possibility A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
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Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: ADA 40 mg EOW

[redacted] AGE:4[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:114.70 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: ADA 40 mg EOW									
[redacted] AGE:4[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:114.70 KG									
	BLIND	1 TO 246	136	136	136	R: ANXIETY CRISIS S: 精神障害 P: 不安 L: Anxiety attack	E: 137 L: 2 DAYS	T: Severe R: No reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: RELATED TO PRE-EXISTING BIPOLAR DISORDER AND CURRENT PSYCHOSOCIAL PROBLEMS A: NO REASONABLE POSSIBILITY
	POST	247 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:88.60 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:88.60 KG								
	BLIND	1 TO 292	286	286	286	R: CUTANEOUS DISSEMINATED HERPES ZOSTER S: 感染症および寄生虫症 P: 皮膚播種性帯状疱疹 L: Herpes zoster cutaneous disseminated	E: 309 L: 24 DAYS	T: Severe R: Reasonable possibility A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY E: NO
	POST	293 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:95.00 KG

PRE TO -1

BLIND 1 TO 392

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo to UPA 15 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:95.00 KG								
	OL	393 TO 405	1	393	225	R: ADENOCARCINOMA OF THE RIGHT LUNG S: 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） P: 肺腺癌 L: Adenocarcinoma lung	O: YES	T: Life threatening R: Reasonable possibility A: DRUG WITHDRAWN O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,CHEMOTHERAPY,DIS CONTINUED STUDY)	S: YES, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY E: NO
	POST	406 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 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.
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

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Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:69.50 KG

PRE TO -1

BLIND 1 TO 159

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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:69.50 KG								
	POST	160 TO	1	160	160	R: ADENOCARCINOMA G-3 BRONCHUS S: 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） P: 肺腺癌 L: Adenocarcinoma lung	O: YES	T: Moderate R: No reasonable possibility A: DRUG WITHDRAWN O: NONE	S: YES, Important medical or surgical intervention O: SMOKER 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 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.
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: UPA 30 mg QD

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:83.00 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 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.
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

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INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:6[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:83.00 KG					
	BLIND	1 TO 56	37	37	37	R: BACTEREMIA S: 感染症および寄生虫症 P: 菌血症 L: Bacteremia	E: 71 L: 35 DAYS	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
	POST	57 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 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.
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: UPA 30 mg QD									
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:45.00 KG								
	PRE	TO -1							
	BLIND	1 TO 392							
	OL	393 TO	49	441	441	R: ACUTE RIGHT-SIDED SALPINGITIS S: 感染症および寄生虫症 P: 卵管炎 L: Salpingitis	E: 443 L: 3 DAYS	T: Severe R: Reasonable possibility A: DRUG INTERRUPTED O: DIAGNOSTIC LAPAROSCOPIC SURGERY	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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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(Safety Analysis Set)

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INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:45.00 KG								
	OL	393 TO 489	881	881		R: PELVIC PURULENT PERITONITIS S: 感染症および寄生虫症 P: 腹膜炎 L: Pelvic peritonitis	O: YES	T: Severe R: No reasonable possibility A: DRUG INTERRUPTED O: DRAINAGE OF THE ABDOMINAL CAVITY	S: YES, Hospitalization or prolonged hospitalization O: ACUTE PURULENT SALPINGITIS A: NO REASONABLE POSSIBILITY E: NO

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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

Listing of Subjects with Treatment-Emergent Serious Adverse Events - Long Term
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Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:52.00 KG								
	PRE	TO -1							
	BLIND	1 TO 455	392	392	392	R: LEFT BUTTOCK ABSCESS S: 感染症および寄生虫症 P: 四肢膿瘍 L: Abscess on buttock	E: 402 L: 11 DAYS	T: Severe R: Reasonable possibility A: DRUG INTERRUPTED O: MULTIPLE:(CONCOMITANT MEDICATION OR THERAPY STARTED,SUBJECT HAD OPENING AND DRAINAGE OF THE ABSCESS)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: REASONABLE POSSIBILITY
	OL	456 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 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.
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Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:93.80 KG					
	PRE	TO -1							
	BLIND	1 TO 57	53	53	53	R: SEPTICEMIA S: 感染症および寄生虫症 P: 敗血症 L: Septicemia	E: 66 L: 14 DAYS I: YES	T: Severe R: Reasonable possibility A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY
	POST	58 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 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.
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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:66.50 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA/ADA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:66.50 KG								
		BLIND	1 TO 385	211	211	211	R: LUMBAR DISC HERNIATION AGGRAVATES S: 筋骨格系および結合組織障害 P: 椎間板突出 L: Lumbar disc herniation	I: YES	T: Moderate R: No reasonable possibility A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: THIS A WORSENING OF MEDICAL HISTORY LUMBAR INTERVERTEBRAL DISC 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 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.
PRE = Screening; BLIND = Blinded treatment; OL = Open label treatment; POST = Post study drug.

Program Source Code: [redacted]

表 2.7.4.7-101. 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）：M15-554 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 = 290) (PYs = 419.4) Events (E/100 PYs)	UPA 30 mg QD (N = 308) (PYs = 423.5) Events (E/100 PYs)
Any adverse event	60 (14.3)	67 (15.8)
血液およびリンパ系障害	1 (0.2)	2 (0.5)
失血性貧血	1 (0.2)	1 (0.2)
汎血球減少症	0	1 (0.2)
心臓障害	7 (1.7)	7 (1.7)
急性心筋梗塞	1 (0.2)	0
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	0	2 (0.5)
徐脈	0	1 (0.2)
心不全	1 (0.2)	1 (0.2)
心肺停止	1 (0.2)	0
冠動脈狭窄	0	1 (0.2)
心筋梗塞	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.
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 = 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.)		
上室性頻脈	0	1 (0.2)
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)
胃腸障害	3 (0.7)	7 (1.7)
腹痛	0	1 (0.2)
下痢	0	1 (0.2)
十二指腸潰瘍	0	1 (0.2)
出血性十二指腸潰瘍	1 (0.2)	1 (0.2)
胃炎	1 (0.2)	0
びらん性胃炎	1 (0.2)	0
吐血	0	1 (0.2)
鼠径ヘルニア	0	1 (0.2)
小腸潰瘍	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.
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 = 290) (PYs = 419.4) Events (E/100 PYs)	UPA 30 mg QD (N = 308) (PYs = 423.5) Events (E/100 PYs)
一般・全身障害および投与部位の状態	0	2 (0.5)
発熱	0	1 (0.2)
全身性炎症反応症候群	0	1 (0.2)
肝胆道系障害	2 (0.5)	1 (0.2)
胆石症	2 (0.5)	0
薬物性肝障害	0	1 (0.2)
感染症および寄生虫症	11 (2.6)	25 (5.9)
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
気管支炎	0	1 (0.2)
蜂巣炎	2 (0.5)	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)

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/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 = 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.)		
胃腸炎	1 (0.2)	1 (0.2)
ウイルス性胃腸炎	1 (0.2)	2 (0.5)
帯状疱疹	0	1 (0.2)
肝膿瘍	1 (0.2)	0
肺感染	1 (0.2)	0
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	3 (0.7)	5 (1.2)
インフルエンザ性肺炎	0	1 (0.2)
敗血症	0	2 (0.5)
上気道感染	0	1 (0.2)
尿路感染	0	1 (0.2)
ウイルス性上気道感染	0	1 (0.2)
傷害、中毒および処置合併症	8 (1.9)	1 (0.2)
頚椎骨折	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.
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 = 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.)		
転倒	1 (0.2)	0
大腿骨頚部骨折	0	1 (0.2)
腰椎骨折	1 (0.2)	0
処置後胆汁漏出	1 (0.2)	0
交通事故	1 (0.2)	0
腱断裂	1 (0.2)	0
胸椎骨折	1 (0.2)	0
外傷性血胸	1 (0.2)	0
代謝および栄養障害	3 (0.7)	1 (0.2)
脱水	1 (0.2)	0
糖尿病	1 (0.2)	0
低ナトリウム血症	1 (0.2)	0
1型糖尿病	0	1 (0.2)
筋骨格系および結合組織障害	9 (2.1)	1 (0.2)
背部痛	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.
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 = 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 (Cont.)		
側腹部痛	1 (0.2)	0
変形性関節症	1 (0.2)	1 (0.2)
乾癬性関節症	4 (1.0)	0
急速進行性変形性関節症	1 (0.2)	0
全身性エリテマトーデス	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）	5 (1.2)	4 (0.9)
肛門性器疣贅	0	1 (0.2)
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	1 (0.2)	1 (0.2)
良性副甲状腺腫瘍	1 (0.2)	0
前立腺癌	1 (0.2)	0
直腸腺癌	0	1 (0.2)
直腸癌	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.
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 = 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	3 (0.7)	2 (0.5)
浮動性めまい	2 (0.5)	0
顔面麻痺	0	1 (0.2)
会話障害	1 (0.2)	0
一過性全健忘	0	1 (0.2)
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	1 (0.2)	2 (0.5)
失見当識	1 (0.2)	0
精神状態変化	0	1 (0.2)
自殺企図	0	1 (0.2)
腎および尿路障害	4 (1.0)	2 (0.5)
急性腎障害	2 (0.5)	1 (0.2)
腎結石症	2 (0.5)	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.
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__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 = 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	1 (0.2)	1 (0.2)
良性前立腺肥大症	0	1 (0.2)
子宮頚部上皮異形成	1 (0.2)	0
呼吸器、胸郭および縦隔障害	2 (0.5)	6 (1.4)
急性呼吸不全	1 (0.2)	1 (0.2)
喘息	0	1 (0.2)
慢性閉塞性肺疾患	0	1 (0.2)
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)

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/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 2.7.4.7-102. 投与 56 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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 312	277	277	277	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	O: YES	T: Moderate R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: NONE	S: YES, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY
		POST	313 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	153 153	R: MODERATELY DIFFERENTIATED INVASIVE ADENOCARCINOMA (RECTUM) S: 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） 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	25	419	419	R: ACUTE BLOOD LOSS ANEMIA S: 血液およびリンパ系障害 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	419	R: DUODENAL ULCER BLEEDING S: 胃腸障害 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

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

Subject Number	Epoch Name	Epoch Interval	RX Day of Day	Study Day of UPA Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	67	R: ACUTE HYPOXEMIC RESPIRATORY FAILURE S: 呼吸器、胸郭および縦隔障害 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

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

Subject Number	Name	Epoch	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

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

Subject Number	Epoch Name	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	450	R: UPPER RESPIRATORY INFECTION S: 感染症および寄生虫症 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	49	449	281	R: CELLULITIS OF LEFT HAND S: 感染症および寄生虫症 P: 蜂巣炎 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

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

Subject Number	Epoch Name	Epoch Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	192	R: CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION S: 呼吸器、胸郭および縦隔障害 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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:48.76 KG

PRE TO -1

BLIND 1 TO 398

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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:48.76 KG								
	OL	399 TO 484	484	882	882	R: NON RHEUMATIC AORTIC VALVE STENOSIS S: 心臓障害 P: 大動脈弁狭窄 L: Aortic valve stenosis	E: 883 L: 2 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CORANARY ANGIOGRAPHY WAS DONE ON [redacted]-[redacted]-20[redacted]. BLOCKAGE DX. STENT PLACED TO LAD)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: HYPERLIPIDMIA 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

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

Subject Number	Epoch Name	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	165	R: PNEUMONIA S: 感染症および寄生虫症 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

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

Subject Number	Epoch Name	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	57	R: LEFT INGUINOSCROTAL HERNIA S: 胃腸障害 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: Placebo to UPA 15 mg QD										
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:62.00 KG									
		PRE	TO -1							
		BLIND	1 TO 392	230	230	62	R: PRIMOMANIFESTATION OF HEART FAILURE S: 心臓障害 P: 心不全 L: Heart failure	E: 233 L: 4 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: YES, Hospitalization or prolonged hospitalization O: VERTEBROALGIC SYNDROME 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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:154.80 KG

PRE TO -1

BLIND 1 TO 392

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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: Placebo to UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:154.80 KG								
	OL	393 TO 417+	25	417	248	R: HEART FAILURE S: 心臓障害 P: 心不全 L: Heart failure	E: 425 L: 9 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CONCOMITANT MEDICATION OR THERAPY DISCONTINUED, CORONAROGRAPHY PERFORMED ON [redacted]20[redacted]: ISCHEMIC ETIOLOGY OF HEART FAILURE IS UNLIKELY)	S: YES, Hospitalization or prolonged hospitalization O: DILATED CARDIOMYOPATHY A: NO REASONABLE POSSIBILITY E: NO

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 is ongoing.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.60 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.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.60 KG								
		BLIND	1 TO 392	239	239	R: RIGHT PARATHYROID ADENOMA S: 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） P: 良性副甲状腺腫瘍 L: Parathyroid adenoma		T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MIBI SCINTIGRAPHY PERFORMED ON [redacted]20[redacted] MINIMALLY INVASIVE VIDEO-ASSISTED PARATHYROIDECTOMY PERFORMED ON [redacted]20[redacted]	S: YES, Hospitalization or prolonged hospitalization O: INCREASED ACTIVITY OF THE RADIOPHARMACEUTICAL IN RIGHT SIDE OF THE THYROID 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

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

Subject Number	Epoch Name	Epoch Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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: 心臓障害 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	17	R: RIGHT FEMORAL NECK FRACTURE S: 傷害、中毒および処置合併症 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

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

Subject Number	Epoch Name	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	117	R: PNEUMONIA S: 感染症および寄生虫症 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	88	R: TRANSIENT GLOBAL AMNESIA S: 神経系障害 P: 一過性全健忘 L: Transient global amnesia	E: 91 L: 4 DAYS	T: Mild R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED 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

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

Subject Number	Epoch Name	Epoch Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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: 心臓障害 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD										
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:112.00 KG									
		PRE	TO -1							
		BLIND	1 TO 385							
		OL	386 TO 717	267	652 &	652	R: ARTHRITIS PSORIATICA S: 筋骨格系および結合組織障害 P: 乾癬性関節症 L: Psoriatic arthritis	O: YES	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, PHYSIOTHERAPY, DISCONTINUED STUDY)	S: YES, Hospitalization or prolonged hospitalization O: SECONDARY LOSS OFF EFFICACY A: NO REASONABLE POSSIBILITY
		POST	718 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.
& Date is estimated.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	Epoch Name	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	248	R: APICAL MYOCARDIAL INFARCTION S: 心臓障害 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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	238	R: STRUMA NODOSA-ENLARGED THYROID GLAND S: 内分泌障害 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

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

Subject Number	Name	Epoch	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	156		R: ACUTE KIDNEY INJURY AND BACTERIEMIA S: 感染症および寄生虫症 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

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

Subject Number	Name	Epoch	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	156	R: ACUTE KIDNEY INJURY AND BACTERIEMIA S: 腎および尿路障害 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	158	R: LOWER BACK EPIDURAL ABSCESS S: 感染症および寄生虫症 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

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

Subject Number	Name	Epoch	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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: 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） 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:98.88 KG								
	PRE	TO -1							
	BLIND	1 TO 393							
	OL	394 TO 646+	239	632	632	R: OVARIAN CANCER S: 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） P: 卵巣癌 L: Ovarian cancer	O: YES	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Important medical or surgical intervention, Life threatening O: UNKNOWN ETIOLOGY A: NO REASONABLE POSSIBILITY E: NO

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 is ongoing.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	57	R: ECTOPIC PREGNANCY S: 妊娠、産褥および周産期の状態 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted]([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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	115 115	R: SYSTEMIC INFLAMMATORY RESPONSE SYNDROME S: 一般・全身障害および投与部位の状態 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([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: 感染症および寄生虫症 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

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

Subject Number	Epoch Name	Epoch Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	345 173	R: PULMONARY INFECTION S: 感染症および寄生虫症 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
	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

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

Subject Number	Epoch Name	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	86	R: WORSENING PSORIATIC ARTHRITIS S: 筋骨格系および結合組織障害 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

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

Subject Number	Name	Epoch Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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 768	43	428	260	R: LEFT FACIAL NERVE PALSY S: 神経系障害 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.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- RX Day of Day	Study Day of UPA Onset	Exposure	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 E: Event Related to COVID-19 Infection?
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 768	212	597	429	R: VIRAL ENTERITIS S: 感染症および寄生虫症 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
	POST	769 TO	1	769	601	R: WORSENING OF BRONCHIAL ASTHEMA S: 呼吸器、胸郭および縦隔障害 P: 喘息 L: Asthma bronchial	E: 775 L: 7 DAYS	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: DUE TO COMMON COLD A: NO REASONABLE POSSIBILITY E: NO

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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	441	R: ANGINA S: 心臓障害 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	60	R: SYMPTOMATIC BRADYCARDIA S: 心臓障害 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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	265	R: LEFT AXIAL ABSCESS S: 感染症および寄生虫症 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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 510	118	510	R: CELLULITIS LEFT LEG, ACUTE RENAL FAILURE S: 感染症および寄生虫症 P: 蜂巣炎 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

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

Subject Number	Name	Epoch	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	510	R: CELLULITIS LEFT LEG, ACUTE RENAL FAILURE S: 腎および尿路障害 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	133	R: KELLGREN LAWRENCE GRADE 4 OSTEOARTHRITIS RIGHT HIP S: 筋骨格系および結合組織障害 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: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, 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

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

Subject Number	Epoch Name	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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: 腎および尿路障害 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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	441	R: GASTROENTERITIS S: 感染症および寄生虫症 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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	441	R: HEMATEMESIS S: 胃腸障害 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

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

Subject Number	Epoch Name	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	161	R: RIGHT KNEE OSTEOARTHRITIS S: 筋骨格系および結合組織障害 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

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

Subject Number	Epoch Name	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	227	R: VIRAL GASTROENTERITIS S: 感染症および寄生虫症 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	27	282	282	R: SEPSIS SECONDARY TO RIGHT LOWER LEG CELLULITIS S: 感染症および寄生虫症 P: 蜂巣炎 L: Cellulitis of leg	O: YES	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 20APR2019 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	27	282	282	R: SEPSIS SECONDARY TO RIGHT LOWER LEG CELLULITIS S: 感染症および寄生虫症 P: 敗血症 L: Sepsis secondary	O: YES	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 20APR2019 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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:63.96 KG

PRE TO -1

BLIND 1 TO 389

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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo to UPA 30 mg QD									
[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:63.96 KG									
	OL	390 TO 477	87	476	314	R: SUICIDE ATTEMPT S: 精神障害 P: 自殺企図 L: Suicide attempt	E: 490 L: 15 DAYS	T: Mild R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Life threatening O: SUBJECT HAD AN ARGUMENT WITH HUSBAND ON THE NIGHT OF SUICIDE ATTEMPT ON [redacted]20[redacted]. STRESS MAY OF CAUSE THE SERIOUS EVENT. A: NO REASONABLE POSSIBILITY E: NO

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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: Placebo to UPA 30 mg QD									
[redacted]	AGE:7[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:63.96 KG					
	POST	478 TO	23	500	338	R: PULMONARY EMBOLISM IN THE LEFT LOWER LOBE POSTERIOR SEGMENTAL S: 呼吸器、胸郭および縦隔障害 P: 肺塞栓症 L: Pulmonary embolism	E: 503 L: 4 DAYS	T: Severe R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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 531	70	462	294	R: CHOLELITHIASIS S: 肝胆道系障害 P: 胆石症 L: Cholelithiasis	E: 466 L: 5 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, 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.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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 531	83	475	307	R: BILIARY DUCT LEAK (PROCEDURAL INJURY) S: 傷害、中毒および処置合併症 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.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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 531	138	530	362	R: LIVER ABSCESS S: 感染症および寄生虫症 P: 肝膿瘍 L: Liver abscess	E: 610 L: 81 DAYS	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: BILIARY SPHINCTEROTOMY A: NO REASONABLE POSSIBILITY
	POST	532 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo to UPA 15 mg QD									
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:95.80 KG								
	PRE	TO -1							
	BLIND	1 TO 391							
	OL	392 TO	204	595	421	R: WORSENING OF BACK PAIN S: 筋骨格系および結合組織障害 P: 背部痛 L: Back pain aggravated	I: YES	T: Moderate R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: HISTORY OF BACK PAIN A: NO REASONABLE POSSIBILITY E: NO

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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	42	R: SYSTEMIC LUPUS ERYTHEMATOSUS S: 筋骨格系および結合組織障害 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

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

Subject Number	Epoch Name	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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 391	28	28	28	R: UNSTABLE ANGINA PECTORIS S: 心臓障害 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
	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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	365	R: CONDYLOMA S: 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） 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

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

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

Subject Number	Name	Epoch	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:82.40 KG								
		OL	392 TO 411	802	802	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia		T: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: NO

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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	456	R: HERPES ZOSTER S: 感染症および寄生虫症 P: 帯状疱疹 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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted] TRT: Placebo to UPA 30 mg QD									
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:60.70 KG								
		PRE	TO -1						
		BLIND	1 TO 391						
		OL	392 TO 234	625	457	R: ACUTE PHARYNGITIS S: 感染症および寄生虫症 P: 咽頭炎 L: Acute pharyngitis	E: 629 L: 5 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: INJURY WITH FISH BORN, BACTERIAL INFECTION. A: NO REASONABLE POSSIBILITY E: NO

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

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

Subject Number	---- Epoch Name	Interval	---- RX Day of Day	Study Day of UPA Onset	Exposure	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 E: Event Related to COVID-19 Infection?
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	281	R: TENDON RUPTURE (RIGHT HAND EXTENSOR TENDON) S: 傷害、中毒および処置合併症 P: 腱断裂 L: Tendon rupture	E: 432 L: 152 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: SURGERY, PLATE REMOVAL	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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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: 感染症および寄生虫症 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

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

Subject Number	Name	Epoch	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	113	R: OVARY CANCER S: 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） P: 卵巣癌 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

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

Subject Number	Epoch Name	Epoch Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	71	R: ADENOCARCINOMA OF PROSTATE GLAND 7 (3 + 4) S: 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） 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:47.90 KG								
		PRE	TO -1						
		BLIND	1 TO 395						
		OL	396 TO 491	17	412	412	R: SPONTANEOUS MISCARRIAGE S: 妊娠、産褥および周産期の状態 P: 自然流産 L: Miscarriage	E: 413 L: 2 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: MULTIPLE (DRUG INTERRUPTED, DRUG WITHDRAWN) O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: YES, Important medical or surgical intervention O: PROBABLE CAUSE OF MISCARRIAGE IS DECOMPENSATION OF TYPE 1 DIABETES

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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:47.90 KG								
	OL	396 TO 491	39	434	434	R: DECOMPENSATION OF TYPE 1 DIABETES S: 代謝および栄養障害 P: 1型糖尿病 L: Type 1 diabetes mellitus	E: 435 L: 2 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: THE DISEASE ITSELF AND POOR CONTROL OF THE DISEASE BY THE PARTICIPANT
	POST	492 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	82		R: RAPID DESTRUCTIVE OSTEOARTHRITIS OF THE HIP S: 筋骨格系および結合組織障害 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:82.10 KG

PRE TO -1

BLIND 1 TO 392

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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: Placebo to UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:82.10 KG								
	OL	393 TO 411	803	635		R: ACUTE DIZZINESS S: 神経系障害 P: 浮動性めまい L: Dizziness	E: 805 L: 3 DAYS	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CONCOMITANT MEDICATION OR THERAPY DISCONTINUED)	S: YES, Hospitalization or prolonged hospitalization O: DEHYDRATION 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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: 腎および尿路障害 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	47	R: RIGHT SIDE FLANK PAIN S: 筋骨格系および結合組織障害 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

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

Subject Number	Epoch Name	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	138	R: ALTERED MENTAL STATUS S: 精神障害 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	138	R: FEVER S: 一般・全身障害および投与部位の状態 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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:111.58 KG								
	PRE	TO -1							
	BLIND	1 TO 392							
	OL	393 TO	113	505	505	R: ACUTE GASTROENTERITIS S: 感染症および寄生虫症 P: 胃腸炎 L: Acute gastroenteritis	E: 515 L: 11 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: INFECTION A: NO REASONABLE POSSIBILITY E: NO

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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD										
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:111.58 KG									
		OL	393 TO	120	512	512	R: ACUTE RENAL FAILURE S: 腎および尿路障害 P: 急性腎障害 L: Acute renal failure	E: 515 L: 4 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, ULTRASOUND RENAL BILATERAL(2 U/S))	S: YES, Hospitalization or prolonged hospitalization O: ACUTE GASTROENTERITIS A: NO REASONABLE POSSIBILITY E: NO

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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:111.58 KG								
		OL	393 TO 120	512	512	R: DEHYDRATION S: 代謝および栄養障害 P: 脱水 L: Dehydration	E: 515 L: 4 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: ACUTE GASTROENTERITIS A: NO REASONABLE POSSIBILITY E: NO
				512	512	R: HYPONATREMIA S: 代謝および栄養障害 P: 低ナトリウム血症 L: Hyponatremia	E: 515 L: 4 DAYS	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: ACUTE GASTROENTERITIS A: NO REASONABLE POSSIBILITY E: NO

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

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

Subject Number	Epoch Name	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	97	R: WORSENING BENIGN PROSTATIC HYPERTROPHY S: 生殖系および乳房障害 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

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

Subject Number	Epoch Name	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	23	R: ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE S: 心臓障害 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

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

Subject Number	Epoch Name	Epoch Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	460	R: LARGE HEMOPNEUMOTHORAX S: 傷害、中毒および処置合併症 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

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

Subject Number	Epoch Name	Epoch Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	460	R: MOTOR VEHICLE ACCIDENT, CERVICAL SPINE FRACTURE, THORACIC SPINE FRACTURE S: 傷害、中毒および処置合併症 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

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

Subject Number	---- Epoch Name	Interval	---- RX Day of Day	Study Day of UPA Onset	Exposure	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 E: Event Related to COVID-19 Infection?
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	460	R: MOTOR VEHICLE ACCIDENT, CERVICAL SPINE FRACTURE, THORACIC SPINE FRACTURE S: 傷害、中毒および処置合併症 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	460		R: MOTOR VEHICLE ACCIDENT, CERVICAL SPINE FRACTURE, THORACIC SPINE FRACTURE S: 傷害、中毒および処置合併症 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	460	R: NON DISPLACED FRACTURE OF BILATERAL PEDICLES OF L3 S: 傷害、中毒および処置合併症 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	299	R: DIVERTICULITS S: 感染症および寄生虫症 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

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

Subject Number	Epoch Name	Epoch Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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 393	177	177	R: PNEUMONIA S: 感染症および寄生虫症 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
	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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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: 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） 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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:81.92 KG

PRE TO -1

BLIND 1 TO 392

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

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

Subject Number	---- Name	Epoch	---- Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo to UPA 15 mg QD									
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:81.92 KG									
	OL	393 TO	121	513	343	R: GASTRITIS S: 胃腸障害 P: 胃炎 L: Gastritis	I: YES	T: Mild 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: NO REASONABLE POSSIBILITY, DUE TO NSAID USE 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	88	R: DIZZINESS, DIFFICULTY TO SPEAK, DISORIENTED, PATIENT FELL S: 傷害、中毒および処置合併症 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

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

Subject Number	Name	Epoch	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	88	R: DIZZINESS, DIFFICULTY TO SPEAK, DISORIENTED, PATIENT FELL S: 神経系障害 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: 神経系障害 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	88	R: DIZZINESS, DIFFICULTY TO SPEAK, DISORIENTED, PATIENT FELL S: 精神障害 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

INV: [redacted] ([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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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: 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） 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

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

Subject Number	Name	Epoch	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	366 366	R: VIRAL GASTROENTEROCOLITIS S: 感染症および寄生虫症 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

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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:106.70 KG								
	OL	393 TO 332		724	724	R: WORSENING OF PSORIATIC ARTHRITIS S: 筋骨格系および結合組織障害 P: 乾癬性関節症 L: Psoriatic arthritis aggravated		T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: THIS EVENT IS CAUSED BY PROGRESSION OF THE PRIMARY DISEASE,THE CAUSAL RELATIONSHIP BETWEEN THE EVENT AND THE STUDY DRUG WAS ASSESSED AS UNRELATED. A: NO REASONABLE POSSIBILITY E: NO

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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	118	R: DRUG INDUCED PNEUMONIA S: 感染症および寄生虫症 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:64.80 KG								
		PRE	TO -1						
		BLIND	1 TO 385	385	385	385	R: PNEUMONIA INFLUENZAL S: 感染症および寄生虫症 P: インフルエンザ性肺炎 L: Pneumonia influenzal	T: Moderate R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization O: INFLUENZA A VIRUS 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 / E: Event Related to COVID-19 Infection?
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	230 230	R: HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESIONS (CIN2) S: 生殖系および乳房障害 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:98.40 KG								
		PRE	TO -1						
		BLIND	1 TO 392						
		OL	393 TO 357	749	749	R: RIGHT LEG CELLULITIS S: 感染症および寄生虫症 P: 蜂巣炎 L: Cellulitis of leg	E: 767 L: 19 DAYS	T: Moderate R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: NO

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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD									
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:61.90 KG								
	PRE	TO -1							
	BLIND	1 TO 399							
	OL	400 TO	344	743	743	R: CHOLELITHIASIS S: 肝胆道系障害 P: 胆石症 L: Cholelithiasis	E: 743 L: 1 DAY	T: Moderate R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, LAPAROSCOPIC CHOLECYSTECTOMY)	S: YES, Hospitalization or prolonged hospitalization O: MULTIFACTORIAL (FEMALE OLDER THAN 40 YEARS, OVERWEIGHT AND HIGH FAT DIET) A: NO REASONABLE POSSIBILITY E: NO

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

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

Subject Number	Epoch Name	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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: 感染症および寄生虫症 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	111	R: UPPER RESPIRATORY VIRAL ILLNESS S: 感染症および寄生虫症 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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 392	327	327	327	R: UPPER GI BLEED DUE TO DUODENAL ULCERS S: 胃腸障害 P: 出血性十二指腸潰瘍 L: Duodenal ulcer bleeding	E: 338 L: 12 DAYS	T: Severe R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, ENDOSCOPY)	S: YES, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: CONCOMITANT MEDICATIONS 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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: 心臓障害 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

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

Subject Number	Epoch Name	Epoch Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	164 164	R: RENAL LITHIASIS ON THE RIGHT S: 腎および尿路障害 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

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

Subject Number	Name	Epoch	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted]([redacted]) TRT: Placebo to UPA 30 mg QD									
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:112.10 KG								
		PRE	TO -1						
		BLIND	1 TO 390						
		OL	391 TO 409	19	237	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	E: 443 L: 35 DAYS	T: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, 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.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	---- Name	Epoch	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo to UPA 30 mg QD									
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:112.10 KG								
	OL	391 TO	19	409	237	R: SEPSIS S: 感染症および寄生虫症 P: 敗血症 L: Sepsis	E: 443 L: 35 DAYS	T: Life threatening R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization, Life threatening A: REASONABLE POSSIBILITY E: NO

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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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 392	281	281	113	R: WORSENING OF DIABETES MELLITUS S: 代謝および栄養障害 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

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

Subject Number	---- Name	Epoch Interval	---- RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

[redacted]AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:52.70 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	465	R: INTERSTITIAL PNEUMONIA S: 呼吸器、胸郭および縦隔障害 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

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

Subject Number	Epoch Name	Epoch Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo to UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:60.10 KG								
[redacted]	POST	633 TO 1	633	465	R: RIGHT PNEUMOTHORAX S: 呼吸器、胸郭および縦隔障害 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	469	R: PANCYTOPENIA S: 血液およびリンパ系障害 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	469	R: PNEUMOCYSTIS PNEUMONIA S: 感染症および寄生虫症 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

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

Subject Number	Epoch Name	Epoch Interval	RX Day of Day	Study Day of UPA Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	472		R: CYTOMEGALOVIRUS INFECTION S: 感染症および寄生虫症 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	480		R: DUODENAL ULCER S: 胃腸障害 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

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

Subject Number	Name	Epoch	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?

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

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

Subject Number	---- Name	Epoch Interval	---- Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	31	R: SMALL INTESTINAL ULCER S: 胃腸障害 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

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

Subject Number	Name	Epoch	Day	RX Day of Onset	Study Day of UPA Exposure	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 / E: Event Related to COVID-19 Infection?
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	23	R: EXACERBATION OF PSORIATIC ARTHRITIS S: 筋骨格系および結合組織障害 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.
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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted]	AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:125.50 KG								
	PRE	TO -1							
	BLIND	1 TO 392							
	OL	393 TO	370	762	762	R: PERIANAL ABCESS S: 感染症および寄生虫症 P: 肛門膿瘍 L: Perianal abscess		T: Life threatening R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: NO

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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted])									
TRT: UPA 30 mg QD									
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:93.10 KG								
		PRE	TO -1						
		BLIND	1 TO 392						
		OL	393 TO 497						
		POST	498 TO	23	520	520	R: DRUG-INDUCED HEPATITIS S: 肝胆道系障害 P: 薬物性肝障害 L: Drug-induced hepatitis		T: Life threatening R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: YES, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY E: NO

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

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(Safety Analysis Set)

Subject Number	Epoch Name	Epoch Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	156	R: LEFT SIDE ABDOMINAL PAIN RADIATING TO LEFT FLANK UNKNOWN ETIOLOGY, DIARRHEA S: 胃腸障害 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

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

Subject Number	Epoch Name	Interval	RX Day of Day	Study Day of UPA Onset	Exposure	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 E: Event Related to COVID-19 Infection?
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	156	R: LEFT SIDE ABDOMINAL PAIN RADIATING TO LEFT FLANK UNKNOWN ETIOLOGY, DIARRHEA S: 胃腸障害 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.
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Program Source Code: [redacted]

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(Safety Analysis Set)

Subject Number	Epoch Name	Epoch Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	493	R: PAROXYSMAL SUPRAVENTRICULAR TACHYCARDIA S: 心臓障害 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

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

Subject Number	Epoch Name	Epoch Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	161	R: ACUTE BLOOD LOSS ANEMIA S: 血液およびリンパ系障害 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]

TABLE 14.3__2.18.1

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	161		R: ACUTE HYPOXIC RESPIRATORY FAILURE S: 呼吸器、胸郭および縦隔障害 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	161		R: BILATERAL PULMONARY EMBOLI S: 呼吸器、胸郭および縦隔障害 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.
# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3__2.18.1

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	161		R: CARDIOPULMONARY ARREST S: 心臓障害 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

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

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	161	R: EROSIVE GASTRITIS S: 胃腸障害 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	161	R: PNEUMONIA S: 感染症および寄生虫症 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

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

Subject Number	Name	Epoch	Interval	RX Day of Onset	Study Day of UPA Exposure	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 E: Event Related to COVID-19 Infection?
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	161		R: VENTRICULAR FIBRILLATION S: 心臓障害 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 2.7.4.7-103. 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）の治験薬の投与中止に至った有害事象（100 人年あたりの発現状況）

[redacted]
ABT-494 (PSA)
120-DAY SAFETY UPDATE
R&D/20/0773 - CLINICAL/STATISTICAL

TABLE 2.4__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 = 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	64 (6.7) [6.7]	80 (8.5) [8.5]	83 (6.7) [6.7]	98 (7.8) [7.8]
*** Not Coded ***	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
*** Not Coded ***	2 (0.2) [0.2]	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	1 (0.1) [0.1]	7 (0.7) [0.7]	2 (0.2) [0.2]	8 (0.6) [0.6]
貧血	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
失血性貧血	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
白血球減少症	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	0	3 (0.3) [0.3]	0	3 (0.2) [0.2]
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	0	1 (<0.1) [<0.1]	0
心臓障害	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	3 (0.2) [0.2]
心不全	0	0	0	1 (<0.1) [<0.1]
心肺停止	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
うっ血性心筋症	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__3.6

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 = 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.)				
冠動脈狭窄	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
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
胃腸障害	2 (0.2) [0.2]	11 (1.2) [1.2]	2 (0.2) [0.2]	12 (1.0) [1.0]
腹痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
上腹部痛	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
腹水	0	0	0	1 (<0.1) [<0.1]
大腸炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
下痢	0	3 (0.3) [0.3]	0	3 (0.2) [0.2]
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
びらん性胃炎	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
悪心	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
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]

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__3.6

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 = 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.)				
嘔吐	0	1 (0.1) [0.1]	0	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]
インフルエンザ様疾患	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
倦怠感	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
発熱	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	4 (0.3) [0.3]
肝胆道系障害	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	4 (0.3) [0.3]
薬物性肝障害	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肝硬変	0	0	0	1 (<0.1) [<0.1]
肝機能異常	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肝毒性	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
感染症および寄生虫症	16 (1.7) [1.7]	26 (2.8) [2.7]	24 (1.9) [1.9]	29 (2.3) [2.3]
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	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 (0.1) [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__3.6

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 = 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.)				
菌血症	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
体部白癬	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
気管支炎	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
細菌性気管支炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
蜂巣炎	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
コクシジオイデス症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
コロナウイルス感染	0	0	0	1 (<0.1) [<0.1]
憩室炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
毛包炎	0	2 (0.2) [0.2]	0	2 (0.2) [0.2]
陰部ヘルペス	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
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]	2 (0.2) [0.2]	2 (0.2) [0.2]	3 (0.2) [0.2]
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	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
肝膿瘍	0	0	1 (<0.1) [<0.1]	0
下気道感染	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__3.6

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 = 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.)				
肺感染	0	1 (0.1) [0.1]	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 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
肺炎	1 (0.1) [0.1]	3 (0.3) [0.3]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
ウイルス性気道感染	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]	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]	0
気管炎	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
上気道感染	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
尿路感染	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	2 (0.2) [0.2]
細菌性尿路感染	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]
ウイルス性上気道感染	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
臨床検査	7 (0.7) [0.7]	10 (1.1) [1.1]	9 (0.7) [0.7]	12 (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__3.6

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 = 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	0	3 (0.3) [0.3]	0	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	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
血中クレアチンホスホキナーゼ増加	0	3 (0.3) [0.3]	2 (0.2) [0.2]	4 (0.3) [0.3]
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	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
肝酵素上昇	0	2 (0.2) [0.2]	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 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
赤血球数減少	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
トランスアミナーゼ上昇	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
白血球数減少	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
代謝および栄養障害	3 (0.3) [0.3]	0	3 (0.2) [0.2]	0
高血糖	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
低カリウム血症	1 (0.1) [0.1]	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
筋骨格系および結合組織障害	9 (0.9) [0.9]	2 (0.2) [0.2]	10 (0.8) [0.8]	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__3.6

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 = 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.)				
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
骨壊死	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
乾癬性関節症	6 (0.6) [0.6]	1 (0.1) [0.1]	6 (0.5) [0.5]	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
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）	7 (0.7) [0.7]	4 (0.4) [0.4]	10 (0.8) [0.8]	5 (0.4) [0.4]
基底細胞癌	0	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
子宮内膜腺癌	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	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]	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__3.6

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 = 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]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)				
前立腺癌	1 (0.1) [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	2 (0.2) [0.2]	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]
浮動性めまい	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
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
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	1 (0.1) [0.1]	2 (0.2) [0.2]	1 (<0.1) [<0.1]	3 (0.2) [0.2]
うつ病	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
不眠症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
パニック発作	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
自殺企図	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__3.6

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 = 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]
呼吸器、胸郭および縦隔障害	3 (0.3) [0.3]	5 (0.5) [0.5]	3 (0.2) [0.2]	8 (0.6) [0.6]
急性呼吸不全	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
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]
咳嗽	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
気胸	0	0	0	1 (<0.1) [<0.1]
肺塞栓症	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]	2 (0.2) [0.2]
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	5 (0.5) [0.5]	0	8 (0.6) [0.6]	2 (0.2) [0.2]
ざ瘡	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
血管浮腫	0	0	1 (<0.1) [<0.1]	0
水疱	0	0	0	1 (<0.1) [<0.1]
湿疹	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
紅斑	0	0	0	1 (<0.1) [<0.1]
乾癬	1 (0.1) [0.1]	0	2 (0.2) [0.2]	0
発疹	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__3.6

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 = 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
血管障害	1 (0.1) [0.1]	1 (0.1) [0.1]	1 (<0.1) [<0.1]	1 (<0.1) [<0.1]
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]

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 2.7.4.7-104. 投与 56 週時データカットオフまで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，安全性解析対象集団）：M15-572 試験

TABLE 14.3__2.2

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug 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	39 (4.6)	56 (6.6)	47 (7.4)
血液およびリンパ系障害	1 (0.1)	6 (0.7)	0
白血球減少症	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	0	3 (0.4)	0
正色素性貧血	0	1 (0.1)	0
血小板減少症	1 (0.1)	0	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
胃腸障害	2 (0.2)	2 (0.2)	5 (0.8)
上腹部痛	0	0	1 (0.2)
便秘	0	0	1 (0.2)
下痢	1 (0.1)	1 (0.1)	0
穿孔性胃潰瘍	1 (0.1)	0	0
血便排泄	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__2.2

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug 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.)			
口腔内白斑症	0	0	1 (0.2)
悪心	0	1 (0.1)	1 (0.2)
一般・全身障害および投与部位の状態	2 (0.2)	4 (0.5)	5 (0.8)
医薬品副作用	0	0	1 (0.2)
疲労	0	0	1 (0.2)
インフルエンザ様疾患	0	1 (0.1)	0
注射部位過敏反応	0	0	1 (0.2)
注射部位蕁麻疹	0	0	1 (0.2)
倦怠感	1 (0.1)	0	1 (0.2)
発熱	1 (0.1)	3 (0.4)	0
肝胆道系障害	1 (0.1)	2 (0.2)	3 (0.5)
肝機能異常	0	1 (0.1)	1 (0.2)
脂肪肝	0	0	1 (0.2)
肝毒性	1 (0.1)	1 (0.1)	0
門脈血栓症	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__2.2

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug 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)
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	13 (1.5)	23 (2.7)	3 (0.5)
細菌性関節炎	1 (0.1)	0	0
異型肺炎	0	1 (0.1)	0
菌血症	0	1 (0.1)	0
体部白癬	1 (0.1)	0	0
気管支炎	0	2 (0.2)	0
細菌性気管支炎	0	1 (0.1)	0
蜂巣炎	1 (0.1)	1 (0.1)	1 (0.2)
結膜炎	0	1 (0.1)	0
コロナウイルス感染	0	1 (0.1)	0
憩室炎	1 (0.1)	0	0
毛包炎	0	2 (0.2)	0
陰部ヘルペス	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__2.2

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug 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.)			
H1N1インフルエンザ	1 (0.1)	0	0
帯状疱疹	2 (0.2)	2 (0.2)	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
下気道感染	1 (0.1)	0	0
肺感染	0	1 (0.1)	0
上咽頭炎	0	1 (0.1)	0
肺炎	0	1 (0.1)	1 (0.2)
ウイルス性気道感染	0	1 (0.1)	0
サルモネラ症	0	0	1 (0.2)
敗血症	2 (0.2)	0	0
ブドウ球菌性菌血症	0	1 (0.1)	0
ブドウ球菌性敗血症	0	1 (0.1)	0
皮下組織膿瘍	0	1 (0.1)	0
気管炎	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__2.2

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug 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.)			
上気道感染	1 (0.1)	1 (0.1)	0
尿路性敗血症	0	1 (0.1)	0
傷害、中毒および処置合併症	0	0	2 (0.3)
多発性外傷	0	0	1 (0.2)
交通事故	0	0	1 (0.2)
臨床検査	2 (0.2)	4 (0.5)	8 (1.3)
アラニンアミノトランスフェラーゼ増加	0	1 (0.1)	3 (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	3 (0.5)
血中クレアチンホスホキナーゼ増加	2 (0.2)	2 (0.2)	0
肝機能検査値上昇	0	1 (0.1)	0
トランスアミナーゼ上昇	0	0	1 (0.2)
体重増加	0	0	1 (0.2)
筋骨格系および結合組織障害	2 (0.2)	2 (0.2)	4 (0.6)
背部痛	0	0	1 (0.2)
腰部脊柱管狭窄症	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.
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__2.2

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug 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.)			
骨壊死	0	1 (0.1)	0
乾癬性関節症	1 (0.1)	1 (0.1)	3 (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)	6 (0.7)	6 (0.7)	4 (0.6)
結腸腺癌	0	1 (0.1)	0
基底細胞癌	1 (0.1)	1 (0.1)	0
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
肺腺癌	1 (0.1)	1 (0.1)	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)
遠隔転移を伴う膵癌	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__2.2

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug 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.)			
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	2 (0.2)	0	2 (0.3)
筋萎縮性側索硬化症	0	0	1 (0.2)
浮動性めまい	1 (0.1)	0	0
肝性脳症	0	0	1 (0.2)
ラクナ脳卒中	1 (0.1)	0	0
精神障害	1 (0.1)	0	0
不眠症	1 (0.1)	0	0
生殖系および乳房障害	0	0	2 (0.3)
無月経	0	0	1 (0.2)
良性前立腺肥大症	0	0	1 (0.2)
呼吸器、胸郭および縦隔障害	1 (0.1)	4 (0.5)	1 (0.2)
慢性閉塞性肺疾患	0	1 (0.1)	0
肺塞栓症	1 (0.1)	2 (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 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__2.2

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug 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.)			
肺線維症	0	1 (0.1)	0
肺腫瘤	0	0	1 (0.2)
皮膚および皮下組織障害	4 (0.5)	2 (0.2)	7 (1.1)
脱毛症	0	0	2 (0.3)
血管浮腫	1 (0.1)	0	0
水疱	0	1 (0.1)	0
皮膚炎	0	0	1 (0.2)
湿疹	1 (0.1)	0	0
紅斑	0	1 (0.1)	0
乾癬	0	0	3 (0.5)
膿疱性乾癬	0	0	1 (0.2)
発疹	1 (0.1)	0	0
皮膚病変	1 (0.1)	0	0
血管障害	1 (0.1)	0	1 (0.2)
深部静脈血栓症	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.
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__2.2

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug 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)
血管障害 (Cont.)			
血管炎	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]

表 2.7.4.7-105. 投与 56 週時データカットオフまで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，安全性解析対象集団）：M15-554 試験

TABLE 14.3__2.2

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug 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	42 (10.0)	47 (11.1)
血液およびリンパ系障害	1 (0.2)	2 (0.5)
貧血	0	1 (0.2)
失血性貧血	1 (0.2)	0
汎血球減少症	0	1 (0.2)
心臓障害	2 (0.5)	2 (0.5)
心不全	0	1 (0.2)
心肺停止	1 (0.2)	0
冠動脈狭窄	0	1 (0.2)
心室細動	1 (0.2)	0
胃腸障害	1 (0.2)	10 (2.4)
腹痛	0	1 (0.2)
上腹部痛	0	1 (0.2)
腹水	0	1 (0.2)
大腸炎	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.
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__2.2

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug 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.)		
下痢	0	2 (0.5)
胃出血	0	1 (0.2)
びらん性胃炎	1 (0.2)	0
小腸出血	0	1 (0.2)
小腸潰瘍	0	1 (0.2)
嘔吐	0	1 (0.2)
一般・全身障害および投与部位の状態	0	1 (0.2)
発熱	0	1 (0.2)
肝胆道系障害	0	2 (0.5)
薬物性肝障害	0	1 (0.2)
肝硬変	0	1 (0.2)
感染症および寄生虫症	11 (2.6)	9 (2.1)
膿瘍	1 (0.2)	0
四肢膿瘍	0	1 (0.2)
肛門膿瘍	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.
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__2.2

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug 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	1 (0.2)	0
蜂巣炎	0	1 (0.2)
コクシジオイデス症	1 (0.2)	0
憩室炎	0	1 (0.2)
帯状疱疹	0	2 (0.5)
肝膿瘍	1 (0.2)	0
肺感染	1 (0.2)	0
レンサ球菌性咽頭炎	1 (0.2)	0
肺炎	1 (0.2)	2 (0.5)
尿路感染	1 (0.2)	2 (0.5)
細菌性尿路感染	1 (0.2)	0
ウイルス性上気道感染	1 (0.2)	0
臨床検査	7 (1.7)	8 (1.9)
アラニンアミノトランスフェラーゼ増加	0	2 (0.5)
アスパラギン酸アミノトランスフェラーゼ増加	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.
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__2.2

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug 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)
臨床検査 (Cont.)		
血中クレアチンホスホキナーゼ増加	0	2 (0.5)
ヘマトクリット減少	1 (0.2)	0
ヘモグロビン減少	1 (0.2)	1 (0.2)
肝酵素上昇	0	2 (0.5)
リンパ球数減少	1 (0.2)	0
赤血球数減少	1 (0.2)	0
トランスアミナーゼ上昇	1 (0.2)	0
白血球数減少	2 (0.5)	0
代謝および栄養障害	3 (0.7)	0
高血糖	1 (0.2)	0
低カリウム血症	1 (0.2)	0
低ナトリウム血症	1 (0.2)	0
筋骨格系および結合組織障害	7 (1.7)	1 (0.2)
乾癬性関節症	5 (1.2)	1 (0.2)
急速進行性変形性関節症	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.
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__2.2

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug 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 (Cont.)		
全身性エリテマトーデス	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）	5 (1.2)	2 (0.5)
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	1 (0.2)	0
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	0	1 (0.2)
頭痛	0	1 (0.2)
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	3 (0.7)
うつ病	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.
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__2.2

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug 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)
精神障害 (Cont.)		
パニック発作	0	1 (0.2)
自殺企図	0	1 (0.2)
呼吸器、胸郭および縦隔障害	2 (0.5)	4 (0.9)
急性呼吸不全	1 (0.2)	0
喘息	0	1 (0.2)
慢性閉塞性肺疾患	0	1 (0.2)
咳嗽	0	1 (0.2)
気胸	0	1 (0.2)
肺塞栓症	1 (0.2)	0
皮膚および皮下組織障害	3 (0.7)	0
ざ瘡	1 (0.2)	0
乾癬	2 (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 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/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 2.7.4.7-106. 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__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 = 921) 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	394/517.8 (76.1) [76.2]	429/458.3 (93.6) [93.7]	528/698.3 (75.6) [75.6]	565/645.9 (87.5) [87.5]	213/351.4 (60.6)	17.6 (5.9, 29.2)	11.9 (2.2, 21.5)
Any serious infections	20/938.9 (2.1) [2.1]	41/927.3 (4.4) [4.4]	27/1233.9 (2.2) [2.2]	57/1229.5 (4.6) [4.6]	6/546.3 (1.1)	2.3 (0.6, 3.9)	2.4 (1.0, 3.9)
Any opportunistic infection excluding tuberculosis and herpes zoster	3/949.8 (0.3) [0.3]	6/943.4 (0.6) [0.6]	5/1243.2 (0.4) [0.4]	8/1254.9 (0.6) [0.6]	0/549.7	0.3 (-0.3, 0.9)	0.2 (-0.3, 0.8)
Any herpes zoster	29/931.6 (3.1) [3.1]	50/904.0 (5.5) [5.5]	42/1220.5 (3.4) [3.4]	72/1196.6 (6.0) [6.0]	3/547.3 (0.5)	2.4 (0.5, 4.3)	2.6 (0.8, 4.3)
Any active tuberculosis	0/951.5	0/945.4	0/1247.2	0/1257.4	0/549.7	0.0	0.0
Any possible malignancy	14/943.1 (1.5) [1.5]	14/938.3 (1.5) [1.5]	19/1237.1 (1.5) [1.5]	17/1249.0 (1.4) [1.4]	7/546.8 (1.3)	0.0 (-1.1, 1.1)	-0.2 (-1.1, 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__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 = 921) 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	12/945.5 (1.3) [1.3]	13/939.2 (1.4) [1.4]	17/1239.5 (1.4) [1.4]	16/1249.8 (1.3) [1.3]	6/548.3 (1.1)	0.1 (-0.9, 1.2)	-0.1 (-1.0, 0.8)
Any non-melanoma skin cancer (NMSC)	5/945.8 (0.5) [0.5]	6/940.6 (0.6) [0.6]	9/1239.9 (0.7) [0.7]	7/1252.0 (0.6) [0.6]	2/548.8 (0.4)	0.1 (-0.6, 0.8)	-0.2 (-0.8, 0.5)
Any malignancy other than NMSC	7/951.2 (0.7) [0.7]	8/943.1 (0.8) [0.9]	9/1246.7 (0.7) [0.7]	10/1254.4 (0.8) [0.8]	4/549.1 (0.7)	0.1 (-0.7, 0.9)	0.1 (-0.6, 0.8)
Any lymphoma	1/949.0 (0.1) [0.1]	0/945.4	2/1243.8 (0.2) [0.2]	0/1257.4	0/549.7	-0.1 (-0.3, 0.1)	-0.2 (-0.4, 0.1)
Any hepatic disorder	73/878.8 (8.3) [8.4]	103/834.3 (12.3) [12.3]	99/1149.7 (8.6) [8.6]	134/1123.9 (11.9) [11.9]	87/472.4 (18.4)	4.0 (0.9, 7.0)	3.3 (0.6, 5.9)
Any adjudicated gastrointestinal perforation	1/951.4 (0.1) [0.1]	0/945.4	1/1247.1 (<0.1) [<0.1]	0/1257.4	0/549.7	-0.1 (-0.3, 0.1)	-0.1 (-0.2, 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, 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__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 = 921) 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 anemia	20/935.4 (2.1) [2.1]	44/903.3 (4.9) [4.9]	23/1230.0 (1.9) [1.9]	56/1207.7 (4.6) [4.6]	8/541.2 (1.5)	2.7 (1.0, 4.5)	2.8 (1.3, 4.2)
Any neutropenia	15/934.5 (1.6) [1.6]	39/908.5 (4.3) [4.3]	19/1227.9 (1.5) [1.5]	48/1214.9 (4.0) [4.0]	18/531.2 (3.4)	2.7 (1.1, 4.2)	2.4 (1.1, 3.7)
Any lymphopenia	15/937.1 (1.6) [1.6]	25/915.5 (2.7) [2.7]	16/1231.5 (1.3) [1.3]	27/1225.1 (2.2) [2.2]	1/549.6 (0.2)	1.1 (-0.2, 2.5)	0.9 (-0.1, 2.0)
Any creatine phosphokinase (CPK) elevation	69/872.8 (7.9) [7.9]	92/830.1 (11.1) [11.1]	84/1155.5 (7.3) [7.3]	119/1118.3 (10.6) [10.6]	31/516.4 (6.0)	3.1 (0.2, 6.1)	3.4 (0.9, 5.8)
Any renal dysfunction	3/949.1 (0.3) [0.3]	3/945.4 (0.3) [0.3]	3/1244.8 (0.2) [0.2]	3/1257.4 (0.2) [0.2]	0/549.7	0.0 (-0.5, 0.5)	-0.0 (-0.4, 0.4)
Any adjudicated MACE*	4/947.5 (0.4) [0.4]	2/943.3 (0.2) [0.2]	4/1243.2 (0.3) [0.3]	3/1255.3 (0.2) [0.2]	3/548.6 (0.5)	-0.2 (-0.7, 0.3)	-0.1 (-0.5, 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.

Program Source Code: [redacted]

[redacted]

TABLE 2.4__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 = 921) 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 adjudicated VTE**	4/950.3 (0.4) [0.4]	2/945.4 (0.2) [0.2]	4/1245.9 (0.3) [0.3]	3/1257.4 (0.2) [0.2]	2/547.0 (0.4)	-0.2 (-0.7, 0.3)	-0.1 (-0.5, 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.
** VTE: Venous thromboembolic events, defined as deep vein thrombosis (DVT) and pulmonary embolism (PE) (fatal and non-fatal).

Program Source Code: [redacted]

表 2.7.4.7-107.　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，日本人部分集団）

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	13/9.2 (141.3) [140.6]	17/9.5 (178.9) [180.8]	15/15.7 (95.5) [95.0]	24/11.5 (208.7) [211.5]	1/6.1 (16.4)	40.2 (-75.0, 155.4)	116.6 (18.9, 214.3)
Any serious infections	1/25.1 (4.0) [3.7]	6/26.0 (23.1) [23.8]	1/33.6 (3.0) [2.7]	9/36.2 (24.9) [26.2]	0/6.6	20.1 (-0.4, 40.6)	23.5 (5.5, 41.5)
Any opportunistic infection excluding tuberculosis and herpes zoster	0/26.7	0/29.3	0/35.2	1/40.1 (2.5) [2.7]	0/6.6	0.0	2.7 (-2.6, 8.0)
Any herpes zoster	3/23.9 (12.6) [11.7]	7/25.6 (27.3) [27.5]	3/32.3 (9.3) [8.5]	8/36.3 (22.0) [22.3]	0/6.6	15.8 (-8.6, 40.2)	13.8 (-4.6, 32.1)
Any active tuberculosis	0/26.7	0/29.3	0/35.2	0/40.1	0/6.6	0.0	0.0
Any possible malignancy	0/26.7	1/29.3 (3.4) [3.7]	0/35.2	1/40.2 (2.5) [2.7]	1/6.1 (16.4)	3.7 (-3.5, 10.9)	2.7 (-2.6, 8.0)

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	0/26.7	1/29.3 (3.4) [3.7]	0/35.2	1/40.2 (2.5) [2.7]	1/6.1 (16.4)	3.7 (-3.5, 10.9)	2.7 (-2.6, 8.0)
Any non-melanoma skin cancer (NMSC)	0/26.7	0/29.3	0/35.2	0/40.1	0/6.6	0.0	0.0
Any malignancy other than NMSC	0/26.7	1/29.3 (3.4) [3.7]	0/35.2	1/40.2 (2.5) [2.7]	1/6.1 (16.4)	3.7 (-3.5, 10.9)	2.7 (-2.6, 8.0)
Any lymphoma	1/24.2 (4.1) [3.9]	0/29.3	2/31.8 (6.3) [5.8]	0/40.1	0/6.6	-3.9 (-11.4, 3.7)	-5.8 (-13.9, 2.2)
Any hepatic disorder	4/22.0 (18.2) [23.3]	3/26.5 (11.3) [12.7]	5/28.7 (17.4) [20.9]	5/35.6 (14.0) [15.7]	1/5.7 (17.5)	-10.7 (-38.6, 17.3)	-5.3 (-28.9, 18.4)
Any adjudicated gastrointestinal perforation	0/26.7	0/29.3	0/35.2	0/40.1	0/6.6	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 anemia	1/25.2 (4.0) [3.6]	2/24.9 (8.0) [9.0]	1/33.7 (3.0) [2.7]	3/35.1 (8.5) [9.5]	0/6.6	5.4 (-8.9, 19.7)	6.8 (-5.1, 18.8)
Any neutropenia	1/24.2 (4.1) [4.0]	1/27.2 (3.7) [3.4]	1/32.7 (3.1) [2.9]	1/38.1 (2.6) [2.3]	0/6.6	-0.7 (-10.9, 9.6)	-0.6 (-7.9, 6.6)
Any lymphopenia	1/24.7 (4.0) [3.9]	2/26.0 (7.7) [7.4]	1/33.2 (3.0) [2.9]	3/35.9 (8.4) [7.7]	0/6.6	3.5 (-9.3, 16.3)	4.8 (-5.6, 15.2)
Any creatine phosphokinase (CPK) elevation	2/22.9 (8.7) [10.0]	6/19.9 (30.2) [29.3]	4/28.7 (13.9) [14.6]	6/30.7 (19.5) [19.1]	1/5.0 (20.0)	19.3 (-8.3, 46.8)	4.4 (-16.7, 25.6)
Any renal dysfunction	0/26.7	0/29.3	0/35.2	0/40.1	0/6.6	0.0	0.0
Any adjudicated MACE*	0/26.7	0/29.3	0/35.2	1/40.2 (2.5) [2.7]	0/6.6	0.0	2.7 (-2.6, 8.0)

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.

Program Source Code: [redacted]

[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 adjudicated VTE**	0/26.7	0/29.3	0/35.2	0/40.1	0/6.6	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.
** VTE: Venous thromboembolic events, defined as deep vein thrombosis (DVT) and pulmonary embolism (PE) (fatal and non-fatal).

Program Source Code: [redacted]

表 2.7.4.7-108. 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）の重篤な感染症の発現状況（100 人年あたりの発現件数）

TABLE 2.4__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 = 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	20 (2.1) [2.1]	46 (4.9) [4.9]	29 (2.3) [2.3]	65 (5.2) [5.2]
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

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__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 = 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.)				
硬膜外膿瘍	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
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]

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__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 = 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.)				
レンサ球菌性肺炎	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]
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]
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 (0.1) [0.1]	0	1 (<0.1) [<0.1]
肛門性器疣贅	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]

表 2.7.4.7-109. 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]
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TABLE 2.4__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)

	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	3 (0.3) [0.3]	7 (0.7) [0.7]	5 (0.4) [0.4]	11 (0.9) [0.9]
感染症および寄生虫症	3 (0.3) [0.3]	7 (0.7) [0.7]	5 (0.4) [0.4]	11 (0.9) [0.9]
気管支肺アスペルギルス症	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
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]
コクシジオイデス症	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]
食道カンジダ症	0	0	1 (<0.1) [<0.1]	0
口腔真菌感染	0	2 (0.2) [0.2]	0	4 (0.3) [0.3]
中咽頭カンジダ症	0	2 (0.2) [0.2]	1 (<0.1) [<0.1]	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.
E/100 PYs = Events per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-110. 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）の帯状疱疹の発現状況（100 人年あたりの発現件数）

TABLE 2.4__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 = 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	33 (3.5) [3.5]	59 (6.2) [6.2]	48 (3.8) [3.8]	84 (6.7) [6.7]
感染症および寄生虫症	31 (3.3) [3.3]	52 (5.5) [5.5]	44 (3.5) [3.5]	75 (6.0) [6.0]
陰部帯状疱疹	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
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]
神経系障害	2 (0.2) [0.2]	7 (0.7) [0.7]	4 (0.3) [0.3]	9 (0.7) [0.7]
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]

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 2.7.4.7-111. 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）の活動性結核の発現状況（100 人年あたりの発現件数）

[redacted]
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TABLE 2.4__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			
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	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 2.7.4.7-112. 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）の悪性腫瘍の発現状況（100 人年あたりの発現被験者数）

[redacted]
ABT-494 (PSA)
120-DAY SAFETY UPDATE
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TABLE 2.4__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 = 921) n/PYs (n/100 PYs) [SSA n/100 PYs]
Any Adverse Event	12/945.5 (1.3) [1.3]	13/939.2 (1.4) [1.4]	17/1239.5 (1.4) [1.4]	16/1249.8 (1.3) [1.3]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	12/945.5 (1.3) [1.3]	13/939.2 (1.4) [1.4]	17/1239.5 (1.4) [1.4]	16/1249.8 (1.3) [1.3]
基底細胞癌	3/948.0 (0.3) [0.3]	4/942.0 (0.4) [0.4]	7/1242.1 (0.6) [0.6]	5/1253.3 (0.4) [0.4]
基底扁平上皮癌	0/951.5	1/944.6 (0.1) [0.1]	0/1247.2	1/1256.5 (<0.1) [<0.1]
ボーエン病	0/951.5	1/944.9 (0.1) [0.1]	0/1247.2	1/1256.9 (<0.1) [<0.1]
乳癌	0/951.5	1/945.3 (0.1) [0.1]	0/1247.2	1/1257.3 (<0.1) [<0.1]
子宮内膜腺癌	1/951.5 (0.1) [0.1]	0/945.4	1/1247.1 (<0.1) [<0.1]	0/1257.4
子宮内膜癌	0/951.5	1/945.5 (0.1) [0.1]	0/1247.2	1/1257.4 (<0.1) [<0.1]
肺腺癌	0/951.5	1/945.4 (0.1) [0.1]	0/1247.2	1/1257.4 (<0.1) [<0.1]
遠隔転移を伴う肺癌	1/951.5 (0.1) [0.1]	0/945.4	1/1247.1 (<0.1) [<0.1]	0/1257.4
悪性黒色腫	0/951.5	1/944.2 (0.1) [0.1]	1/1247.1 (<0.1) [<0.1]	1/1256.1 (<0.1) [<0.1]
悪性黒色腫第3期	1/951.5 (0.1) [0.1]	0/945.4	1/1247.2 (<0.1) [<0.1]	0/1257.4
神経内分泌癌	1/951.5 (0.1) [0.1]	0/945.4	1/1247.1 (<0.1) [<0.1]	0/1257.4
中咽頭扁平上皮癌	0/951.5	1/945.4 (0.1) [0.1]	0/1247.2	1/1257.3 (<0.1) [<0.1]
卵巣癌	1/951.4 (0.1) [0.1]	1/945.4 (0.1) [0.1]	1/1247.1 (<0.1) [<0.1]	1/1257.4 (<0.1) [<0.1]
形質細胞性骨髄腫	0/951.5	1/945.3 (0.1) [0.1]	0/1247.2	1/1257.3 (<0.1) [<0.1]
前立腺癌	1/951.5 (0.1) [0.1]	0/945.4	2/1247.1 (0.2) [0.2]	0/1257.4
直腸腺癌	0/951.5	1/945.3 (0.1) [0.1]	0/1247.2	1/1257.3 (<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]

TABLE 2.4__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 = 921) n/PYs (n/100 PYs) [SSA n/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.)				
直腸癌	1/951.5 (0.1) [0.1]	0/945.4	1/1247.1 (<0.1) [<0.1]	0/1257.4
腎癌	0/951.5	0/945.4	0/1247.2	1/1257.4 (<0.1) [<0.1]
扁平上皮癌	0/951.5	0/945.4	0/1247.2	1/1256.6 (<0.1) [<0.1]
皮膚有棘細胞癌	3/949.2 (0.3) [0.3]	1/944.6 (0.1) [0.1]	3/1244.8 (0.2) [0.2]	1/1256.5 (<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 2.7.4.7-113. 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__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 = 921) n/PYs (n/100 PYs) [SSA n/100 PYs]
Any Adverse Event	7/951.2 (0.7) [0.7]	8/943.1 (0.8) [0.9]	9/1246.7 (0.7) [0.7]	10/1254.4 (0.8) [0.8]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	7/951.2 (0.7) [0.7]	8/943.1 (0.8) [0.9]	9/1246.7 (0.7) [0.7]	10/1254.4 (0.8) [0.8]
基底扁平上皮癌	0/951.5	1/944.6 (0.1) [0.1]	0/1247.2	1/1256.5 (<0.1) [<0.1]
乳癌	0/951.5	1/945.3 (0.1) [0.1]	0/1247.2	1/1257.3 (<0.1) [<0.1]
子宮内膜腺癌	1/951.5 (0.1) [0.1]	0/945.4	1/1247.1 (<0.1) [<0.1]	0/1257.4
子宮内膜癌	0/951.5	1/945.5 (0.1) [0.1]	0/1247.2	1/1257.4 (<0.1) [<0.1]
肺腺癌	0/951.5	1/945.4 (0.1) [0.1]	0/1247.2	1/1257.4 (<0.1) [<0.1]
遠隔転移を伴う肺癌	1/951.5 (0.1) [0.1]	0/945.4	1/1247.1 (<0.1) [<0.1]	0/1257.4
悪性黒色腫	0/951.5	1/944.2 (0.1) [0.1]	1/1247.1 (<0.1) [<0.1]	1/1256.1 (<0.1) [<0.1]
悪性黒色腫第3期	1/951.5 (0.1) [0.1]	0/945.4	1/1247.2 (<0.1) [<0.1]	0/1257.4
神経内分泌癌	1/951.5 (0.1) [0.1]	0/945.4	1/1247.1 (<0.1) [<0.1]	0/1257.4
中咽頭扁平上皮癌	0/951.5	1/945.4 (0.1) [0.1]	0/1247.2	1/1257.3 (<0.1) [<0.1]
卵巣癌	1/951.4 (0.1) [0.1]	1/945.4 (0.1) [0.1]	1/1247.1 (<0.1) [<0.1]	1/1257.4 (<0.1) [<0.1]
形質細胞性骨髄腫	0/951.5	1/945.3 (0.1) [0.1]	0/1247.2	1/1257.3 (<0.1) [<0.1]
前立腺癌	1/951.5 (0.1) [0.1]	0/945.4	2/1247.1 (0.2) [0.2]	0/1257.4
直腸腺癌	0/951.5	1/945.3 (0.1) [0.1]	0/1247.2	1/1257.3 (<0.1) [<0.1]
直腸癌	1/951.5 (0.1) [0.1]	0/945.4	1/1247.1 (<0.1) [<0.1]	0/1257.4
腎癌	0/951.5	0/945.4	0/1247.2	1/1257.4 (<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]

TABLE 2.4__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 = 921) n/PYs (n/100 PYs) [SSA n/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.)				
扁平上皮癌	0/951.5	0/945.4	0/1247.2	1/1256.6 (<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 2.7.4.7-114. 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 NMSC の発現状況（100 人年あたりの発現被験者数）

[redacted]
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TABLE 2.4__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)

	Upadacitinib			
System Organ Class MedDRA 22.0 Preferred Term	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 = 921) n/PYs (n/100 PYs) [SSA n/100 PYs]
Any Adverse Event	5/945.8 (0.5) [0.5]	6/940.6 (0.6) [0.6]	9/1239.9 (0.7) [0.7]	7/1252.0 (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）	5/945.8 (0.5) [0.5]	6/940.6 (0.6) [0.6]	9/1239.9 (0.7) [0.7]	7/1252.0 (0.6) [0.6]
基底細胞癌	3/948.0 (0.3) [0.3]	4/942.0 (0.4) [0.4]	7/1242.1 (0.6) [0.6]	5/1253.3 (0.4) [0.4]
ボーエン病	0/951.5	1/944.9 (0.1) [0.1]	0/1247.2	1/1256.9 (<0.1) [<0.1]
皮膚有棘細胞癌	3/949.2 (0.3) [0.3]	1/944.6 (0.1) [0.1]	3/1244.8 (0.2) [0.2]	1/1256.5 (<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 2.7.4.7-115. 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)
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TABLE 2.4__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)

	Upadacitinib			
System Organ Class MedDRA 22.0 Preferred Term	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 = 921) n/PYs (n/100 PYs) [SSA n/100 PYs]
Any Adverse Event	1/949.0 (0.1) [0.1]	0/945.4	2/1243.8 (0.2) [0.2]	0/1257.4
臨床検査	1/949.0 (0.1) [0.1]	0/945.4	2/1243.8 (0.2) [0.2]	0/1257.4
リンパ球形態異常	1/949.0 (0.1) [0.1]	0/945.4	2/1243.8 (0.2) [0.2]	0/1257.4

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.
n/100 PYs = Number of subjects with at least one event per 100 patient-years; SSA = Study size adjusted.

Program Source Code: [redacted]

表 2.7.4.7-116. 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__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 = 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	136 (14.3) [14.3]	183 (19.4) [19.3]	169 (13.6) [13.5]	234 (18.6) [18.6]
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	22 (2.3) [2.3]	41 (4.3) [4.3]	33 (2.6) [2.6]	52 (4.1) [4.1]
薬物性肝障害	0	3 (0.3) [0.3]	0	4 (0.3) [0.3]
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]
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]
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]

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__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 = 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]
脂肪性肝炎	2 (0.2) [0.2]	0	2 (0.2) [0.2]	0
臨床検査	114 (12.0) [12.0]	142 (15.0) [15.0]	136 (10.9) [10.9]	180 (14.3) [14.3]
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]
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]
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]
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]
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]
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]
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	0	1 (<0.1) [<0.1]
肝臓血管腫	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 2.7.4.7-117. 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）の消化管穿孔の発現状況（100 人年あたりの発現件数）

[redacted]

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TABLE 2.4__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)

	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	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]	0
胃腸障害	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

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 2.7.4.7-118. 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）の貧血の発現状況（100 人年あたりの発現件数）

[redacted]

TABLE 2.4__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 = 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	25 (2.6) [2.6]	55 (5.8) [5.8]	28 (2.2) [2.2]	70 (5.6) [5.6]
血液およびリンパ系障害	19 (2.0) [2.0]	39 (4.1) [4.1]	22 (1.8) [1.8]	47 (3.7) [3.7]
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]
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]
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]
正色素性貧血	0	1 (0.1) [0.1]	0	1 (<0.1) [<0.1]
臨床検査	6 (0.6) [0.6]	16 (1.7) [1.7]	6 (0.5) [0.5]	23 (1.8) [1.8]
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]
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]

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 2.7.4.7-119. 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）の好中球減少症の発現状況（100 人年あたりの発現件数）

[redacted]
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TABLE 2.4__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 = 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	18 (1.9) [1.9]	52 (5.5) [5.5]	22 (1.8) [1.8]	64 (5.1) [5.1]
血液およびリンパ系障害	16 (1.7) [1.7]	36 (3.8) [3.8]	20 (1.6) [1.6]	45 (3.6) [3.6]
顆粒球減少症	0	1 (0.1) [0.1]	0	3 (0.2) [0.2]
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]
臨床検査	2 (0.2) [0.2]	16 (1.7) [1.7]	2 (0.2) [0.2]	19 (1.5) [1.5]
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]

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 2.7.4.7-120. 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__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 = 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	26 (2.7) [2.7]	35 (3.7) [3.7]	27 (2.2) [2.2]	38 (3.0) [3.0]
血液およびリンパ系障害	20 (2.1) [2.1]	30 (3.2) [3.2]	21 (1.7) [1.7]	32 (2.5) [2.5]
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]
臨床検査	6 (0.6) [0.6]	5 (0.5) [0.5]	6 (0.5) [0.5]	6 (0.5) [0.5]
リンパ球数減少	6 (0.6) [0.6]	5 (0.5) [0.5]	6 (0.5) [0.5]	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]

表 2.7.4.7-121. 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 CPK 増加の発現状況（100 人年あたりの発現件数）

[redacted]
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TABLE 2.4__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)

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	93 (9.8) [9.8]	139 (14.7) [14.7]	113 (9.1) [9.1]	173 (13.8) [13.8]
臨床検査	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]

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 2.7.4.7-122. 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）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

[redacted]

TABLE 2.5__3.1

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 = 921) n/N_OBS (%) [SSA %]
ALANINE AMINOTRANSFERASE (U/L)				
GRADE 2 (>3.0-5.0 xULN)	21/635 (3.3) [3.3]	36/638 (5.6) [5.6]	32/901 (3.6) [3.5]	50/918 (5.4) [5.4]
GRADE 3 (>5.0-20.0 xULN)	9/635 (1.4) [1.4]	12/638 (1.9) [1.9]	11/901 (1.2) [1.2]	14/918 (1.5) [1.5]
GRADE 4 (>20.0 xULN)	0/635	0/638	0/901	1/918 (0.1) [0.1]
>= GRADE 3	9/635 (1.4) [1.4]	12/638 (1.9) [1.9]	11/901 (1.2) [1.2]	15/918 (1.6) [1.6]
ASPARTATE AMINOTRANSFERASE (U/L)				
GRADE 2 (>3.0-5.0 xULN)	10/635 (1.6) [1.6]	18/637 (2.8) [2.8]	17/901 (1.9) [1.9]	26/917 (2.8) [2.8]
GRADE 3 (>5.0-20.0 xULN)	4/635 (0.6) [0.6]	12/637 (1.9) [1.9]	6/901 (0.7) [0.7]	14/917 (1.5) [1.5]
GRADE 4 (>20.0 xULN)	0/635	1/637 (0.2) [0.2]	0/901	2/917 (0.2) [0.2]
>= GRADE 3	4/635 (0.6) [0.6]	13/637 (2.0) [2.0]	6/901 (0.7) [0.7]	16/917 (1.7) [1.7]

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__3.1

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 = 921) n/N_OBS (%) [SSA %]
ALKALINE PHOSPHATASE (U/L)				
GRADE 2 (>2.5-5.0 xULN)	1/635 (0.2) [0.2]	0/638	1/901 (0.1) [0.1]	1/918 (0.1) [0.1]
GRADE 3 (>5.0-20.0 xULN)	0/635	0/638	0/901	0/918
GRADE 4 (>20.0 xULN)	0/635	0/638	0/901	0/918
>= GRADE 3	0/635	0/638	0/901	0/918
BILIRUBIN (UMOL/L)				
GRADE 2 (>1.5-3.0 xULN)	11/635 (1.7) [1.7]	18/638 (2.8) [2.8]	13/901 (1.4) [1.4]	25/918 (2.7) [2.7]
GRADE 3 (>3.0-10.0 xULN)	1/635 (0.2) [0.2]	0/638	1/901 (0.1) [0.1]	0/918
GRADE 4 (>10.0 xULN)	0/635	0/638	0/901	0/918
>= GRADE 3	1/635 (0.2) [0.2]	0/638	1/901 (0.1) [0.1]	0/918

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__3.1

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 = 921) n/N_OBS (%) [SSA %]
CREATINE KINASE (U/L)				
GRADE 2 (>2.5-5.0 xULN)	62/635 (9.8) [9.8]	91/638 (14.3) [14.2]	85/901 (9.4) [9.4]	114/918 (12.4) [12.4]
GRADE 3 (>5.0-10.0 xULN)	14/635 (2.2) [2.2]	18/638 (2.8) [2.8]	18/901 (2.0) [2.0]	26/918 (2.8) [2.8]
GRADE 4 (>10.0 xULN)	6/635 (0.9) [0.9]	10/638 (1.6) [1.6]	8/901 (0.9) [0.9]	15/918 (1.6) [1.6]
>= GRADE 3	20/635 (3.1) [3.2]	28/638 (4.4) [4.4]	26/901 (2.9) [2.9]	41/918 (4.5) [4.5]
CREATININE (UMOL/L)				
GRADE 2 (>1.5-3.0 xULN OR >1.5-3.0 xBASELINE)	40/635 (6.3) [6.3]	50/638 (7.8) [7.8]	48/901 (5.3) [5.3]	60/918 (6.5) [6.5]
GRADE 3 (>3.0-6.0 xULN OR >3.0 xBASELINE)	1/635 (0.2) [0.2]	2/638 (0.3) [0.3]	1/901 (0.1) [0.1]	4/918 (0.4) [0.4]
GRADE 4 (>6.0 xULN)	2/635 (0.3) [0.3]	2/638 (0.3) [0.3]	2/901 (0.2) [0.2]	2/918 (0.2) [0.2]
>= GRADE 3	3/635 (0.5) [0.5]	4/638 (0.6) [0.6]	3/901 (0.3) [0.3]	6/918 (0.7) [0.7]

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 2.7.4.7-123. 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）の腎機能障害の発現状況（100 人年あたりの発現件数）

[redacted]
ABT-494 (PSA)
120-DAY SAFETY UPDATE
R&D/20/0773 - CLINICAL/STATISTICAL

TABLE 2.4__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)

	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	3 (0.3) [0.3]	3 (0.3) [0.3]	3 (0.2) [0.2]	3 (0.2) [0.2]
腎および尿路障害	3 (0.3) [0.3]	3 (0.3) [0.3]	3 (0.2) [0.2]	3 (0.2) [0.2]
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]
腎機能障害	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]

表 2.7.4.7-124. 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 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__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 = 921) n/PYs (n/100 PYs) [SSA n/100 PYs]
Any Adverse Event	5/947.0 (0.5) [0.5]	7/939.2 (0.7) [0.7]	5/1242.7 (0.4) [0.4]	9/1251.2 (0.7) [0.7]
MACE *	4/947.5 (0.4) [0.4]	2/943.3 (0.2) [0.2]	4/1243.2 (0.3) [0.3]	3/1255.3 (0.2) [0.2]
Cardiovascular death	0/951.5	0/945.4	0/1247.2	0/1257.4
Fatal acute myocardial infarction	0/951.5	0/945.4	0/1247.2	0/1257.4
Sudden cardiac death	0/951.5	0/945.4	0/1247.2	0/1257.4
Heart failure	0/951.5	0/945.4	0/1247.2	0/1257.4
Cardiovascular procedure-related death	0/951.5	0/945.4	0/1247.2	0/1257.4
Death due to cardiovascular hemorrhage	0/951.5	0/945.4	0/1247.2	0/1257.4
Fatal stroke	0/951.5	0/945.4	0/1247.2	0/1257.4
Pulmonary embolism **	0/951.5	0/945.4	0/1247.2	0/1257.4
Venous thrombosis **	0/951.5	0/945.4	0/1247.2	0/1257.4
Non-cardiac/non-neurologic arterial thrombosis	0/951.5	0/945.4	0/1247.2	0/1257.4
Other	0/951.5	0/945.4	0/1247.2	0/1257.4
Non-fatal myocardial infarction	2/948.6 (0.2) [0.2]	2/943.3 (0.2) [0.2]	2/1244.2 (0.2) [0.2]	2/1255.2 (0.2) [0.2]
Non-fatal stroke	2/950.5 (0.2) [0.2]	0/945.4	2/1246.1 (0.2) [0.2]	1/1257.4 (<0.1) [<0.1]
Undetermined/UNK cause of death	0/951.5	0/945.4	0/1247.2	0/1257.4
Undetermined/UNK cause of death	0/951.5	0/945.4	0/1247.2	0/1257.4

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.
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__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 = 921) n/PYs (n/100 PYs) [SSA n/100 PYs]
Other cardiovascular events (non-fatal)	1/951.0 (0.1) [0.1]	5/941.4 (0.5) [0.5]	1/1246.6 (<0.1) [<0.1]	6/1253.3 (0.5) [0.5]
Cardiovascular procedures	1/951.0 (0.1) [0.1]	3/943.0 (0.3) [0.3]	1/1246.6 (<0.1) [<0.1]	3/1254.9 (0.2) [0.2]
Unstable angina requiring hospitalization	0/951.5	0/945.4	0/1247.2	0/1257.4
Hospital based treatment for heart failure	0/951.5	0/945.4	0/1247.2	1/1257.3 (<0.1) [<0.1]
Transient ischemic attack	0/951.5	2/943.8 (0.2) [0.2]	0/1247.2	2/1255.8 (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 2.7.4.7-125. 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）の血栓症の発現状況（100 人年あたりの発現被験者数）

[redacted]

TABLE 2.4__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 = 921) n/PYs (n/100 PYs) [SSA n/100 PYs]
Any Adverse Event	4/950.3 (0.4) [0.4]	2/945.4 (0.2) [0.2]	4/1245.9 (0.3) [0.3]	3/1257.4 (0.2) [0.2]
Venous thromboembolic events (fatal and non-fatal)	4/950.3 (0.4) [0.4]	2/945.4 (0.2) [0.2]	4/1245.9 (0.3) [0.3]	3/1257.4 (0.2) [0.2]
Venous thromboembolic events (fatal) *	0/951.5	0/945.4	0/1247.2	0/1257.4
Pulmonary embolism	0/951.5	0/945.4	0/1247.2	0/1257.4
Venous thrombosis	0/951.5	0/945.4	0/1247.2	0/1257.4
Venous thromboembolic events (non-fatal) **	4/950.3 (0.4) [0.4]	2/945.4 (0.2) [0.2]	4/1245.9 (0.3) [0.3]	3/1257.4 (0.2) [0.2]
Deep vein thrombosis (DVT)	2/950.2 (0.2) [0.2]	0/945.4	2/1245.9 (0.2) [0.2]	0/1257.4
Pulmonary embolism (PE)	3/951.5 (0.3) [0.3]	2/945.4 (0.2) [0.2]	3/1247.2 (0.2) [0.2]	3/1257.4 (0.2) [0.2]
DVT and PE (concurrent)	1/951.5 (0.1) [0.1]	0/945.4	1/1247.1 (<0.1) [<0.1]	0/1257.4
Other venous thrombosis (non-fatal)	0/951.5	0/945.4	0/1247.2	0/1257.4
Other venous thrombosis (non-fatal)	0/951.5	0/945.4	0/1247.2	0/1257.4
Arterial thromboembolic events (non-cardiac, non-neurologic)(non-fatal)	0/951.5	0/945.4	0/1247.2	0/1257.4
Arterial thromboembolic events (non-cardiac, non-neurologic)(non-fatal)	0/951.5	0/945.4	0/1247.2	0/1257.4

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.
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 2.7.4.7-126. 投与 56 週時データカットオフまでの有害事象（100 人年あたりの発現件数，安全性解析対象集団，日本人部分集団）：M15-572 試験

TABLE 14.3__1.2_J

Treatment-Emergent 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 = 6.0) Events (E/100 PYs)	UPA 30 mg QD (N = 6) (PYs = 11.9) Events (E/100 PYs)	ADA 40 mg EOW (N = 4) (PYs = 7.2) Events (E/100 PYs)
Any adverse event	17 (283.3)	36 (302.5)	10 (138.9)
血液およびリンパ系障害	0	2 (16.8)	0
リンパ球減少症	0	1 (8.4)	0
好中球減少症	0	1 (8.4)	0
先天性、家族性および遺伝性障害	0	1 (8.4)	0
2a型高脂血症	0	1 (8.4)	0
胃腸障害	2 (33.3)	4 (33.6)	0
腹痛	0	1 (8.4)	0
慢性胃炎	0	1 (8.4)	0
下痢	0	1 (8.4)	0
悪心	2 (33.3)	1 (8.4)	0
一般・全身障害および投与部位の状態	0	1 (8.4)	1 (13.9)
注射部位反応	0	0	1 (13.9)
発熱	0	1 (8.4)	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__1.2_J

Treatment-Emergent 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 = 6.0) Events (E/100 PYs)	UPA 30 mg QD (N = 6) (PYs = 11.9) Events (E/100 PYs)	ADA 40 mg EOW (N = 4) (PYs = 7.2) Events (E/100 PYs)
肝胆道系障害	1 (16.7)	0	0
肝機能異常	1 (16.7)	0	0
感染症および寄生虫症	6 (100)	10 (84.0)	1 (13.9)
気管支炎	0	1 (8.4)	0
毛包炎	1 (16.7)	0	0
胃腸炎	1 (16.7)	0	0
帯状疱疹	0	2 (16.8)	0
インフルエンザ	1 (16.7)	1 (8.4)	0
上咽頭炎	2 (33.3)	3 (25.2)	1 (13.9)
口腔カンジダ症	0	1 (8.4)	0
トリコフィトン感染症	1 (16.7)	0	0
上気道感染	0	2 (16.8)	0
傷害、中毒および処置合併症	1 (16.7)	0	0
挫傷	1 (16.7)	0	0
臨床検査	2 (33.3)	8 (67.2)	3 (41.7)
アラニンアミノトランスフェラーゼ増加	0	0	1 (13.9)

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__1.2_J

Treatment-Emergent 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 = 6.0) Events (E/100 PYs)	UPA 30 mg QD (N = 6) (PYs = 11.9) Events (E/100 PYs)	ADA 40 mg EOW (N = 4) (PYs = 7.2) 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	0	0	1 (13.9)
血中クレアチンホスホキナーゼ増加	1 (16.7)	2 (16.8)	1 (13.9)
肝機能検査値上昇	1 (16.7)	0	0
リンパ球数減少	0	2 (16.8)	0
骨髄球存在	0	1 (8.4)	0
白血球数減少	0	3 (25.2)	0
代謝および栄養障害	0	1 (8.4)	1 (13.9)
脂質異常症	0	1 (8.4)	0
高トリグリセリド血症	0	0	1 (13.9)
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)	2 (33.3)	0	1 (13.9)
皮膚乳頭腫	2 (33.3)	0	0
子宮癌	0	0	1 (13.9)
神経系障害	1 (16.7)	2 (16.8)	0
頭痛	1 (16.7)	1 (8.4)	0
片頭痛	0	1 (8.4)	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__1.2_J

Treatment-Emergent 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 = 6.0) Events (E/100 PYs)	UPA 30 mg QD (N = 6) (PYs = 11.9) Events (E/100 PYs)	ADA 40 mg EOW (N = 4) (PYs = 7.2) Events (E/100 PYs)
精神障害	0	1 (8.4)	0
不眠症	0	1 (8.4)	0
腎および尿路障害	0	1 (8.4)	0
腎結石症	0	1 (8.4)	0
生殖系および乳房障害	0	0	1 (13.9)
子宮頚管ポリープ	0	0	1 (13.9)
呼吸器、胸郭および縦隔障害	1 (16.7)	1 (8.4)	1 (13.9)
湿性咳嗽	0	0	1 (13.9)
上気道の炎症	1 (16.7)	1 (8.4)	0
皮膚および皮下組織障害	1 (16.7)	2 (16.8)	1 (13.9)
水疱	0	1 (8.4)	0
薬疹	0	1 (8.4)	0
皮膚乾燥	1 (16.7)	0	1 (13.9)
血管障害	0	2 (16.8)	0
起立性低血圧	0	2 (16.8)	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]

表 2.7.4.7-127. 投与 56 週時データカットオフまで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，安全性解析対象集団，日本人部分集団）：M15-572 試験

TABLE 14.3__1.3_J

Treatment-Emergent Adverse Events with Reasonably Possibly of Being Related to Study Drug 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 = 6.0) Events (E/100 PYs)	UPA 30 mg QD (N = 6) (PYs = 11.9) Events (E/100 PYs)	ADA 40 mg EOW (N = 4) (PYs = 7.2) Events (E/100 PYs)
Any adverse event	8 (133.3)	18 (151.3)	3 (41.7)
血液およびリンパ系障害	0	2 (16.8)	0
リンパ球減少症	0	1 (8.4)	0
好中球減少症	0	1 (8.4)	0
胃腸障害	1 (16.7)	0	0
悪心	1 (16.7)	0	0
一般・全身障害および投与部位の状態	0	0	1 (13.9)
注射部位反応	0	0	1 (13.9)
感染症および寄生虫症	4 (66.7)	6 (50.4)	0
気管支炎	0	1 (8.4)	0
胃腸炎	1 (16.7)	0	0
帯状疱疹	0	2 (16.8)	0
インフルエンザ	0	1 (8.4)	0
上咽頭炎	2 (33.3)	0	0
口腔カンジダ症	0	1 (8.4)	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 relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
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__1.3_J

Treatment-Emergent Adverse Events with Reasonably Possibly of Being Related to Study Drug 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 = 6.0) Events (E/100 PYs)	UPA 30 mg QD (N = 6) (PYs = 11.9) Events (E/100 PYs)	ADA 40 mg EOW (N = 4) (PYs = 7.2) Events (E/100 PYs)
感染症および寄生虫症 (Cont.)			
トリコフィトン感染症	1 (16.7)	0	0
上気道感染	0	1 (8.4)	0
臨床検査	1 (16.7)	7 (58.8)	0
血中クレアチンホスホキナーゼ増加	0	1 (8.4)	0
肝機能検査値上昇	1 (16.7)	0	0
リンパ球数減少	0	2 (16.8)	0
骨髄球存在	0	1 (8.4)	0
白血球数減少	0	3 (25.2)	0
代謝および栄養障害	0	1 (8.4)	1 (13.9)
脂質異常症	0	1 (8.4)	0
高トリグリセリド血症	0	0	1 (13.9)
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 (16.7)	0	0
皮膚乳頭腫	1 (16.7)	0	0
呼吸器、胸郭および縦隔障害	1 (16.7)	1 (8.4)	1 (13.9)
湿性咳嗽	0	0	1 (13.9)

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 relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
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__1.3_J

Treatment-Emergent Adverse Events with Reasonably Possibly of Being Related to Study Drug 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 = 6.0) Events (E/100 PYs)	UPA 30 mg QD (N = 6) (PYs = 11.9) Events (E/100 PYs)	ADA 40 mg EOW (N = 4) (PYs = 7.2) Events (E/100 PYs)
呼吸器、胸郭および縦隔障害 (Cont.)			
上気道の炎症	1 (16.7)	1 (8.4)	0
皮膚および皮下組織障害	0	1 (8.4)	0
水疱	0	1 (8.4)	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 relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
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 2.7.4.7-128. 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，日本人部分集団）：M15-572 試験

TABLE 14.3__1.4_J

Treatment-Emergent Severe 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 = 6.0) Events (E/100 PYs)	UPA 30 mg QD (N = 6) (PYs = 11.9) Events (E/100 PYs)	ADA 40 mg EOW (N = 4) (PYs = 7.2) Events (E/100 PYs)
Any adverse event	0	3 (25.2)	3 (41.7)
血液およびリンパ系障害	0	1 (8.4)	0
リンパ球減少症	0	1 (8.4)	0
感染症および寄生虫症	0	2 (16.8)	0
気管支炎	0	1 (8.4)	0
帯状疱疹	0	1 (8.4)	0
臨床検査	0	0	1 (13.9)
血中クレアチンホスホキナーゼ増加	0	0	1 (13.9)
代謝および栄養障害	0	0	1 (13.9)
高トリグリセリド血症	0	0	1 (13.9)
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）	0	0	1 (13.9)
子宮癌	0	0	1 (13.9)

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 2.7.4.7-129. 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，日本人部分集団）：M15-572 試験

[redacted]
ABT-494 (PSA)
STUDY M15-572 - WEEK 56 (DATA CUTOFF - [redacted]20[redacted])
R&D/20/1009 - CLINICAL/STATISTICAL

TABLE 14.3__2.1_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 = 6.0) Events (E/100 PYs)	UPA 30 mg QD (N = 6) (PYs = 11.9) Events (E/100 PYs)	ADA 40 mg EOW (N = 4) (PYs = 7.2) Events (E/100 PYs)
Any adverse event	0	2 (16.8)	1 (13.9)
感染症および寄生虫症	0	2 (16.8)	0
気管支炎	0	1 (8.4)	0
帯状疱疹	0	1 (8.4)	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 (13.9)
子宮癌	0	0	1 (13.9)

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]

表 2.7.4.7-130. 投与 56 週時データカットオフまで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，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 56 (DATA CUTOFF - [redacted]20[redacted])
R&D/20/1009 - CLINICAL/STATISTICAL

TABLE 14.3__2.2_J

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug 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 = 6.0) Events (E/100 PYs)	UPA 30 mg QD (N = 6) (PYs = 11.9) Events (E/100 PYs)	ADA 40 mg EOW (N = 4) (PYs = 7.2) Events (E/100 PYs)
Any adverse event	0	0	1 (13.9)
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)	0	0	1 (13.9)
子宮癌	0	0	1 (13.9)

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]

表 2.7.4.7-131. 投与 56 週時データカットオフまでの有害事象（100 人年あたりの発現件数，安全性解析対象集団，日本人部分集団）：M15-554 試験

TABLE 14.3__1.2_J

Treatment-Emergent 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
Any adverse event	101 (359.4)	159 (580.3)
血液およびリンパ系障害	2 (7.1)	5 (18.2)
貧血	0	1 (3.6)
血球減少症	0	1 (3.6)
播種性血管内凝固	0	1 (3.6)
鉄欠乏性貧血	1 (3.6)	0
リンパ球減少症	0	1 (3.6)
好中球減少症	1 (3.6)	0
汎血球減少症	0	1 (3.6)
心臓障害	2 (7.1)	0
動悸	2 (7.1)	0
耳および迷路障害	1 (3.6)	1 (3.6)
耳不快感	0	1 (3.6)
回転性めまい	1 (3.6)	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/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__1.2_J

Treatment-Emergent 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
眼障害	1 (3.6)	1 (3.6)
眼精疲労	0	1 (3.6)
アレルギー性結膜炎	1 (3.6)	0
胃腸障害	13 (46.3)	19 (69.3)
腹部不快感	4 (14.2)	0
口角口唇炎	1 (3.6)	0
アフタ性潰瘍	1 (3.6)	0
便秘	5 (17.8)	2 (7.3)
下痢	0	2 (7.3)
腸憩室	0	1 (3.6)
十二指腸潰瘍	0	1 (3.6)
消化不良	1 (3.6)	0
胃食道逆流性疾患	0	1 (3.6)
痔核	0	1 (3.6)
大腸ポリープ	0	1 (3.6)
悪心	0	2 (7.3)

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/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__1.2_J

Treatment-Emergent 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
胃腸障害 (Cont.)		
小腸潰瘍	0	1 (3.6)
口内炎	1 (3.6)	6 (21.9)
嘔吐	0	1 (3.6)
一般・全身障害および投与部位の状態	2 (7.1)	1 (3.6)
発熱	2 (7.1)	1 (3.6)
肝胆道系障害	2 (7.1)	8 (29.2)
胆石症	0	1 (3.6)
薬物性肝障害	0	3 (10.9)
肝機能異常	1 (3.6)	0
脂肪肝	1 (3.6)	1 (3.6)
過形成性胆嚢症	0	1 (3.6)
肝損傷	0	2 (7.3)
免疫系障害	0	1 (3.6)
薬物過敏症	0	1 (3.6)

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/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__1.2_J

Treatment-Emergent 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
感染症および寄生虫症	33 (117.4)	64 (233.6)
肛門膿瘍	0	1 (3.6)
肛門直腸蜂巣炎	0	1 (3.6)
細菌性膣症	1 (3.6)	1 (3.6)
気管支炎	0	2 (7.3)
膀胱炎	0	2 (7.3)
サイトメガロウイルス感染	0	1 (3.6)
爪の皮膚糸状菌症	0	2 (7.3)
毛包炎	2 (7.1)	4 (14.6)
胃腸炎	0	2 (7.3)
ウイルス性胃腸炎	1 (3.6)	1 (3.6)
性器カンジダ症	0	1 (3.6)
陰部ヘルペス	1 (3.6)	0
単純ヘルペス	0	2 (7.3)
帯状疱疹	3 (10.7)	6 (21.9)
インフルエンザ	2 (7.1)	2 (7.3)

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/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__1.2_J

Treatment-Emergent 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
感染症および寄生虫症 (Cont.)		
上咽頭炎	13 (46.3)	13 (47.4)
眼部単純ヘルペス	0	1 (3.6)
口腔カンジダ症	1 (3.6)	1 (3.6)
口腔ヘルペス	3 (10.7)	5 (18.2)
歯冠周囲炎	1 (3.6)	0
歯周炎	1 (3.6)	1 (3.6)
咽頭炎	1 (3.6)	3 (10.9)
ニューモシスチス・イロベチイ肺炎	0	1 (3.6)
肺炎	0	2 (7.3)
シュードモナス感染	0	1 (3.6)
皮膚感染	0	1 (3.6)
ブドウ球菌皮膚感染	1 (3.6)	0
白癬感染	0	1 (3.6)
足部白癬	1 (3.6)	2 (7.3)
扁桃炎	1 (3.6)	1 (3.6)

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/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__1.2_J

Treatment-Emergent 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
感染症および寄生虫症 (Cont.)		
上気道感染	0	2 (7.3)
尿路感染	0	1 (3.6)
傷害、中毒および処置合併症	5 (17.8)	4 (14.6)
節足動物咬傷	0	1 (3.6)
挫傷	0	1 (3.6)
手骨折	1 (3.6)	0
つち指	1 (3.6)	0
処置による疼痛	1 (3.6)	0
肋骨骨折	0	1 (3.6)
皮膚裂傷	1 (3.6)	0
胸骨骨折	0	1 (3.6)
腱断裂	1 (3.6)	0
臨床検査	9 (32.0)	9 (32.8)
アラニンアミノトランスフェラーゼ増加	0	1 (3.6)
血中ビリルビン増加	1 (3.6)	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/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__1.2_J

Treatment-Emergent 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
臨床検査 (Cont.)		
血中クレアチンホスホキナーゼ増加	3 (10.7)	4 (14.6)
ヘモグロビン減少	0	2 (7.3)
リンパ球数減少	1 (3.6)	0
リンパ球形態異常	2 (7.1)	0
赤血球数減少	0	1 (3.6)
体重増加	1 (3.6)	0
白血球数減少	1 (3.6)	1 (3.6)
代謝および栄養障害	3 (10.7)	1 (3.6)
糖尿病	1 (3.6)	0
脂質異常症	0	1 (3.6)
高脂血症	1 (3.6)	0
高トリグリセリド血症	1 (3.6)	0
筋骨格系および結合組織障害	7 (24.9)	5 (18.2)
背部痛	0	1 (3.6)
椎間板突出	1 (3.6)	2 (7.3)

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/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__1.2_J

Treatment-Emergent 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
筋骨格系および結合組織障害 (Cont.)		
半月板変性	1 (3.6)	0
筋痙縮	2 (7.1)	0
筋肉痛	1 (3.6)	1 (3.6)
頚部痛	0	1 (3.6)
乾癬性関節症	2 (7.1)	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	6 (21.9)
肛門性器疣贅	0	2 (7.3)
大腸腺腫	0	1 (3.6)
子宮内膜癌	0	1 (3.6)
乳管内乳頭腫	0	1 (3.6)
卵巣癌	0	1 (3.6)
神経系障害	2 (7.1)	9 (32.8)
手根管症候群	0	1 (3.6)
脳梗塞	0	1 (3.6)
頚腕症候群	1 (3.6)	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/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__1.2_J

Treatment-Emergent 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
神経系障害 (Cont.)		
浮動性めまい	1 (3.6)	1 (3.6)
顔面麻痺	0	1 (3.6)
頭痛	0	1 (3.6)
感覚鈍麻	0	1 (3.6)
肋間神経痛	0	1 (3.6)
ヘルペス後神経痛	0	2 (7.3)
精神障害	3 (10.7)	2 (7.3)
不眠症	3 (10.7)	2 (7.3)
生殖系および乳房障害	2 (7.1)	0
亀頭包皮炎	1 (3.6)	0
陰嚢痛	1 (3.6)	0
呼吸器、胸郭および縦隔障害	2 (7.1)	6 (21.9)
喘息	0	2 (7.3)
咳嗽	2 (7.1)	0
間質性肺疾患	0	1 (3.6)

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/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__1.2_J

Treatment-Emergent 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
呼吸器、胸郭および縦隔障害 (Cont.)		
口腔咽頭痛	0	1 (3.6)
気胸	0	1 (3.6)
上気道の炎症	0	1 (3.6)
皮膚および皮下組織障害	10 (35.6)	16 (58.4)
ざ瘡	2 (7.1)	1 (3.6)
皮脂欠乏症	0	1 (3.6)
皮膚炎	0	1 (3.6)
接触皮膚炎	1 (3.6)	1 (3.6)
薬疹	0	3 (10.9)
皮膚乾燥	2 (7.1)	0
異汗性湿疹	0	1 (3.6)
湿疹	1 (3.6)	2 (7.3)
白斑症	0	1 (3.6)
汗疹	0	1 (3.6)
乾癬	0	1 (3.6)

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/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__1.2_J

Treatment-Emergent 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
皮膚および皮下組織障害 (Cont.)		
発疹	1 (3.6)	2 (7.3)
脂漏性皮膚炎	1 (3.6)	0
皮膚潰瘍	1 (3.6)	0
蕁麻疹	1 (3.6)	1 (3.6)
社会環境	0	1 (3.6)
閉経	0	1 (3.6)
血管障害	2 (7.1)	0
高血圧	2 (7.1)	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/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 2.7.4.7-132.　投与 56 週時データカットオフまで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，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 56 (DATA CUTOFF - [redacted]20[redacted])
R&D/20/0898 - CLINICAL/STATISTICAL

TABLE 14.3__1.3_J

Treatment-Emergent Adverse Events with Reasonably Possibly of Being Related to Study Drug 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
Any adverse event	28 (99.6)	63 (229.9)
血液およびリンパ系障害	0	5 (18.2)
貧血	0	1 (3.6)
血球減少症	0	1 (3.6)
播種性血管内凝固	0	1 (3.6)
リンパ球減少症	0	1 (3.6)
汎血球減少症	0	1 (3.6)
耳および迷路障害	1 (3.6)	0
回転性めまい	1 (3.6)	0
胃腸障害	0	6 (21.9)
十二指腸潰瘍	0	1 (3.6)
小腸潰瘍	0	1 (3.6)
口内炎	0	3 (10.9)
嘔吐	0	1 (3.6)

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 relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
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__1.3_J

Treatment-Emergent Adverse Events with Reasonably Possibly of Being Related to Study Drug 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
肝胆道系障害	1 (3.6)	4 (14.6)
薬物性肝障害	0	2 (7.3)
肝機能異常	1 (3.6)	0
肝損傷	0	2 (7.3)
感染症および寄生虫症	14 (49.8)	35 (127.7)
肛門膿瘍	0	1 (3.6)
肛門直腸蜂巣炎	0	1 (3.6)
細菌性膣症	1 (3.6)	1 (3.6)
気管支炎	0	1 (3.6)
サイトメガロウイルス感染	0	1 (3.6)
毛包炎	1 (3.6)	1 (3.6)
ウイルス性胃腸炎	1 (3.6)	1 (3.6)
性器カンジダ症	0	1 (3.6)
単純ヘルペス	0	2 (7.3)
帯状疱疹	3 (10.7)	6 (21.9)
上咽頭炎	2 (7.1)	4 (14.6)

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 relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
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__1.3_J

Treatment-Emergent Adverse Events with Reasonably Possibly of Being Related to Study Drug 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
感染症および寄生虫症 (Cont.)		
眼部単純ヘルペス	0	1 (3.6)
口腔ヘルペス	3 (10.7)	4 (14.6)
歯周炎	1 (3.6)	0
咽頭炎	1 (3.6)	2 (7.3)
ニューモシスチス・イロベチイ肺炎	0	1 (3.6)
肺炎	0	2 (7.3)
シュードモナス感染	0	1 (3.6)
白癬感染	0	1 (3.6)
足部白癬	1 (3.6)	1 (3.6)
扁桃炎	0	1 (3.6)
尿路感染	0	1 (3.6)
臨床検査	4 (14.2)	7 (25.5)
アラニンアミノトランスフェラーゼ増加	0	1 (3.6)
血中クレアチンホスホキナーゼ増加	2 (7.1)	3 (10.9)
ヘモグロビン減少	0	1 (3.6)

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 relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
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__1.3_J

Treatment-Emergent Adverse Events with Reasonably Possibly of Being Related to Study Drug 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
臨床検査 (Cont.)		
リンパ球数減少	1 (3.6)	0
赤血球数減少	0	1 (3.6)
体重増加	1 (3.6)	0
白血球数減少	0	1 (3.6)
代謝および栄養障害	2 (7.1)	0
高脂血症	1 (3.6)	0
高トリグリセリド血症	1 (3.6)	0
筋骨格系および結合組織障害	2 (7.1)	0
筋肉痛	1 (3.6)	0
乾癬性関節症	1 (3.6)	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 (7.3)
肛門性器疣贅	0	2 (7.3)
神経系障害	0	3 (10.9)
浮動性めまい	0	1 (3.6)
顔面麻痺	0	1 (3.6)

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 relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
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__1.3_J

Treatment-Emergent Adverse Events with Reasonably Possibly of Being Related to Study Drug 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
神経系障害 (Cont.)		
ヘルペス後神経痛	0	1 (3.6)
生殖系および乳房障害	1 (3.6)	0
陰嚢痛	1 (3.6)	0
呼吸器、胸郭および縦隔障害	0	1 (3.6)
間質性肺疾患	0	1 (3.6)
皮膚および皮下組織障害	3 (10.7)	0
ざ瘡	2 (7.1)	0
発疹	1 (3.6)	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 relationship to study drug is being counted as having a reasonable possibility of being related to study drug.
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 2.7.4.7-133. 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，日本人部分集団）：M15-554 試験

TABLE 14.3__1.4_J

Treatment-Emergent Severe 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
Any adverse event	4 (14.2)	24 (87.6)
血液およびリンパ系障害	0	3 (10.9)
血球減少症	0	1 (3.6)
播種性血管内凝固	0	1 (3.6)
汎血球減少症	0	1 (3.6)
胃腸障害	0	2 (7.3)
十二指腸潰瘍	0	1 (3.6)
小腸潰瘍	0	1 (3.6)
肝胆道系障害	0	2 (7.3)
薬物性肝障害	0	1 (3.6)
肝損傷	0	1 (3.6)
感染症および寄生虫症	0	9 (32.8)
肛門膿瘍	0	1 (3.6)
サイトメガロウイルス感染	0	1 (3.6)
ウイルス性胃腸炎	0	1 (3.6)

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_J

Treatment-Emergent Severe 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
感染症および寄生虫症 (Cont.)		
帯状疱疹	0	1 (3.6)
咽頭炎	0	1 (3.6)
ニューモシスチス・イロベチイ肺炎	0	1 (3.6)
肺炎	0	2 (7.3)
尿路感染	0	1 (3.6)
傷害、中毒および処置合併症	1 (3.6)	0
腱断裂	1 (3.6)	0
臨床検査	1 (3.6)	3 (10.9)
ヘモグロビン減少	0	1 (3.6)
リンパ球数減少	1 (3.6)	0
赤血球数減少	0	1 (3.6)
白血球数減少	0	1 (3.6)
代謝および栄養障害	1 (3.6)	0
糖尿病	1 (3.6)	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_J

Treatment-Emergent Severe 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
筋骨格系および結合組織障害	1 (3.6)	0
乾癬性関節症	1 (3.6)	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 (3.6)
卵巣癌	0	1 (3.6)
神経系障害	0	2 (7.3)
顔面麻痺	0	1 (3.6)
ヘルペス後神経痛	0	1 (3.6)
呼吸器、胸郭および縦隔障害	0	2 (7.3)
間質性肺疾患	0	1 (3.6)
気胸	0	1 (3.6)

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 2.7.4.7-134. 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，日本人部分集団）：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__2.1_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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
Any adverse event	5 (17.8)	19 (69.3)
血液およびリンパ系障害	0	1 (3.6)
汎血球減少症	0	1 (3.6)
胃腸障害	0	2 (7.3)
十二指腸潰瘍	0	1 (3.6)
小腸潰瘍	0	1 (3.6)
肝胆道系障害	0	1 (3.6)
薬物性肝障害	0	1 (3.6)
感染症および寄生虫症	1 (3.6)	9 (32.8)
肛門膿瘍	0	1 (3.6)
サイトメガロウイルス感染	0	1 (3.6)
ウイルス性胃腸炎	1 (3.6)	1 (3.6)
帯状疱疹	0	1 (3.6)
咽頭炎	0	1 (3.6)
ニューモシスチス・イロベチイ肺炎	0	1 (3.6)

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/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_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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
感染症および寄生虫症 (Cont.)		
肺炎	0	2 (7.3)
尿路感染	0	1 (3.6)
傷害、中毒および処置合併症	1 (3.6)	0
腱断裂	1 (3.6)	0
代謝および栄養障害	1 (3.6)	0
糖尿病	1 (3.6)	0
筋骨格系および結合組織障害	2 (7.1)	0
乾癬性関節症	2 (7.1)	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 (7.3)
肛門性器疣贅	0	1 (3.6)
卵巣癌	0	1 (3.6)
神経系障害	0	1 (3.6)
顔面麻痺	0	1 (3.6)
呼吸器、胸郭および縦隔障害	0	3 (10.9)
喘息	0	1 (3.6)

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/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_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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
呼吸器、胸郭および縦隔障害 (Cont.)		
間質性肺疾患	0	1 (3.6)
気胸	0	1 (3.6)

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/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 2.7.4.7-135. 投与 56 週時データカットオフまで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，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 56 (DATA CUTOFF - [redacted]20[redacted])
R&D/20/0898 - CLINICAL/STATISTICAL

TABLE 14.3__2.2_J

Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug 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 = 28.1) Events (E/100 PYs)	UPA 30 mg QD (N = 20) (PYs = 27.4) Events (E/100 PYs)
Any adverse event	1 (3.6)	7 (25.5)
血液およびリンパ系障害	0	1 (3.6)
汎血球減少症	0	1 (3.6)
胃腸障害	0	1 (3.6)
小腸潰瘍	0	1 (3.6)
肝胆道系障害	0	1 (3.6)
薬物性肝障害	0	1 (3.6)
感染症および寄生虫症	0	2 (7.3)
肺炎	0	1 (3.6)
尿路感染	0	1 (3.6)
筋骨格系および結合組織障害	1 (3.6)	0
乾癬性関節症	1 (3.6)	0
呼吸器、胸郭および縦隔障害	0	2 (7.3)
喘息	0	1 (3.6)
気胸	0	1 (3.6)

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/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]