Laboratory Testing

[redacted]20[redacted] (RX DAY 124): HEMOGLOBIN: 114 [117 - 160] G/L; NPTST016-C-REAKTIVE PROTEIN: 109.3 [NOT REPORTED - NOT REPORTED] MG/L; PLATELETS: 141 [150 - 400] 10^9/L; [redacted]20[redacted] (RX DAY 133): HEMOGLOBIN: 116 [117 - 160] G/L; NPTST016-C-REAKTIVE PROTEIN: 18.6 [NOT REPORTED - NOT REPORTED] MG/L; PLATELETS: 211 [150 - 400] 10^9/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 124): CHEST CT:BILATERAL PNEUMONIA

AE Stopped Rx Day	134
Duration of AE	13 DAYS
Severity	Grade 3
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
Investigator Alternative Etiology	COVID PNEUMONIA BILATERAL
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:14:15

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M19-944

治験責任医師からの報告。本被験者はチェコ共和国の 5[redacted] 歳女性で，米国アッヴィ社の ABT-494（ウパダシチニブ）の治験で盲検化された治験薬及びウパダシチニブが投与され，新型コロナウイルス感染症を発現した。

Event 1 の臨床経過：

関連病歴は，軸性脊椎関節炎，気管支喘息，肥満，非喫煙者及び非飲酒者であった。

被験者は 14 週時までは盲検化プラセボ対照期に参加していた。投与開始から 99 日後，ウパダシチニブの非盲検投与期に移行した。

投与開始から 122 日後，被験者は新型コロナウイルス感染症を発現した。投与開始から 134 日後，新型コロナウイルス感染症は消失した。

投与開始から 122 日後，被験者は新型コロナウイルス感染症の検査を受け陽性と判断された。

投与開始から 124 日後，被験者は安静時呼吸困難のため入院した。徴候や症状として，37.9°C の発熱，咳嗽，鼻閉，疲労，皮膚蒼白及び全身の不快感がみられた。胸部 X 線検査で，25%–50%の両側性肺炎が認められた。投与開始から 134 日後，被験者は退院した。

治験責任医師によると，被験者のリスク因子には気管支喘息があった。

投与された薬剤はパラセタモールであった。

The patient's past medications include:

IBUPROFEN for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

DICLOFENAC DUO for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

REMSIMA/INFLIXIMAB for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) COVID-19 (10084268) (COVID-19 (10084268)) [v.23.1] [10084268]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Causality for UPADACITINIB (Open Label)

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1) COVID-19 (10084268) (COVID-19 (10084268)) [v.23.1] [10084268]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for UPADACITINIB (Blinded)

Event of COVID-19 INFECTION

- **Investigator:** COVID pneumonia bilateral

- **AbbVie:** Event is more likely related to the COVID-19 pandemic outbreak.

Alternative Etiology for UPADACITINIB (Open Label)

Event of COVID-19 INFECTION

- **Investigator:** COVID pneumonia bilateral

- **AbbVie:** Event is more likely related to the COVID-19 pandemic outbreak.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BMI:** 34.1 kg/m2

[redacted] **20[redacted] CHEST CT:** Bilateral pneumonia

[redacted] **20[redacted] SARS-COV-2 TEST:** Nasopharyngeal Swab:Tested positive

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
COVID-19 肺炎	X			X

Treatment Group	Age at Study Start	Sex	Race
P1:ABT-494 15 MG QD /P2:ABT-494 15 MG QD	7[redacted]	FEMALE	WHITE

Medical History	Onset Year
MEDICAL HISTORY: LEFT WRIST FRACTURE	19[redacted]
MEDICAL HISTORY: HYPERTENSION	19[redacted]
MEDICAL HISTORY: CHOLECYSTITIS	20[redacted]
MEDICAL HISTORY: POSTMENOPAUSAL	20[redacted]
MEDICAL HISTORY: CATARACTA OF RIGHT EYE	20[redacted]
AXIAL SPONDYLOARTHRITIS DISEASE HISTORY: AXIAL SPONDYLOARTHRITIS	20[redacted]
MEDICAL HISTORY: HYPERURICHAEMY	20[redacted]
MEDICAL HISTORY: OSTEOPENIA	20[redacted]

Prior Procedures	Procedure Year
PRIOR PROCEDURES: CHOLECYSTECTOMY	20[redacted]
PRIOR PROCEDURES: CATARACTA SURGERY OF RIGHT EYE	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ABT-494	15 mg	ORAL	QD	[redacted] / 1	[redacted] / 95	95
ABT-494	15 mg	ORAL	QD	[redacted] / 183	/	

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
INDAPAMIDE;PERINDOPRIL ERBUMINE	1.25 mg	QD	Y-M: 20[redacted]
DICLOFENAC	75 mg	BID	Y-M: 20[redacted]
NAPROXEN	550 mg	QD	Y-M: 20[redacted]
ETORICOXIB	NOT REPORTED	QD	Y-M: 20[redacted]
ALLOPURINOL	100 mg	QD	Y-M: 20[redacted]
CALCIUM CITRATE	200 mg	TID	Y-M: 20[redacted]
COLECALCIFEROL	1000 IU	QD	Y-M: 20[redacted]
ADALIMUMAB	40 mg	OTHER: EVERY 2 WEEKS	Y-M: 20[redacted] / -92

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
INDAPAMIDE;PERINDOPRIL ERBUMINE	1.25 MG	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 97
ETORICOXIB	NOT REPORTED	QD	Y-M: 20[redacted]	NOT REPORTED
ALLOPURINOL	100 MG	QD	Y-M: 20[redacted]	NOT REPORTED
CALCIUM CITRATE	200 MG	TID	Y-M: 20[redacted]	Y-M: 20[redacted] / 97
COLECALCIFEROL	1000 IU	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 97
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 66	Y-M: / 66
REMDESIVIR	200 MG	QD	Y-M: 20[redacted] / 97	Y-M: 20[redacted] / 97
FAVIPIRAVIR	1600 MG	BID	Y-M: 20[redacted] / 97	Y-M: 20[redacted] / 98
CEFTRIAXONE SODIUM	2 G	QD	Y-M: 20[redacted] / 97	Y-M: 20[redacted] / 104
ACETYLCYSTEINE	600 MG	QD	Y-M: 20[redacted] / 97	Y-M: 20[redacted] / 105
CLARITHROMYCIN	500 MG	QD	Y-M: 20[redacted]4 / 97	Y-M: 20[redacted] / 105
DEXAMETHASONE	8 MG	QD	Y-M: 20[redacted] / 97	Y-M: 20[redacted] / 113
REMDESIVIR	100 MG	QD	Y-M: 20[redacted] / 98	Y-M: 20[redacted] / 104
FAVIPIRAVIR	600 MG	BID	Y-M: 20[redacted] / 98	Y-M: 20[redacted] / 105

PANTOPRAZOLE	40 MG	QD	Y-M: 20[redacted] / 105	NOT REPORTED
PARACETAMOL;TRAMADOL HYDROCHLORIDE	37.5/325 MG	BID	Y-M: 20[redacted] / 105	NOT REPORTED
METHYLPREDNISOLONE	8 MG	QD	Y-M: 20[redacted] / 105	Y-M: 20[redacted] / 112
ENOXAPARIN SODIUM	0.4 ML	QD	Y-M: 20[redacted] / 105	Y-M: 20[redacted] / 114
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 175	Y-M: / 175

Event #1: Serious Adverse Event, Event of Interest - Serious Infections

Event Description	COVID-19 INFECTION PNEUMONIA
Preferred Term	COVID-19 肺炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 89
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 97): NPTST023-CRP: 327.3 [0 - 5] MG/L; NPTST030-FERRITIN: 693 [4 - 161] UG/L; NPTST039-LDH: 1002 [200 - 400] U/L; [redacted]20[redacted] (RX DAY 99): NPTST023-CRP: 356.1 [0 - 5] MG/L; NPTST039-LDH: 618 [200 - 400] U/L; [redacted]20[redacted] (RX DAY 101): NPTST023-CRP: 105.6 [0 - 5] MG/L; NPTST039-LDH: 601 [200 - 400] U/L; [redacted]20[redacted] (RX DAY 105): NPTST023-CRP: 9.6 [0 - 5] MG/L; NPTST039-LDH: 387 [0 - 5] U/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 98): CHEST X-RAY:PNEUMONIA; [redacted]20[redacted] (RX DAY 104): CHEST X-RAY:BRONCHITIS

AE Stopped Rx Day	176
Duration of AE	88 DAYS
Severity	Grade 2
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
Investigator Alternative Etiology	SARS-COV2 VIRUS CAUSED THIS EVENT
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:14:15

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M19-944

治験責任医師からの報告。本被験者はハンガリーの 7[redacted] 歳女性で，米国アッヴィ社の ABT-494（ウパダシチニブ）の治験で盲検化された治験薬が投与され，新型コロナウイルス肺炎を発現した。

Event 1 の臨床経過：

関連病歴は，高血圧，軸性脊椎関節炎，非喫煙者及び非飲酒者であった。

投与開始から 89 日後，被験者は新型コロナウイルス肺炎を発現した。投与開始から 176 日後，新型コロナウイルス肺炎は消散した。

投与開始から 89 日後，被験者は乾性咳嗽，脱力感及び発熱を発現した。投与開始から 95 日後，被験者は新型コロナウイルス感染症検査で陽性が判明し，かかりつけ医によりファビピラビルを投与された。投与開始から 97 日後，被験者は脱水のため病院に運ばれた。入院時，被験者の両肺にわたり捻髪音を認め，胸部 X 線検査で新型コロナウイルス肺炎が認められた。被験者は入院期間中を通して，抗ウイルス薬，抗生物質，ステロイド，低分子量ヘパリン，非経口補液療法を受けた。被験者は経鼻チューブからの持続酸素療法を必要とした。投与開始から 99 日後，被験者は血漿を投与された。治療を受け，被験者の状態は改善した。被験者の検査所見は正常化し，酸素投与は不要となった。自宅において，クレキサン皮下注を 10 日間，メドロール 8 mg を 1 週間，パントプラゾールを 1 週間，milurit 100 mg 及び doreta の投与を継続することを勧められた。投与開始から 105 日後，被験者は退院した。

投与された薬剤は，レムデシビル，ロセフィン，klacid，acc，酸素，血漿，メドロール，doreta，デキサメタゾン，クレキサン及びファビピラビルであった。

The patient's past medications include:

APRANAX for AXIAL SPONDYLOARTHRITIS (20[redacted] - 20[redacted])

DICLOFENAC for AXIAL SPONDYLOARTHRITIS (20[redacted] - 20[redacted])

HYRIMOZ for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) COVID-19 pneumonia (10084380) (COVID-19 pneumonia (10084380)) [v.24.0] [10084380]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of COVID-19 INFECTION PNEUMONIA

- **Investigator:** SARS-CoV2 virus caused this event

- **AbbVie:** Event is more likely related to the COVID-19 pandemic outbreak.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CHEST X RAY:** Bronchitis

[redacted] **20[redacted] CHEST X-RAY:** Pneumonia

[redacted] **20[redacted] COVID 19 TEST:** Nasopharyngeal swab: positive

[redacted] **20[redacted] CRP:** 356.1 MG/L (normal 0 to 5)

[redacted] **20[redacted] CRP:** 105.6 MG/L (normal 0 to 5)

[redacted] **20[redacted] CRP:** 9.6 MG/L (normal 0 to 5)

[redacted] **20[redacted] FERRITIN:** 693 MCG/L (normal 4 to 161)

[redacted] **20[redacted] LDH:** 618 U/L (normal 200 to 400)

[redacted] **20[redacted] LDH:** 601 U/L (normal 200 to 400)

[redacted] **20[redacted] LDH:** 387 U/L (normal 200 to 400)

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
COVID-19	X			X

Treatment Group	Age at Study Start	Sex	Race
P1:ABT-494 15 MG QD /P2:ABT-494 15 MG QD	5[redacted]	FEMALE	WHITE

Medical History	Onset Year
AXIAL SPONDYLOARTHRITIS DISEASE HISTORY: AXIAL SPONDYLOARTHRITIS	20[redacted]
MEDICAL HISTORY: BILATERAL ARTHRITIS OF THE HIP JOINTS	20[redacted]
MEDICAL HISTORY: ?HRONICAL GASTRITIS	20[redacted]
MEDICAL HISTORY: ANEMIA	20[redacted]
MEDICAL HISTORY: ANTERIOR SCALENE SYNDROME	20[redacted]
MEDICAL HISTORY: BILATERAL COMBINED HIP CONTRACTURES	20[redacted]
MEDICAL HISTORY: BILATERAL CONTRACTURES OF THE ANKLE JOINTS	20[redacted]
MEDICAL HISTORY: BILATERAL CONTRACTURES OF THE SHOULDER JOINTS	20[redacted]
MEDICAL HISTORY: BILATERAL COXARTHROSIS I	20[redacted]
MEDICAL HISTORY: BILATERAL ELBOW JOINT CONTRACTURES	20[redacted]
MEDICAL HISTORY: BILATERAL GONARTHROSIS I	20[redacted]
MEDICAL HISTORY: BILATERAL WRIST CONTRACTURES	20[redacted]
MEDICAL HISTORY: CHRONICAL ESOPHAGITIS	20[redacted]
MEDICAL HISTORY: COMMON DORSOPATHY OF THE SPINE	20[redacted]
MEDICAL HISTORY: CORONARY ARTERY DISEASE	20[redacted]
MEDICAL HISTORY: DUODENOGASTRIC REFLUX	20[redacted]
MEDICAL HISTORY: HYPERTENSION	20[redacted]
MEDICAL HISTORY: MITRAL VALVE INSUFFICIENCY I	20[redacted]
MEDICAL HISTORY: PAROXYSMAL SUPRAVENTRICULAR TACHYCARDIA	20[redacted]
MEDICAL HISTORY: SUBFEBRILE	20[redacted]
MEDICAL HISTORY: TRICUSPIDAL VALVE INSUFFICIENCY I	20[redacted]
MEDICAL HISTORY: VENTRICULAR EXTRASYSTOLE	20[redacted]
MEDICAL HISTORY: CHRONICAL BRONCHITIS	20[redacted]
MEDICAL HISTORY: HEPATOMEGALY	20[redacted]

MEDICAL HISTORY: SYNCOPE	20[redacted]
MEDICAL HISTORY: POSTMENOPAUSE	20[redacted]
MEDICAL HISTORY: CHRONIC ENDOMETRITIS	20[redacted]
MEDICAL HISTORY: CHRONICAL DUODENITIS	20[redacted]
MEDICAL HISTORY: ENDOMETRIOSIS	20[redacted]
MEDICAL HISTORY: DYSLIPIDEMIA	20[redacted]
MEDICAL HISTORY: HYPERGLYCEMIA	20[redacted]
MEDICAL HISTORY: OBESITY I	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	CURRENT	10 CIGARETTE	25	
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ABT-494	15 mg	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 100	100
ABT-494	15 mg	ORAL	QD	[redacted]20[redacted] / 101	/	

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BCG Vaccine	NOT REPORTED	NOT REPORTED	Y-M: 19[redacted]
MELOXICAM	7.5 mg	BID	Y-M: 20[redacted]
SULFASALAZINE	1 g	BID	Y-M: 20[redacted]
ACETYLSALICYLIC ACID	100 mg	QD	Y-M: 20[redacted]
BISOPROLOL FUMARATE	5 mg	QD	Y-M: 20[redacted]
LORNOXICAM	8 mg	BID	Y-M: 20[redacted]

METHYLPREDNISOLONE	1 g	QD	Y-M: 20[redacted]
OMEPRAZOLE	20 mg	QD	Y-M: 20[redacted]
METHOTREXATE	10 mg	OTHER: WEEKLY	Y-M: 20[redacted]
METHYLPREDNISOLONE	250 mg	QD	Y-M: 20[redacted]
METHOTREXATE	10 mg	OTHER: SINGLE DOSE	Y-M: 20[redacted]
DICLOFENAC	50 mg	TID	Y-M: 20[redacted]
TRAMADOL	50 mg	QD	Y-M: 20[redacted]
MELOXICAM	7.5 mg	BID	Y-M: 20[redacted]
ETORICOXIB	NOT REPORTED	BID	Y-M: 20[redacted] / -185
DEXAMETHASONE	8 mg	QD	Y-M: 20[redacted] / -183
LORNOXICAM	8 mg	QD	Y-M: 20[redacted] / -183
ETANERCEPT	50 mg	QD	Y-M: 20[redacted] / -148

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
SULFASALAZINE	1 G	BID	Y-M: 20[redacted]	NOT REPORTED
ACETYLSALICYLIC ACID	100 MG	QD	Y-M: 20[redacted]	NOT REPORTED
BISOPROLOL FUMARATE	5 MG	QD	Y-M: 20[redacted]	NOT REPORTED
OMEPRAZOLE	20 MG	QD	Y-M: 20[redacted]	NOT REPORTED
ETORICOXIB	NOT REPORTED	BID	Y-M: 20[redacted] / -185	NOT REPORTED
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE	2 OTHER: MEASURING SPOON	QID	Y-M: 20[redacted] / 27	Y-M: 20[redacted] / 89
CEFTRIAXONE	1 G	QD	Y-M: 20[redacted] / 118	Y-M: 20[redacted] / 126
DEXAMETHASONE	8 MG	QD	Y-M: 20[redacted] / 118	Y-M: 20[redacted] / 126
ENOXAPARIN SODIUM	0.4 ML	BID	Y-M: 20[redacted] / 118	Y-M: 20[redacted] / 126
OXYGEN	N/A OTHER: N/A	PRN	Y-M: 20[redacted] / 118	Y-M: 20[redacted] / 126
PARACETAMOL	500 MG	QD	Y-M: 20[redacted] / 118	Y-M: 20[redacted] / 126
ACETYLCYSTEINE	200 MG	QD	Y-M: 20[redacted] / 127	Y-M: 20[redacted] / 136
LACTOBACILLUS ACIDOPHILUS;POLYSACCHARIDES NOS	1 OTHER: CAPSULE	QD	Y-M: 20[redacted] / 127	Y-M: 20[redacted] / 140
RIVAROXABAN	10 MG	QD	Y-M: 20[redacted] / 127	Y-M: 20[redacted] / 140
COLECALCIFEROL	3125 IU	QD	Y-M: 20[redacted] / 127	Y-M: 20[redacted] / 157

Event #1: Serious Adverse Event, Event of Interest - Serious Infections

Event Description	COVID-19 INFECTION

Preferred Term	COVID-19
AE Onset Date / Rx Day	[redacted]20[redacted] / 116
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 119): ALBUMIN: 53 [35 - 50] G/L; EOSINOPHILS/LEUKOCYTES: 2 [1 - 5] %; ERYTHROCYTE SEDIMENTATION RATE: 19 [2 - 30] MM/H; ERYTHROCYTES: 3.6 [3.8 - 4.5] 10^12/L; HEMATOCRIT: 0.35 [0.36 - 0.46] FRACTION OF 1; HEMOGLOBIN: 117 [120 - 140] G/L; HEPATITIS B VIRUS SURFACE ANTIGEN: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; HEPATITIS C VIRUS ANTIBODY: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; LEUKOCYTES: 4.7 [4 - 9] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 32 [18 - 40] %; MONOCYTES/LEUKOCYTES: 3 [3 - 11] %; NEUTROPHILS/LEUKOCYTES: 63 [48 - 73] %; PLATELETS: 238 [170 - 320] 10^9/L; PROTHROMBIN INTL. NORMALIZED RATIO: 1.03 [0.8 - 1.2] RATIO; [redacted]20[redacted] (RX DAY 120): ALANINE AMINOTRANSFERASE: 32 [0 - 31] U/L; ALBUMIN: 52 [35 - 50] G/L; ASPARTATE AMINOTRANSFERASE: 29 [0 - 31] U/L; CREATININE: 62 [36 - 90] UMOL/L; ERYTHROCYTE SEDIMENTATION RATE: 25 [2 - 30] MM/H; ERYTHROCYTES: 3.6 [3.8 - 4.5] 10^12/L; GLUCOSE: 4.4 [3.3 - 5.5] MMOL/L; HEMATOCRIT: 0.34 [0.36 - 0.46] FRACTION OF 1; HEMOGLOBIN: 116 [120 - 140] G/L; LEUKOCYTES: 9.7 [4 - 9] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 37 [18 - 40] %; MONOCYTES/LEUKOCYTES: 7 [3 - 11] %; NEUTROPHILS/LEUKOCYTES: 56 [48 - 73] %; PLATELETS: 252 [170 - 320] 10^9/L; POTASSIUM: 4.4 [3.5 - 5] MMOL/L; [redacted]20[redacted] (RX DAY 123): C REACTIVE PROTEIN: 40.6 [0 - 3] MG/L; [redacted]20[redacted] (RX DAY 126): SPECIFIC GRAVITY: 1.013 [1.01 - 1.02] UNIT NOT REPORTED

Microbiology

[redacted]20[redacted] (RX DAY 119): OTHER NASAL DISCHARGE PCR: POSITIVE-VIRUS SARS-COV-2 RNA DETECTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 118): SPIRAL COMPUTED TOMOGRAPHY:LEFT-SIDED POLYSEGMENTAL PNEUMONIA WITH LESIONS OF THE LUNG AREA UP TO 15%. CHRONICAL BRONCHITIS.; [redacted]20[redacted] (RX DAY 119): ECG:HEART RATE 66 PER MINUTE. PQ 0.18 QRS 0.08 THE RHYTHM IS SINUS. INTERMEDIATE POSITION OF THE ELECTRICAL AXIS OF THE HEART. SIGNS OF LEFT VENTRICULAR HYPERTROPHY.

AE Stopped Rx Day	140
Duration of AE	25 DAYS
Severity	Grade 3
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
Investigator Alternative Etiology	SARS-COV-2
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:14:15

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M19-944

治験責任医師からの報告。本被験者はロシア連邦の 5[redacted] 歳女性で，米国アッヴィ社の ABT-494（ウパダシチニブ）の治験で盲検化された治験薬及びウパダシチニブが投与され，新型コロナウイルス感染症を発現した。

Event 1 の臨床経過：

関連病歴は，軸性脊椎関節炎，冠動脈疾患，高血圧，慢性気管支炎，脂質異常症，高血糖，現喫煙者（1 日 10 本を 25 年間）及び現飲酒者（1 日 2 杯未満）であった。

被験者は 14 週時までは盲検化プラセボ対照期に参加していた。投与開始から 101 日後，ウパダシチニブの非盲検投与期に移行した。

投与開始から 116 日後，被験者は新型コロナウイルス感染症を発現した。投与開始から 140 日後，新型コロナウイルス感染症は消失した。

投与開始から 116 日後，被験者は 38°C の発熱及び重度の全身性脱力感を発現した。被験者の母親も同じ症状を発現した。投与開始から 118 日後，被験者は治療のため単独で医療センターを受診した。被験者の徴候や症状として，発熱，重度の全身性脱力感，疲労，浮動性めまい，眼痛，呼吸困難及び咳嗽がみられた。鼻及び咽頭スワブによる新型コロナウイルス感染症検査は陽性であった。被験者及び被験者と同じく新型コロナウイルス感染症検査が陽性であった被験者の母親は同日，感染症病棟に緊急入院し，院内治療を受け，被験者が母親と濃厚接触することで生じる新型コロナウイルス感染症の合併症を避けた。検査及び治療が行われ，被験者は助言を受けた。投与開始から 126 日後，被験者は退院した。

治験責任医師によると，本事象のリスク因子は被験者の母親の新型コロナウイルス感染症検査陽性であった。

投与された薬剤は，ビタミン D3，リバーロキサバン，アセチルシステインナトリウム，パラセタモール，セフトリアキソン，デキサメタゾン，エノキサパリンナトリウム，及び酸素であった。

The patient's past medications include:

MELOXICAMUM for AXIAL SPONDYLOARTHRITIS (20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

METYPRED for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

XEFOCAM for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

METHOTREXATUM for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted]- [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

DICLOPHENACUM for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

TRAMADOLUM for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

DEXAMETHASONUM for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

LORNOXICAMUM for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

ENBREL for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) COVID-19 respiratory infection (10084401) (COVID-19 (10084268)) [v.24.0] [10084401]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Causality for UPADACITINIB (Open Label)

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1) COVID-19 respiratory infection (10084401) (COVID-19 (10084268)) [v.24.0] [10084401]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for UPADACITINIB (Blinded)

Event of COVID-19 INFECTION

- **Investigator:** SARS-COV-2

- **AbbVie:** Event is more likely related to the COVID-19 pandemic outbreak.

Alternative Etiology for UPADACITINIB (Open Label)

Event of COVID-19 INFECTION

- **Investigator:** SARS-COV-2

- **AbbVie:** Event is more likely related to the COVID-19 pandemic outbreak.

COVID-19 Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ALT:** 32 U/L (normal 0 to 31)

[redacted] **20[redacted] AST:** 29 U/L (normal 0 to 31)

[redacted] **20[redacted] BODY MASS INDEX:** 31.6 kg/m2

[redacted] **20[redacted] BODY TEMPERATURE:** 38 Degrees C

[redacted] **20[redacted] COVID-19 PCR:** Nasal discharge: Virus SARS-CoV-2 RNA detected

[redacted] **20[redacted] ECG:** Heart rate 66 per minute. PQ 0.18 QRS 0.08 The rhythm is sinus. Intermediate position of the electrical axis of the heart. Signs of left ventricular hypertrophy.

[redacted] **20[redacted] ESR:** 19 MM/HR (normal 2 to 30)

[redacted] **20[redacted] HEMATOCRIT:** 35% (normal 36 to 46)

[redacted] **20[redacted] HEMOGLOBIN:** 117 G/DL (normal 120 to 140)

[redacted] **20[redacted] HEPATITIS B VIRUS SURFACE ANTIGEN:** Negative

[redacted] **20[redacted] HEPATITIS C VIRUS ANTIBODY:** Negative

[redacted] **20[redacted] HIGH SENSITIVITY CRP:** 40.6 MG/L (normal 0 to 3)

[redacted] **20[redacted] INR:** 1.03 ratio (normal 0.8 to 1.2)

[redacted] **20[redacted] PLT:** 238 X10**9/L (normal 170 to 320)

[redacted] **20[redacted] PLT:** 252 X10**9/L (normal 170 to 320)

[redacted] **20[redacted] POTASSIUM:** 4.37 MMOL/L (normal 3.5 to 5)

[redacted] **20[redacted] SPIRAL CT:** Left-sided polysegmental pneumonia with lesions of the lung area up to 15%. Chronical bronchitis.

[redacted] **20[redacted] WBC:** 4.7 X10**9/L (normal 4 to 9)

[redacted] **20[redacted] WBC:** 9.7 X10**9/L (normal 4 to 9)

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
COVID-19 肺炎	X			X

Treatment Group	Age at Study Start	Sex	Race
P1:ABT-494 15 MG QD /P2:ABT-494 15 MG QD	4[redacted]	MALE	WHITE

Medical History	Onset Year
MEDICAL HISTORY: ACUTE APPENDICITIS	19[redacted]
MEDICAL HISTORY: ACUTE PERITONITIS	19[redacted]
MEDICAL HISTORY: PARAPROCTITIS	20[redacted]
AXIAL SPONDYLOARTHRITIS DISEASE HISTORY: AXIAL SPONDYLOARTHRITIS	20[redacted]
MEDICAL HISTORY: UMBILICAL HERNIA	20[redacted]

Prior Procedures	Procedure Year
PRIOR PROCEDURES: APPENDECTOMY	19[redacted]
PRIOR PROCEDURES: EXCISION OF PARAPROCTITIS	20[redacted]
PRIOR PROCEDURES: HERNIA REPAIR WITH PLASTIC HERNIA ORIFICE ACCORDING TO MAYO	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ABT-494	15 mg	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 93	93
ABT-494	15 mg	ORAL	QD	[redacted]20[redacted] / 157	/	

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BCG Vaccine	NOT REPORTED	NOT REPORTED	Y-M: 19[redacted]
DICLOFENAC	150 mg	QD	Y-M: 20[redacted]
DICLOFENAC	150 mg	QD	Y-M: 20[redacted]
MELOXICAM	15 mg	QD	Y-M: 20[redacted]
MELOXICAM	15 mg	QD	Y-M: 20[redacted]
MELOXICAM	15 mg	QD	Y-M: 20[redacted]
NIMESULIDE	100 mg	BID	Y-M: 20[redacted]
ETORICOXIB	NOT REPORTED	QD	Y-M: 20[redacted]
IXEKIZUMAB	80 mg	OTHER: EVERY 2 WEEKS	Y-M: 20[redacted]

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
ETORICOXIB	NOT REPORTED	QD	Y-M: 20[redacted]	NOT REPORTED
ACETYLCYSTEINE	600 MG	QD	Y-M: 20[redacted] / 81	Y-M: 20[redacted] / 111
ALIMEMAZINE TARTRATE	5 MG	QD	Y-M: 20[redacted] / 81	Y-M: 20[redacted] / 111
BEMIPARIN SODIUM	0.2 ML	BID	Y-M: 20[redacted] / 81	Y-M: 20[redacted] / 111
BIFIDOBACTERIUM INFANTIS;ENTEROCOCCUS FAECIUM;LACTOBACILLUS ACIDOPHILUS	2 OTHER: CAPS	BID	Y-M: 20[redacted] / 81	Y-M: 20[redacted] / 111
CETIRIZINE HYDROCHLORIDE	10 MG	QD	Y-M: 20[redacted] / 81	Y-M: 20[redacted] / 111
DEXAMETHASONE	4 MG	QD	Y-M: 20[redacted] / 81	Y-M: 20[redacted] / 111
METRONIDAZOLE	0.25 G	BID	Y-M: 20[redacted] / 81	Y-M: 20[redacted] / 111
OMEPRAZOLE	20 MG	QD	Y-M: 20[redacted] / 81	Y-M: 20[redacted] / 111
AMOXICILLIN;CLAVULANIC ACID	875+125 MG	BID	Y-M: 20[redacted] / 94	Y-M: 20[redacted] / 95
RIAMILOVIR	250 MG	TID	Y-M: 20[redacted] / 94	Y-M: 20[redacted] / 95
DIOSMECTITE	3.0 G	TID	Y-M: 20[redacted] / 94	Y-M: 20[redacted] / 105
OLOKIZUMAB	0.8 ML	QD	Y-M: 20[redacted] / 98	Y-M: 20[redacted] / 98

METHYLPREDNISOLONE	24 MG	OTHER: TAKING A DOSE FROM 6:00 TO 12:00	Y-M: 20[redacted] / 106	Y-M: 20[redacted] / 110
ASCORBIC ACID	1 G	QD	Y-M: 20[redacted] / 106	Y-M: 20[redacted] / 136
COLECALCIFEROL	4000 IU	QD	Y-M: 20[redacted] / 106	Y-M: 20[redacted] / 136
RIVAROXABAN	10 MG	QD	Y-M: 20[redacted] / 106	Y-M: 20[redacted] / 136
METHYLPREDNISOLONE	20 MG	OTHER: TAKING A DOSE FROM 6:00 TO 12:00	Y-M: 20[redacted] / 111	Y-M: 20[redacted] / 115
METHYLPREDNISOLONE	16 MG	OTHER: TAKING A DOSE FROM 6:00 TO 12:00	Y-M: 20[redacted] / 116	Y-M: 20[redacted]2 / 120
METHYLPREDNISOLONE	12 MG	OTHER: TAKING A DOSE FROM 6:00 TO 12:00	Y-M: 20[redacted] / 121	Y-M: 20[redacted] / 125
METHYLPREDNISOLONE	8 MG	OTHER: TAKING A DOSE FROM 6:00 TO 12:00	Y-M: 20[redacted] / 126	Y-M: 20[redacted] / 130
METHYLPREDNISOLONE	4 MG	QD	Y-M: 20[redacted] / 131	Y-M: 20[redacted] / 135

Event #1: Serious Adverse Event, Event of Interest - Serious Infections

Event Description	COVID-19 PNEUMONIA
Preferred Term	COVID-19 肺炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 95
Age at AE Onset	4[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 92): NPTST062-POLYMERASE CHAIN REACTION: POSITIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; [redacted]20[redacted]RX DAY 96): ALANINE AMINOTRANSFERASE: 167 [0 - 41] U/L; ASPARTATE AMINOTRANSFERASE: 147 [0 - 40] U/L; BILIRUBIN: 9 [0 - 21] UMOL/L; C REACTIVE PROTEIN: 127.99 [0 - 5] MG/L; CREATININE: 90 [62 - 106] UMOL/L; ERYTHROCYTE SEDIMENTATION RATE: 39 [2 - 15] MM/H; GLUCOSE: 5.7 [4.1 - 6.2] MMOL/L; HEMOGLOBIN: 142 [132 - 169] G/L; LEUKOCYTES: 7.5 [3.9 - 9.2] 10^9/L; LYMPHOCYTES: 0.67 [1.24 - 3.05] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 8.9 [20.11 - 46.79] %; NPTST003-ACTIVATED PARTIAL THROMBOPLATIN: 26.6 [21.1 - 36.5] SEC; NPTST025-D-DIMER: 1.01 [0 - 0.55] MG/L; NPTST030-FERRITIN: 2000 [30 - 400] NG/ML; NPTST031-FIBRINOGEN: 5.88 [1.8 - 3.5] G/L; NPTST036-

INTERLEUKIN-6: 56.9 [0 - 7] PG/ML; NPTST064-PROCALCITONIN: 0.17 [0 - 0.05] NG/ML; NPTST078-THROMBIN TIME: 18.7 [14 - 21] SEC; NEUTROPHILS: 6.39 [1.78 - 6.04] 10^9/L; NEUTROPHILS/LEUKOCYTES: 85.3 [40.8 - 70.39] %; POTASSIUM: 4 [3.3 - 5.5] MMOL/L; PROTHROMBIN INTL. NORMALIZED RATIO: 0.99 [0.8 - 1.2] UNIT NOT REPORTED; SODIUM: 140 [132 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 97): C REACTIVE PROTEIN: 101.48 [0 - 5] MG/L; NPTST036-INTERLEUKIN-6: 56,98 [0 - 7] PG / ML; [redacted]20[redacted](RX DAY 99): C REACTIVE PROTEIN: 9.3 [0 - 5] MG/L; ERYTHROCYTE SEDIMENTATION RATE: 26 [2 - 15] MM/H; ERYTHROCYTES: 4.6 [4.2 - 5.7] 10^12/L; HEMOGLOBIN: 122 [132 - 169] G/L; LEUKOCYTES: 10.8 [3.9 - 9.2] 10^9/L; LYMPHOCYTES: 0.9 [1.24 - 3.05] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 8.4 [20.11 - 46.79] %; NPTST036-INTERLEUKIN-6: 3.76 [0 - 7] PG / ML; NEUTROPHILS: 9.23 [1.78 - 6.04] 10^9/L; NEUTROPHILS/LEUKOCYTES: 85.8 [40.8 - 70.39] %; PLATELETS: 377 [146 - 421] 10^9/L; [redacted]20[redacted] (RX DAY 102): NPTST064-PROCALCITONIN: 0.05 [0 - 0.05] NG/ML; [redacted]20[redacted] (RX DAY 104): C REACTIVE PROTEIN: 2.22 [0 - 5] MG/L; NPTST036-INTERLEUKIN-6: 1.74 [0 - 7] PG / ML

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 95): CT SCAN OF THE CHEST:BILATERAL POLYSEGMENTARY PNEUMONIA 3 DEGREES (DAMAGE TO THE RIGHT LUNG 50-75% AND DAMAGE TO THE LEFT LUNG 25-50%).; ECG:NORMAL; [redacted]20[redacted] (RX DAY 104): CT SCAN OF THE CHEST:BILATERAL POLYSEGMENTARY PNEUMONIA MEDIUM-SEVERE (CT-2); [redacted]20[redacted] (RX DAY 150): CT SCAN OF THE CHEST:RESIDUAL CHANGES IN THE TRANSFERRED VIRAL PNEUMONIA

AE Stopped Rx Day	150
Duration of AE	56 DAYS
Severity	Grade 4
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
Investigator Alternative Etiology	COVID-19 INFECTION
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION, LIFE THREATENING

Generated: [redacted]20[redacted]:14:15

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M19-944

治験責任医師からの報告。本被験者はロシア連邦の 4[redacted] 歳男性で，米国アッヴィ社の ABT-494（ウパダシチニブ）の治験で盲検化された治験薬が投与され，新型コロナウイルス肺炎を発現した。

Event 1 の臨床経過：

関連病歴は，軸性脊椎関節炎，非喫煙者及び禁酒であった。

投与開始から 95 日後，被験者は新型コロナウイルス肺炎を発現した。投与開始から 150 日後，新型コロナウイルス肺炎は消散した。

本事象の発現に先立ち，被験者は新型コロナウイルス感染症の被験者家族との接触があった。

投与開始から 92 日後，被験者は咽頭痛，全身性脱力感，筋肉痛，軽度の発熱の症状を発現した。検査で新型コロナウイルス感染症が確認された。

投与開始から 95 日後，被験者は乾性咳嗽，筋肉痛，発熱，下痢及び酸素飽和度の低下の症状悪化を発現した。胸部 CT 検査で両側性ウイルス性肺炎が認められた。被験者は同日入院した。被験者は抗生物質，抗炎症薬，抗凝固療法，抗 IL6 薬，去痰薬及び抗ヒスタミン薬を投与された。被験者の状態は改善した。投与開始から 105 日後，被験者は退院した。

投与された薬剤は，triazavirin，amoksiklav，酸素，olokizumab，デキサメタゾン，zibor，ビタミン C，teraligen，linex，オメプラゾール，smectitum dioctaedricum，espa-nac（acc long; acetylcysteinum），cetrine，metypred，ビタミン D3 及びメトロニダゾールであった。

Causality for UPADACITINIB (Blinded)

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1) COVID-19 pneumonia (10084380) (COVID-19 pneumonia (10084380)) [v.24.0] [10084380]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence isot applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of COVID-19 PNEUMONIA

- **Investigator:** COVID-19 infection

- **AbbVie:** Event is more likely related to the COVID-19 pandemic outbreak.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ACTIVATED PARTIAL THROMBOPLATINUM TIME:** 26.6 SEC (normal 21.1 to 36.5)

[redacted] **20[redacted] ALANINE AMINO TRANSFERASE:** 166.5 U/L (normal 0 to 41)

[redacted] **20[redacted] ASPARTATE AMINO TRANSFERASE:** 146.6 U/L (normal 0 to 40)

[redacted] **20[redacted] BILIRUBIN:** 9.1 MMOL/L (normal 0 to 21)

[redacted] **20[redacted] BMI:** 30.6689 kg/m2

[redacted] **20[redacted] COVID-19 TEST:** Tested positive (Nasopharyngeal swab)

[redacted] **20[redacted] COVID-19 TEST:** Negative

[redacted] **20[redacted] CREATININE:** 90 MMOL/L (normal 62 to 106)

[redacted] **20[redacted] CT CHEST:** Bilateral polysegmentary Pneumonia 3 degrees (damage to the right lung 50-75% and damage to the left lung 25-50%)

[redacted] **20[redacted] CT SCAN OF THE CHEST:** BILATERAL POLYSEGMENTARY PNEUMONIA MEDIUM-SEVERE (CT-2)

[redacted] **20[redacted] CT SCAN OF THE CHEST:** RESIDUAL CHANGES IN THE TRANSFERRED VIRAL PNEUMONIA

[redacted] **20[redacted] D DIMER:** 1.014 MG/L (normal 0 to 0.55)

[redacted] **20[redacted] ECG:** Normal

[redacted] **20[redacted] ERYTHROCYTE SEDIMENTATION RATE:** 39 mm/h (normal 2 to 15)

[redacted] **20[redacted] ERYTHROCYTE SEDIMENTATION RATE:** 26 mm/h (normal 2 to 15)

[redacted] **20[redacted] FERRITIN:** 2000 NG/ML (normal 30 to 400)

[redacted] **20[redacted] FIBRINOGEN:** 5.88 G/L (normal 1.8 to 3.5)

[redacted] **20[redacted] GLUCOSE:** 5.71 MMOL/L (normal 4.11 to 6.2)

[redacted] **20[redacted] HEMOGLOBIN:** 142 G/L (normal 132 to 169)

[redacted] **20[redacted] HEMOGLOBIN:** 122 G/L (normal 132 to 169)

[redacted] **20[redacted] HIGH-SENSITIVITY C REACTIVE PROTEIN:** 127.99 MG/L (normal 0 to 5)

[redacted] **20[redacted] HIGH-SENSITIVITY C REACTIVE PROTEIN:** 2.22 MG/L (normal 0 to 5)

[redacted] 20[redacted] **INTERLEUKIN-6:** 56.9 PG/ML (normal 0 to 7)

[redacted] 20[redacted] **INTERLEUKIN-6:** 1.74 PG/ML (normal 0 to 7)

[redacted] 20[redacted] **INTERNATIONAL NORMALIZED RATIO:** 0.99 No units (normal 0.8 to 1.2)

[redacted] 20[redacted] **LYMPHOCYTES %:** 8.9% (normal 20.11 to 46.79)

[redacted] 20[redacted] **LYMPHOCYTES %:** 8.4% (normal 20.11 to 46.79)

[redacted] 20[redacted] **LYMPHOCYTES ABS:** 0.67 X10**9/L (normal 1.24 to 3.05)

[redacted] 20[redacted] **LYMPHOCYTES ABS:** 0.9 X10**9/L (normal 1.24 to 3.05)

[redacted] 20[redacted] **NEUTROPHILS %:** 85.3% (normal 40.8 to 70.39)

[redacted] 20[redacted] **NEUTROPHILS %:** 85.8% (normal 40.8 to 70.39)

[redacted] 20[redacted] **NEUTROPHILS ABS:** 6.39 X10**9/L (normal 1.78 to 6.04)

[redacted] 20[redacted] **NEUTROPHILS ABS:** 9.23 X10**9/L (normal 1.78 to 6.04)

[redacted] 20[redacted] **PLATELET:** 377 X10**9/L (normal 146 to 421)

[redacted] 20[redacted] **POTASSIUM:** 4.01 MMOL/L (normal 3.3 to 5.5)

[redacted] 20[redacted] **PROCALCITONIN:** 0.17 NG/ML (normal 0 to 0.046)

[redacted] 20[redacted] **PROCALCITONIN:** 0.05 NG/ML (normal 0 to 0.046)

[redacted] 20[redacted] **RED BLOOD CELLS:** 4.63 X10**12/L (normal 4.24 to 5.65)

[redacted] 20[redacted] **SODIUM:** 140 MMOL/L (normal 132 to 146)

[redacted] 20[redacted] **THROMBIN TIME:** 18.7 SEC (normal 14 to 21)

[redacted] 20[redacted] **WHITE BLOOD CELLS:** 7.5 X10**9/L (normal 3.89 to 9.23)

[redacted] 20[redacted] **WHITE BLOOD CELLS:** 10.75 X10**9/L (normal 3.89 to 9.23)

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
合併症を伴う虫垂炎	X			X
腹膜炎	X			X

Treatment Group	Age at Study Start	Sex	Race
P1:ABT-494 15 MG QD /P2:ABT-494 15 MG QD	3[redacted]	MALE	WHITE

Medical History	Onset Year
MEDICAL HISTORY: CONVULSIVE SYNDROME WITH PARTIAL AND SECONDARY GENERALIZED SEIZURES	19[redacted]
MEDICAL HISTORY: RESIDUAL ORGANIC BRAIN DISEASE OF PERINATAL GENESIS	19[redacted]
AXIAL SPONDYLOARTHRITIS DISEASE HISTORY: AXIAL SPONDYLOARTHRITIS	20[redacted]
MEDICAL HISTORY: DEGENERATIVE DISEASE OF THE SPINE	20[redacted]
MEDICAL HISTORY: CHRONIC GATRODUODENITIS	20[redacted]
MEDICAL HISTORY: ENCEPHALOPATHY	20[redacted]
MEDICAL HISTORY: HYPOPLASIA OF THE LEFT VERTEBRAL ARTERY	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ABT-494	15 mg	ORAL	QD	[redacted] / 1	[redacted] / 96	96
ABT-494	15 mg	ORAL	QD	[redacted] / 97	/	

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
MELOXICAM	15 mg	QD	Y-M: 20[redacted]
KETOROLAC	10 mg	QID	Y-M: 20[redacted]
DICLOFENAC	25 mg	QD	Y-M: 20[redacted]
NIMESULIDE	100 mg	BID	Y-M: 20[redacted]
ESOMEPRAZOLE	20 mg	QD	Y-M: 20[redacted]
ETORICOXIB	NOT REPORTED	QD	Y-M: 20[redacted]
GOLIMUMAB	50 mg	OTHER: ONCE A MONTH	Y-M: 20[redacted] / -361

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
ESOMEPRAZOLE	20 MG	QD	Y-M: 20[redacted]	NOT REPORTED
ETORICOXIB	NOT REPORTED	QD	Y-M: 20[redacted]	NOT REPORTED

Event #1: Serious Adverse Event, Event of Interest - Serious Infections

Event Description	COMPLICATED ACUTE PHLEGMONOUS APPENDICITIS
Preferred Term	合併症を伴う虫垂炎
AE Onset Date / Rx Day	[redacted] / 122
Age at AE Onset	3[redacted]

Laboratory Testing

[redacted] (RX DAY 122): BLOOD: 0 [0 - 0] UNIT NOT REPORTED; ERYTHROCYTE SEDIMENTATION RATE: 10 [2 - 10] MM/H; HEMOGLOBIN: 134 [132 - 173] G/L; LEUKOCYTES: 1-2-3 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; LEUKOCYTES: 11.4 [4 - 10] 10^9/L; PLATELETS: 239 [180 - 320] 10^9/L; PROTEIN: 0.02 [NOT REPORTED - NOT REPORTED] G/L; PH: 6.5 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; [redacted] (RX DAY 123): ALANINE AMINOTRANSFERASE: 29 [0 - 44] U/L; ASPARTATE AMINOTRANSFERASE: 29 [0 - 40] U/L; BILIRUBIN: 17700 [3400 - 17000] UMOL/L; BLOOD: 0 [0 - 0] UNIT NOT REPORTED; CREATININE: 91 [72 - 115] UMOL/L; GLUCOSE: 5.8 [3.8 - 5.9] MMOL/L; HEMOGLOBIN: 140 [132 - 173] G/L; LEUKOCYTES: 2-3 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; LEUKOCYTES: 11.8 [4 - 10] 10^9/L; PLATELETS: 142 [180 - 320] 10^9/L; PH: 6.5 [NOT REPORTED - NOT REPORTED] UNKNOWN; [redacted] (RX DAY 127): ALANINE AMINOTRANSFERASE: 32 [0 - 44] U/L; ASPARTATE AMINOTRANSFERASE: 27 [0 - 40] U/L; BILIRUBIN: 14500 [3400 - 17000] UMOL/L; CREATININE: 93 [72 - 115] UMOL/L; ERYTHROCYTE SEDIMENTATION RATE: 30 [2 - 10] MM/H; ERYTHROCYTES: 0 [0 - 0] 10^12/L;

GLUCOSE: 5.4 [3.8 - 5.9] MMOL/L; HEMOGLOBIN: 144 [132 - 173] G/L; LEUKOCYTES: 5.1 [4 - 10] 10^9/L; PLATELETS: 224 [180 - 320] 10^9/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 123): LAPAROSCOPIC APPENDECTOMY:REMOVAL OF THE APPENDIX.; [redacted]20[redacted] (RX DAY 125): ABDOMINAL ULTRASOUND:ENLARGEMENT OF THE LIVER

AE Stopped Rx Day	132
Duration of AE	11 DAYS
Severity	Grade 3
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
Investigator Alternative Etiology	UNKNOWN
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING

Event #2: Serious Adverse Event, Event of Interest - Serious Infections

Event Description	LOCAL PURULENT PERITONITIS
Preferred Term	腹膜炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 122
Age at AE Onset	3[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 122): BLOOD: 0 [0 - 0] UNIT NOT REPORTED; ERYTHROCYTE SEDIMENTATION RATE: 10 [2 - 10] MM/H; HEMOGLOBIN: 134 [132 - 173] G/L; LEUKOCYTES: 1-2-3 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; LEUKOCYTES: 11.4 [4 - 10] 10^9/L; PLATELETS: 239 [180 - 320] 10^9/L; PROTEIN: 0.02 [NOT REPORTED - NOT REPORTED] G/L; PH: 6.5 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; [redacted]20[redacted](RX DAY 123): ALANINE AMINOTRANSFERASE: 29 [0 - 44] U/L; ASPARTATE AMINOTRANSFERASE: 29 [0 - 40] U/L; BILIRUBIN: 17700 [3400 - 17000] UMOL/L; BLOOD: 0 [0 - 0] UNIT NOT REPORTED; CREATININE: 91 [72 - 115] UMOL/L; GLUCOSE: 5.8 [3.8 - 5.9] MMOL/L; HEMOGLOBIN: 140 [132 - 173] G/L; LEUKOCYTES: 2-3 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; LEUKOCYTES: 11.8 [4 - 10] 10^9/L; PLATELETS: 142 [180 - 320] 10^9/L; PH: 6.5 [NOT REPORTED - NOT REPORTED] UNKNOWN; [redacted]20[redacted] (RX DAY 127): ALANINE AMINOTRANSFERASE: 32 [0 - 44] U/L; ASPARTATE AMINOTRANSFERASE: 27 [0 - 40] U/L; BILIRUBIN: 14500 [3400 - 17000] UMOL/L; CREATININE: 93 [72 - 115] UMOL/L; ERYTHROCYTE SEDIMENTATION RATE: 30 [2 - 10] MM/H; ERYTHROCYTES: 0 [0 - 0] 10^12/L; GLUCOSE: 5.4 [3.8 - 5.9] MMOL/L; HEMOGLOBIN: 144 [132 - 173] G/L; LEUKOCYTES: 5.1 [4 - 10] 10^9/L; PLATELETS: 224 [180 - 320] 10^9/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 123): LAPAROSCOPIC APPENDECTOMY:REMOVAL OF THE APPENDIX.; [redacted]20[redacted] (RX

DAY 125): ABDOMINAL ULTRASOUND:ENLARGEMENT OF THE LIVER

AE Stopped Rx Day	132
Duration of AE	11 DAYS
Severity	Grade 3
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
Investigator Alternative Etiology	UNKNOWN
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING

Generated: [redacted] 20[redacted]:14:15

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M19-944

治験責任医師からの報告。本被験者はロシア連邦の 3[redacted] 歳男性で，米国アッヴィ社の ABT-494（ウパダシチニブ）の治験で盲検化された治験薬及びウパダシチニブが投与され，合併症を伴う急性蜂窩織炎性虫垂炎及び限局性化膿性腹膜炎を発現した。

Event 1 及び 2 の臨床経過：

関連病歴は，慢性胃十二指腸炎，軸性脊椎関節炎，非喫煙者及び非飲酒者であった。

被験者は 14 週時までは盲検化プラセボ対照期に参加していた。投与開始から 97 日後，ウパダシチニブの非盲検投与期に移行した。

投与開始から 122 日後，被験者は合併症を伴う急性蜂窩織炎性虫垂炎及び限局性化膿性腹膜炎を発現した。投与開始から 132 日後，合併症を伴う急性蜂窩織炎性虫垂炎及び限局性化膿性腹膜炎は消散した。

投与開始から 122 日後，被験者は右腸骨部の急性腹痛及び発熱のため入院した。被験者は血液検査及び腹部の超音波検査を受けた。被験者は合併症を伴う急性蜂窩織炎性虫垂炎と診断された。投与開始から 123 日後，被験者は腹腔鏡下虫垂切除術を受け，限局性化膿性腹膜炎が認められた。投与開始から 128 日後，被験者は退院した。

The patient's past medications include:

MELOXICAM for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

KETOROLAC for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

DICLOFENAC for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

NIMESULIDE for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

GOLIMUMAB for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Peritonitis suppurative (10034683) (Peritonitis (10034674)) [v.24.0] [10034683]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

2) Complicated appendicitis (10081534) (Complicated appendicitis (10081534)) [v.24.0] [10081534]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Causality for UPADACITINIB (Open Label)

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1) Peritonitis suppurative (10034683) (Peritonitis (10034674)) [v.24.0] [10034683]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

2) Complicated appendicitis (10081534) (Complicated appendicitis (10081534)) [v.24.0] [10081534]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for UPADACITINIB (Blinded)

Event of COMPLICATED ACUTE PHLEGMONOUS APPENDICITIS, LOCAL PURULENT PERITONITIS

- **Investigator:** Unknown

- **AbbVie:** Event of acute appendicitis is common in the general population; lifetime incidence is 8.6 percent in males. Event of local purulent peritonitis is more likely related to concurrent acute appendicitis.

Alternative Etiology for UPADACITINIB (Open Label)

Event of COMPLICATED ACUTE PHLEGMONOUS APPENDICITIS, LOCAL PURULENT PERITONITIS

- **Investigator:** Unknown

- **AbbVie:** Event of acute appendicitis is common in the general population; lifetime incidence is 8.6 percent in males. Event of local purulent peritonitis is more likely related to concurrent acute appendicitis.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BODY TEMPERATURE:** 38.3 Degrees C

[redacted] **20[redacted] ESR:** 10 MM/HR (normal 2 to 10)

[redacted] **20[redacted] ESR:** 30 MM/HR (normal 2 to 10)

[redacted] **20[redacted] HEMOGLOBIN:** 134 G/L (normal 132 to 173)

[redacted] **20[redacted] HEMOGLOBIN:** 140 G/L (normal 132 to 173)

[redacted] **20[redacted] HEMOGLOBIN:** 144 G/L (normal 132 to 173)

[redacted] **20[redacted] PLATELET COUNT:** 239 X10**9/L (normal 180 to 320)

[redacted] **20[redacted] PLATELET COUNT:** 142 X10**9/L (normal 180 to 320)

[redacted] **20[redacted] PLATELET COUNT:** 224 X10**9/L (normal 180 to 320)

[redacted] **20[redacted] TOTAL BILIRUBIN:** 17.7 MMOL/L (normal 3.4 to 17.0)

[redacted] **20[redacted] TOTAL BILIRUBIN:** 14.5 MMOL/L (normal 3.4 to 17.0)

[redacted] **20[redacted] ULTRASOUND OF ABDOMEN:** Enlargement of the liver

[redacted] **20[redacted] URINE LEUKOCYTES:** 1-2-3 no units

[redacted] **20[redacted] URINE LEUKOCYTES:** 2-3 no units

[redacted] **20[redacted] WBC:** 11.4 X10**9/L (normal 4 to 10)

[redacted] **20[redacted] WBC:** 11.8 X10**9/L (normal 4 to 10)

[redacted] **20[redacted] WBC:** 5.1 X10**9/L (normal 4 to 10)

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
ぶどう膜炎	X			X

Treatment Group	Age at Study Start	Sex	Race
P1:ABT-494 15 MG QD /P2:ABT-494 15 MG QD	4[redacted]	MALE	WHITE

Medical History	Onset Year
MEDICAL HISTORY: APPENDICITIS	20[redacted]
MEDICAL HISTORY: NASAL SEPTUM DEVIATION	20[redacted]
AXIAL SPONDYLOARTHRITIS DISEASE HISTORY: AXIAL SPONDYLOARTHRITIS	20[redacted]
MEDICAL HISTORY: CHOLECYSTITIS	20[redacted]
MEDICAL HISTORY: GASTRODUODENITIS	20[redacted]
MEDICAL HISTORY: OBESITY	20[redacted]
MEDICAL HISTORY: IRON-DEFICIENCY ANEMIA	20[redacted]
MEDICAL HISTORY: OSTEOARTHRITIS	20[redacted]

Prior Procedures	Procedure Year
PRIOR PROCEDURES: APPENDECTOMY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ABT-494	15 mg	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 97	97
ABT-494	15 mg	ORAL	QD	[redacted]20[redacted] / 98	/	

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
ETORICOXIB	90 mg	QD	Y-M: 20[redacted]
ADALIMUMAB	40 mg	OTHER: EVERY 2 WEEK	Y-M: 20[redacted]
ACECLOFENAC	100 mg	BID	Y-M: 20[redacted] / -119
ETORICOXIB	NOT REPORTED	QD	Y-M: 20[redacted] / -112

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
ETORICOXIB	NOT REPORTED	QD	Y-M: 20[redacted] / -112	NOT REPORTED
DEXAMETHASONE	20 MG	QD	Y-M: 20[redacted] / 212	Y-M: 20[redacted] / 214
DEXAMETHASONE	1.2 MG	QD	Y-M: 20[redacted] / 212	Y-M: 20[redacted] / 219
DEXAMETHASONE	0.1%	QID	Y-M: 20[redacted] / 212	Y-M: 20[redacted] / 224
BETAMETHASONE	1.0 ML	QD	Y-M: 20[redacted] / 221	Y-M: 20[redacted] / 221

Event #1: Serious Adverse Event, Event of Interest - Serious Infections

Event Description	ACUTE UVEITIS OCULUS DEXTER
Preferred Term	ぶどう膜炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 211
Age at AE Onset	4[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

NOT REPORTED

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	Grade 3
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY

Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY

Generated: [redacted] 20[redacted]:14:15

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M19-944

治験責任医師からの報告。本被験者はロシア連邦の 4[redacted]歳男性で，米国アッヴィ社の ABT-494（ウパダシチニブ）の治験で盲検化された治験薬及びウパダシチニブが投与され，急性右眼ぶどう膜炎を発現した。

Event 1 の臨床経過：

関連病歴は，軸性脊椎関節炎，非喫煙者及び非飲酒者であった。

被験者は 14 週時までは盲検化プラセボ対照期に参加していた。投与開始から 98 日後，ウパダシチニブの非盲検投与期に移行した。

投与開始から 211 日後，被験者は急性右眼ぶどう膜炎を発現した。

投与開始から 211 日後，被験者は右眼の急激な疼痛と充血を発現した。投与開始から 212 日後，被験者は院内治療のため入院した。投与開始から 221 日後，被験者は右眼硝子体内にデキサメタゾンの注射を受け，続いてデキサメタゾンの点滴を受けた。デキサメタゾン点眼も開始された。ブドウ膜炎の症状は徐々に軽減した。投与開始から 224 日後，被験者は退院した。

投与された薬剤はデキサメタゾンであった。

The patient's past medications include:

ADALIMUMAB for AXIAL SPONDYLOARTHRITIS (20[redacted] - [redacted] 20[redacted])

ACECLOFENAC for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Acute uveitis (10066681) (Uveitis (10046851)) [v.24.0] [10066681]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Causality for UPADACITINIB (Open Label)

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1) Acute uveitis (10066681) (Uveitis (10046851)) [v.24.0] [10066681]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: No

Alternative Etiology for UPADACITINIB (Blinded)

Event of ACUTE UVEITIS OCULUS DEXTER

- **Investigator:** Not applicable

- **AbbVie:** Uveitis is a common extra articular manifestation of axial spondyloarthritis. The frequency of uveitis in patients with spondyloarthritis is approximately 25 to 35 percent.

Alternative Etiology for UPADACITINIB (Open Label)

Event of ACUTE UVEITIS OCULUS DEXTER

- **Investigator:** Not applicable

- **AbbVie:** Uveitis is a common extra articular manifestation of axial spondyloarthritis. The frequency of uveitis in patients with spondyloarthritis is approximately 25 to 35 percent.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BMI:** 30.13 kg/m2

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
COVID-19 肺炎	X			X

Treatment Group	Age at Study Start	Sex	Race
P1:ABT-494 15 MG QD /P2:ABT-494 15 MG QD	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
AXIAL SPONDYLOARTHRITIS DISEASE HISTORY: AXIAL SPONDYLOARTHRITIS	20[redacted]
MEDICAL HISTORY: DEFORMING OSTEOARTHRITIS OF BOTH FEET	20[redacted]
MEDICAL HISTORY: MENOPAUSE	20[redacted]
MEDICAL HISTORY: BRONCHIAL ASTHMA	20[redacted]
MEDICAL HISTORY: NSAID ALLERGY	20[redacted]
MEDICAL HISTORY: POLLINOSIS	20[redacted]
MEDICAL HISTORY: ARTERIAL HYPERTENSION	20[redacted]
MEDICAL HISTORY: CHRONIC ATROPHIC GASTRITIS	20[redacted]
MEDICAL HISTORY: DOLICHOSIGMA CONGENITAL	20[redacted]
MEDICAL HISTORY: DRY EYE SYNDROME	20[redacted]
MEDICAL HISTORY: HYPERTENSIVE RETINAL ANGIOPATHY	20[redacted]
MEDICAL HISTORY: LIVER CYST	20[redacted]
MEDICAL HISTORY: OBESITY	20[redacted]
MEDICAL HISTORY: SIGMOID DIVERTICULOSIS	20[redacted]
MEDICAL HISTORY: MAMMARY INVOLUNTARY FIBROTIC CHANGES	20[redacted]
MEDICAL HISTORY: RIGHT NEPHROPTOSIS	20[redacted]
MEDICAL HISTORY: HEMANGIOMAS OF VERTEBRAE.	20[redacted]
MEDICAL HISTORY: SINGLE EXTRASYSTOLES	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ABT-494	15 mg	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 98	98
ABT-494	15 mg	ORAL	QD	[redacted]20[redacted] / 99	[redacted]20[redacted] / 223	125

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
SALBUTAMOL	1 OTHER: PUFF	PRN	Y-M: 20[redacted]
SULFASALAZINE	1 g	BID	Y-M: 20[redacted]-[redacted]
LOSARTAN	50 mg	QD	Y-M: 20[redacted]-[redacted] / -123
INFLIXIMAB	5 mg/kg	OTHER: ONCE	Y-M: 20[redacted]-[redacted] / -117

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
SALBUTAMOL	1 OTHER: PUFF	PRN	Y-M: 20[redacted]	ONGOING
SULFASALAZINE	1 G	BID	Y-M: 20[redacted]-[redacted]	ONGOING
LOSARTAN	50 MG	QD	Y-M: 20[redacted]-[redacted] / -123	ONGOING
CEFTRIAXONE	UNK OTHER: UNK	OTHER: UNK	Y-M: 20[redacted]-[redacted] / 114	Y-M: 20[redacted]-[redacted] / 133
RIAMILOVIR	UNK	NOT REPORTED	Y-M: 20[redacted]-[redacted] / 114	Y-M: 20[redacted]-[redacted] / 133
ACETYLSALICYLIC ACID	100 MG	QD	Y-M: 20[redacted]-[redacted] / 133	ONGOING
ACETYLCYSTEINE	200 MG	TID	Y-M: 20[redacted]-[redacted] / 133	Y-M: 20[redacted]-[redacted] / 147

Event #1: Serious Adverse Event, Event of Interest - Serious Infections

Event Description	COVID-19 PNEUMONIA INFECTION
Preferred Term	COVID-19 肺炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 114
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 118): ALANINE AMINOTRANSFERASE: 30 [NOT REPORTED - NOT REPORTED] U/L; ASPARTATE AMINOTRANSFERASE: 36.4 [NOT REPORTED - NOT REPORTED] U/L; BILIRUBIN: 6 [3 - 19] UMOL/L; BLOOD UREA NITROGEN: 4.4 [2.9 - 8.2] MMOL/L; GLUCOSE: 6.1 [4.6 - 6.4] MMOL/L; POTASSIUM: 3.1 [3.4 - 4.4] MMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 111): OTHER NASOPHARYNGEAL SWAB COVID19: POSITIVE-COVID19 INFECTION

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 114): COMPUTED TOMOGRAPHY:BILATERAL POLYSEGMENTAL VIRAL PNEUMONIA

AE Stopped Rx Day	133
Duration of AE	20 DAYS
Severity	Grade 2
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
Investigator Alternative Etiology	COVID-19 INFECTION
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:14:15
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M19-944

治験責任医師からの報告。本被験者はロシア連邦の 6[redacted] 歳女性で，米国アッヴィ社の ABT-494（ウパダシチニブ）の治験で盲検化された治験薬及びウパダシチニブが投与され，新型コロナウイルス肺炎を発現した。

Event 1 の臨床経過：

関連病歴は，気管支喘息，花粉症，動脈性高血圧，肥満，軸性脊椎関節炎，非喫煙者及び非飲酒者であった。

投与開始から 114 日後，被験者は新型コロナウイルス肺炎を発現した。投与開始から 133 日後，新型コロナウイルス肺炎は消散した。
入院に先立ち，被験者は新型コロナウイルス感染症と診断された。
投与開始から 114 日後，被験者は新型コロナウイルス感染症による肺炎のため入院した。被験者に呼吸困難と咳嗽が認められた。CT スキャンで両側多区域ウイルス性肺炎が認められた。抗生物質及び抗ウイルス薬の投与が開始された。投与開始から 133 日後，被験者は良好な状態で退院した。
被験者に投与された薬剤は triazavirin，セフトリアキソン及び acc であった。

The patient's past medications include:

INFLIXIMAB for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) COVID-19 pneumonia (10084380) (COVID-19 pneumonia (10084380)) [v.23.1] [10084380]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Causality for UPADACITINIB (Open Label)

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1) COVID-19 pneumonia (10084380) (COVID-19 pneumonia (10084380)) [v.23.1] [10084380]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for UPADACITINIB (Blinded)

Event of COVID-19 PNEUMONIA INFECTION

- **Investigator:** COVID-19 INFECTION

- **AbbVie:** Event is more likely related to the COVID-19 pandemic outbreak.

Alternative Etiology for UPADACITINIB (Open Label)

Event of COVID-19 PNEUMONIA INFECTION

- **Investigator:** COVID-19 INFECTION

- **AbbVie:** Event is more likely related to the COVID-19 pandemic outbreak.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ALANINE AMINO TRANSFERASE:** 30 U/L

[redacted] **20[redacted] ASPARTATE AMINO TRANSFERASE:** 35.4 U/L

[redacted] **20[redacted] BILIRUBIN:** 6.2 umol/L

[redacted] **20[redacted] BLOOD UREA NITROGEN:** 4.4 MMOL/L

[redacted] **20[redacted] BMI:** 33.05 kg/m2

[redacted] **20[redacted] CHEST X-RAY:** Normal (Screening)

[redacted] **20[redacted] COVID-19 VIRUS TEST:** nasopharyngeal swab - positive

[redacted] **20[redacted] COVID-19 VIRUS TEST:** nasopharyngeal swab - positive

[redacted] **20[redacted] CT:** BILATERAL POLYSEGMENTAL VIRAL PNEUMONIA

[redacted] **20[redacted] GLUCOSE:** 6.13 MMOL/L

[redacted] **20[redacted] POTASSIUM:** 3.0 MMOL/L

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
扁桃癌	X	X		X

Treatment Group	Age at Study Start	Sex	Race
P1:PLACEBO	6[redacted]	MALE	WHITE

Medical History	Onset Year
TB SCREENING: LATENT TUBERCULOSIS	NOT REPORTED
MEDICAL HISTORY: VOMITING	19[redacted]
MEDICAL HISTORY: DENTAL INFECTION	20[redacted]
MEDICAL HISTORY: ACUTE OTITIS	20[redacted]
MEDICAL HISTORY: PHARYNGITIS	20[redacted]
MEDICAL HISTORY: CONGENITAL CAVUS FEET	20[redacted]
MEDICAL HISTORY: UPPER TRACT RESPIRATORY INFECTION	20[redacted]
MEDICAL HISTORY: UPPER TRACT RESPIRATORY INFECTION	20[redacted]
AXIAL SPONDYLOARTHRITIS DISEASE HISTORY: AXIAL SPONDYLOARTHRITIS	20[redacted]
MEDICAL HISTORY: ANXIETY CRISIS	20[redacted]
MEDICAL HISTORY: ACUTE GASTROENTERITIS	20[redacted]
MEDICAL HISTORY: FLU	20[redacted]
MEDICAL HISTORY: ALOPECIA	20[redacted]
MEDICAL HISTORY: RIGHT WRIST SPRAIN	20[redacted]
MEDICAL HISTORY: FEVER	20[redacted]
MEDICAL HISTORY: DIARRHEA	20[redacted]
MEDICAL HISTORY: LATENT TB	20[redacted]
MEDICAL HISTORY: ACUTE GASTROENTERITIS	20[redacted]
MEDICAL HISTORY: URINARY TRACT INFECTION	20[redacted]
MEDICAL HISTORY: UVEITIS RIGHT EYE	20[redacted]
MEDICAL HISTORY: BLEPHARITIS	20[redacted]
MEDICAL HISTORY: DRY EYES	20[redacted]
MEDICAL HISTORY: PEYRONIE DISEASE	20[redacted]
MEDICAL HISTORY: RECTORRHAGIA	20[redacted]
MEDICAL HISTORY: DIABETES MELLITUS	20[redacted]
MEDICAL HISTORY: DYSLIPEMIA	20[redacted]

Prior Procedures	Procedure Year
PRIOR PROCEDURES: OSTEOTOMY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	20 CIGARETTE	20	20[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
PLACEBO		ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 83	83

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
NAPROXEN	500 mg	BID	Y-M: 20[redacted]
ETORICOXIB	60 mg	QD	Y-M: 20[redacted]
NAPROXEN	500 mg	BID	Y-M: 20[redacted]
ISONIAZID	300 mg	QD	Y-M: 20[redacted]
SECUKINUMAB	150 mg	OTHER: MONTHLY	Y-M: 20[redacted]
METFORMIN	850 mg	QD	Y-M: 20[redacted] / -46
MELOXICAM	NOT REPORTED	QD	Y-M: 20[redacted] / -26

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
METFORMIN	850 MG	QD	Y-M: 20[redacted] / -46	ONGOING
MELOXICAM	NOT REPORTED	QD	Y-M: 20[redacted] / -26	ONGOING
ZOLPIDEM	10 MG	QD	Y-M: 20[redacted] / 113	Y-M: 20[redacted] / 126
PARACETAMOL	1.0 G	TID	Y-M: 20[redacted] / 114	Y-M: 20[redacted] / 119

AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	1 G	TID	Y-M: 20[redacted] / 114	Y-M: 20[redacted] / 120
METAMIZOLE	2.0 G	PRN	Y-M: 20[redacted] / 114	Y-M: 20[redacted] / 120
PARACETAMOL	1 G	TID	Y-M: 20[redacted] / 120	Y-M: 20[redacted] / 122
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875 MG	TID	Y-M: 20[redacted] / 121	Y-M: 20[redacted] / 122
LORMETAZEPAM	1 MG	PRN	Y-M: 20[redacted] / 127	Y-M: 20[redacted] / 132
AMOXICILLIN SODIUM;CLAVULANATE POTASSIUM	1.0 G	TID	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 128
DEXKETOPROFEN	50 MG	TID	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 130
OMEPRAZOLE SODIUM	40 MG	QD	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 130
PARACETAMOL	1 G	TID	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 130

Event #1: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Event of Interest - Malignancies, Event of Interest - Malignant Tumours, Event of Interest - Malignant Tumours NMSC

Event Description	SQUAMOUS CELL CARCINOMA OF LEFT TONSIL
Preferred Term	扁桃癌
AE Onset Date / Rx Day	[redacted]20[redacted] / 14
Age at AE Onset	6[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 87): BIOPSY OF CERVICAL REGION MASS:SQUAMOUS CELL CARCINOMA(METASTASIS UNKNOWN ORIGIN); CT SCAN NECK AND THORAX:SQUAMOUS CELL CARCINOMA SIZE 2 CM LOCATION LEFT CERVICAL REGION ATTACHED DEEP PLANES; [redacted]20[redacted](RX DAY 106): PET SCAN:LEFT MASS ON NECK SUSPECTED OF MALIGNANCY WITH MESENTERIC AND MEDIASTINICS ADENOPATHY.; [redacted]20[redacted](RX DAY 114): CHEST X RAY:NORMAL; [redacted]20[redacted] (RX DAY 119): BODY MAGNETIC RESONANCE:LEFT MASS ON NECK SUSPECTED OF MALIGNANCY NO OTHER FINDINGS; MAGNETIC RESONANCE OF LUMBAR SPINE:NORMAL; [redacted]20[redacted](RX DAY 128): BILATERAL TONSILLECTOMY:SURGERY(BILATERAL TONSILLECTOMY); BIOPSY OF LEFT TONSIL:SQUAMOUS CELL CARCINOMA OF LEFT TONSIL; [redacted]20[redacted] (RX DAY 162): RADIOTHERAPY:END DATE:[redacted] [redacted] 20[redacted]; [redacted]20[redacted] (RX DAY 301): PET SCAN:ADENOPATHYS ON LEFT LATEROCERVICAL REGION(NECK) AND CATCHMENT FOCUS IN RECTAL AMPOULE

AE Stopped Rx Day	128 (45 DAYS AFTER LAST TREATMENT)
Duration of AE	115 DAYS
Severity	Grade 2
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
Investigator Alternative Etiology	FORMER SMOKER
Discontinued Study Drug Due to the Event	YES
SAE Criteria	IMPORTANT MEDICAL OR SURGICAL INTERVENTION

Generated: [redacted] 20[redacted]:14:15

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M19-944

治験責任医師からの報告。本被験者はスペインの 6[redacted] 歳男性で，米国アッヴィ社の ABT-494（ウパダシチニブ）の治験で盲検化された治験薬が投与され，左扁桃扁平上皮癌を発現した。

Event 1 の臨床経過：

関連病歴は，歯感染症，急性耳炎，咽頭炎，上気道感染症，潜在性結核，糖尿病，元喫煙者（1 日 20 本を 20 年間）及び非飲酒者であった。

投与開始から 14 日後，被験者は左扁桃扁平上皮癌を発現した。投与開始から 128 日後，左扁桃扁平上皮癌は消失した。

投与開始の同月，被験者の左頸部に進行性増殖性腫瘤が認められ，咳払い時に疼痛を生じた。被験者は耳鼻咽喉科を受診し，原発不明の癌と診断された。ファイバースコープ検査結果は正常であった。頸部及び胸部の CT スキャン，並びに，腫瘤の生検が行われ，扁平上皮癌が認められた。被験者は治療を受けず，CT-PET 検査を待った。

投与開始から 106 日後，被験者は CT-PET 検査を受け，腸間膜及び縦隔のリンパ節肥大を伴う，悪性が疑われる腫瘤が左頸部に認められた。

投与開始から 128 日後，被験者は両側扁桃摘出術を受け，生検が行われた。術後合併症は認められなかった。投与開始から 133 日後，被験者は退院した。

投与開始から 162 日後から投与開始から 219 日後まで，被験者は放射線治療を受け，合併症は認められなかった。

投与開始から 277 日後，被験者は耳鼻咽喉科を受診し，経過良好であり再発もなく，全て問題なしと判断された。

本事象のため治験薬の投与は中止された。

The patient's past medications include:

NAPROXENE for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

ARCOXIA for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

SECUKINUMAB for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Squamous cell carcinoma of tonsil (10056313) (Tonsil cancer (10044002)) [v.24.0] [10056313]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of SQUAMOUS CELL CARCINOMA OF LEFT TONSIL

- **Investigator:** FORMER SMOKER

- **AbbVie:** Weak temporal association with study drug, exposure to study drug of approximately 2 weeks prior to event onset. Additional risk factor is history of smoking.

Relevant Laboratory & Other Diagnostic Tests

[redacted] [redacted] 20[redacted] **BIOPSY OF CERVICAL REGION MASS:** SQUAMOUS CELL CARCINOMA(METASTASIS UNKNOWN ORIGIN)

[redacted] 20[redacted] **BIOPSY OF THE LEFT TONSIL:** SQUAMOUS CELL CARCINOMA OF THE LEFT TONSIL(PT1N1M0)

[redacted] **20[redacted] BODY MAGNETIC RESONANCE:** left mass on neck suspected of malignancy no other findings

[redacted] **20[redacted] CHEST XRAY:** normal

[redacted] **20[redacted] CT SCAN NECK AND THORAX:** SQUAMOUS CELL CARCINOMA SIZE 2 CM LOCATION LEFT CERVICAL REGION ATTACHED DEEP PLANES

[redacted] **20[redacted] MRI OF LUMBAR SPINE:** normal

[redacted] **20[redacted] PET SCAN:** left mass on neck suspected of malignancy with mesenteric and mediastinics adenopathy.

[redacted] **20[redacted] PET SCAN:** ADENOPATHYS ON LEFT LATEROCERVICAL REGION(NECK) AND CATCHMENT FOCUS IN RECTAL AMPOULE

Unknown date WEIGHT: 72.2 KG

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
基底細胞癌	X			X
帯状疱疹				X

Treatment Group	Age at Study Start	Sex	Race
P1:PLACEBO /P2:ABT-494 15 MG QD	6[redacted]	MALE	WHITE

Medical History	Onset Year
TB SCREENING: LATENT TUBERCULOSIS	NOT REPORTED
MEDICAL HISTORY: PULMONARY SARCOIDOSIS	19[redacted]
MEDICAL HISTORY: HEREDITARY HYPOACUSIA	20[redacted]
MEDICAL HISTORY: ACHILLES TENDINITIS	20[redacted]
MEDICAL HISTORY: ACUTE OTITIS MEDIA	20[redacted]
MEDICAL HISTORY: PROSTATE BENIGN HYPERTROPHY	20[redacted]
MEDICAL HISTORY: GASTROESOPHAGEAL REFLUX	20[redacted]
MEDICAL HISTORY: OBESITY	20[redacted]
MEDICAL HISTORY: DYSPEPSIA	20[redacted]
AXIAL SPONDYLOARTHRITIS DISEASE HISTORY: AXIAL SPONDYLOARTHRITIS	20[redacted]
MEDICAL HISTORY: BILATERAL TROCHANTERITIS	20[redacted]
MEDICAL HISTORY: LATENT TB	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	160 CIGARETTE	14	19[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
PLACEBO		ORAL	QD	[redacted]T20[redacted] / 1	[redacted]20[redacted] / 100	100
ABT-494	15 mg	ORAL	QD	[redacted]20[redacted] / 101	/	

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
IBUPROFEN	600 mg	TID	Y-M: 20[redacted]
DEXKETOPROFEN TROMETAMOL	25 mg	TID	Y-M: 20[redacted]
CELECOXIB	200 mg	BID	Y-M: 20[redacted]
ESOMEPRAZOLE	20 mg	QD	Y-M: 20[redacted]
NAPROXEN	NOT REPORTED	BID	Y-M: 20[redacted]
ISONIAZID	300 mg	QD	Y-M: 20[redacted]
SECUKINUMAB	150 mg	OTHER: MOMTHLY	Y-M: 20[redacted]

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
ESOMEPRAZOLE	20 MG	QD	Y-M: 20[redacted]	NOT REPORTED
NAPROXEN	NOT REPORTED	BID	Y-M: 20[redacted]	NOT REPORTED
BRIVUDINE	125 MG	QD	Y-M: 20[redacted] / 170	Y-M: 20[redacted] / 177

Event #1: Event of Interest - Herpes Zoster

Event Description HERPES ZOSTER ON LEFT INFRAMAMMARY REGION

Preferred Term 帯状疱疹

AE Onset Date / Rx Day [redacted]20[redacted] / 169

Age at AE Onset 6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	218
Duration of AE	50 DAYS
Severity	Grade 2
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
Investigator Alternative Etiology	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event, Event of Interest - Malignancies, Event of Interest - Malignant Tumours, Event of Interest - Skin malignant Tumours

Event Description	BASAL CELL CARCINOMA IN THE RIGHT NASAL REGION
Preferred Term	基底細胞癌
AE Onset Date / Rx Day	[redacted]20[redacted] / 206
Age at AE Onset	6[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted](RX DAY 229): SKIN BIOPSY:BASAL CELL CARCINOMA ON LEFT NASAL REGION SOLIDOCYSTIC; TOTAL EXERESIS BASAL CELL CARCINOMA ON LEFT NASAL REGION:RESULT SATISFACTORY

AE Stopped Rx Day	229
Duration of AE	24 DAYS
Severity	Grade 1
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
Investigator Alternative Etiology	POSSIBLE SUN EXPOSURE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	IMPORTANT MEDICAL OR SURGICAL INTERVENTION

Generated: [redacted]20[redacted]:14:15
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M19-944

治験責任医師からの報告。本被験者はスペインの 6[redacted] 歳男性で，米国アッヴィ社の ABT-494（ウパダシチニブ）の治験で盲検化された治験薬及びウパダシチニブが投与され，右鼻領域の基底細胞癌を発現した。

Event 2 の臨床経過：

関連病歴は，肺サルコイドーシス，肥満，軸性脊椎関節炎，元喫煙者（1 日 160 本を 14 年間）及び非飲酒者であった。

被験者は 14 週時までは盲検化プラセボ対照期に参加していた。投与開始から 101 日後，ウパダシチニブの非盲検投与期に移行した。

投与開始から 206 日後，被験者は右鼻領域の基底細胞癌を発現した。投与開始から 229 日後，右鼻領域の基底細胞癌は消失した。

被験者の徴候及び症状は，投与開始から 212 日後に皮膚科医により診断された基底細胞癌と矛盾しない右鼻領域の疣贅状皮膚病変であった。

投与開始から 229 日後，被験者は左鼻領域の基底細胞癌の全切除及び皮膚生検を受けた。

The patient's past medications include:

IBUPROFENE for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

ENANTYUM for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

METICEL for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

SECUKINUMAB for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Basal cell carcinoma face (10083025) (Basal cell carcinoma (10004146)) [v.24.0] [10083025]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Causality for UPADACINIB (Open Label)

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1) Basal cell carcinoma face (10083025) (Basal cell carcinoma (10004146)) [v.24.0] [10083025]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for UPADACITINIB (Blinded)

Event of BASAL CELL CARCINOMA IN THE RIGHT NASAL REGION

- **Investigator:** Possible sun exposure.

- **AbbVie:** Basal cell carcinoma is common in the general white population with an incidence in men 30 percent higher than in women. Additional risk factor includes advanced age with persons aged 55 to 75 having a 100-fold higher incidence of basal cell carcinoma than those younger than 20.

Alternative Etiology for UPADACITINIB (Open Label)

Event of BASAL CELL CARCINOMA IN THE RIGHT NASAL REGION

- **Investigator:** Possible sun exposure.

- **AbbVie:** Basal cell carcinoma is common in the general white population with an incidence in men 30 percent higher than in women. Additional risk factor includes advanced age with persons aged 55 to 75 having a 100-fold higher incidence of basal cell carcinoma than those younger than 20.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BMI:** 30.93426 kg/m2

NON SERIOUS EVENTS AND **OTHER AREAS OF SAFETY INTEREST

Herpes zoster: one dermatome, study drug interrupted

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
尿管結石症	X			

Treatment Group	Age at Study Start	Sex	Race
P1:ABT-494 15 MG QD /P2:ABT-494 15 MG QD	4[redacted]	MALE	ASIAN

Medical History	Onset Year
AXIAL SPONDYLOARTHRITIS DISEASE HISTORY: AXIAL SPONDYLOARTHRITIS	20[redacted]
MEDICAL HISTORY: ANXIETY DISORDER	20[redacted]
MEDICAL HISTORY: INSOMNIA	20[redacted]
MEDICAL HISTORY: PEPTIC ULCER	20[redacted]
MEDICAL HISTORY: BILATERAL BASAL PLEUROPARENCHYMAL FIBROSIS	20[redacted]
MEDICAL HISTORY: FATTY LIVER	20[redacted]
MEDICAL HISTORY: CENTAL SEROUS CHORIORETINOPATHY	20[redacted]
MEDICAL HISTORY: VISUAL DISCOMFORT	20[redacted]
MEDICAL HISTORY: VITREOUS OPACITIES	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	CURRENT	10 CIGARETTE	20	
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ABT-494	15 mg	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 98	98
ABT-494	15 mg	ORAL	QD	[redacted]20[redacted] / 99	/	

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BCG Vaccine	NOT REPORTED	NOT REPORTED	Y-M: 19[redacted]
ETORICOXIB	60 mg	QD	Y-M: 20[redacted]-[redacted]
ALPRAZOLAM	0.5 mg	OTHER: HS	Y-M: 20[redacted]-[redacted]
ZOLPIDEM TARTRATE	10 mg	QD	Y-M: 20[redacted]-[redacted]
CELECOXIB	NOT REPORTED	BID	Y-M: 20[redacted]-[redacted]
SULFASALAZINE	1 g	BID	Y-M: 20[redacted]-[redacted]
RANITIDINE	150 mg	BID	Y-M: 20[redacted]-[redacted]
TRAZODONE HYDROCHLORIDE	50 mg	BID	Y-M: 20[redacted]-[redacted]
ALPRAZOLAM	0.5 mg	BID	Y-M: 20[redacted]-[redacted]
BRODALUMAB	140 mg	OTHER: Q2W	Y-M: 20[redacted]-[redacted]

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
ZOLPIDEM TARTRATE	10 MG	QD	Y-M: 20[redacted]-[redacted]	NOT REPORTED
CELECOXIB	NOT REPORTED	BID	Y-M: 20[redacted]-[redacted]	NOT REPORTED
SULFASALAZINE	1 G	BID	Y-M: 20[redacted]-[redacted]	NOT REPORTED
ALPRAZOLAM	0.5 MG	BID	Y-M: 20[redacted]-[redacted]	NOT REPORTED
FAMOTIDINE	20 MG	BID	Y-M: 20[redacted]-[redacted] / 29	NOT REPORTED

Event #1: Serious Adverse Event

Event Description LEFT URETER STONE

Preferred Term 尿管結石症

AE Onset Date / Rx Day [redacted]20[redacted] / 225

Age at AE Onset 4[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

[redacted]20[redacted] (RX DAY 208): URINE RBC: POSITIVE-RBC:30-49/HPF

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 226): CT SCAN:LEFT LOWER URETERAL OPAQUE STONE; KIDNEY, URETER, BLADDER(KUB):NORMAL; SUPINE ABDOMEN(KUB:KIDNEY, URETER, BLADDER):LEFT LOWER URETERAL OPAQUE STONE; URETERORENOSCOPIC LITHOTRIPSY:COMPLETE; [redacted]20[redacted] (RX DAY 227): DOUBLE J:COMPLETE

AE Stopped Rx Day	227
Duration of AE	3 DAYS
Severity	Grade 3
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
Investigator Alternative Etiology	THE UROLOGIST ASSESSED THAT THE SUBJECT MAY HAVE TOO LITTLE WATER INTAKE.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:14:15

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M19-944

治験責任医師からの報告。本被験者は台湾の 4[redacted] 歳男性で，米国アッヴィ社の ABT-494（ウパダシチニブ）の治験で盲検化された治験薬及びウパダシチニブが投与され，左尿管結石を発現した。

Event 1 の臨床経過：

関連病歴は，強直性脊椎炎，軸性脊椎関節炎，現喫煙者（1 日 10 本を 20 年間）及び非飲酒者であった。

被験者は 14 週時までは盲検化プラセボ対照期に参加していた。投与開始から 99 日後，ウパダシチニブの非盲検投与期に移行した。

投与開始から 225 日後，被験者は左尿管結石を発現した。投与開始から 227 日後，左尿管結石は消失した。

入院前も被験者は強直性脊椎炎のため定期的に受診していた。被験者に手術歴はなく，不快感もなかった。尿沈渣で顕微鏡的血尿が認められた。被験者は検査のため外来を受診した（日付不明）。被験者は尿検査を受け，赤血球 30–49 個 / HPF，白血球 0–5 個 / HPF が認められた。腎臓超音波検査で 0.6 cm の小結節が認められた。膀胱超音波検査では両側腎に異常は認められなかった。しかし，被験者に肉眼的血尿が認められた。尿路 CT 検査で，不明瞭な左下部尿管結

石が認められ，それが遷延性排尿及び閉塞性尿路疾患の要因であると考えられた。そのため，経尿道的尿路結石除去術の適応と示唆された。

投与開始から 225 日後，被験者は外科的処置のため入院した。投与開始から 226 日後，被験者は経尿道的尿路結石除去術を受けた。投与開始から 227 日後，被験者はダブル J ステント造設術を受けた。同日，被験者は退院した。

The patient's past medications include:

ARCOXIA for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

BRODALUMAB for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Ureteric calculus (10046390) (Ureterolithiasis (10077989)) [v.23.1] [10046390]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Causality for UPADACITINIB (Open Label)

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1) Ureteric calculus (10046390) (Ureterolithiasis (10077989)) [v.23.1] [10046390]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of LEFT URETER STONE

- **Investigator:** The urologist assessed that the subject may have too little water intake.

- **AbbVie:** Renal stone is a relatively common problem with an estimated 16 percent of men will be diagnosedwith a kidney stone by age of 70 years. Additional risk factor includes too little water intake as noted by PI.

Alternative Etiology for UPADACITINIB (Open Label)

Event of LEFT URETER STONE

- **Investigator:** The urologist assessed that the subject may have too little water intake.

- **AbbVie:** Renal stone is a relatively common problem with an estimated 16 percent of men will be diagnosed with a kidney stone by age of 70 years. Additional risk factor includes too little water intake as noted by PI.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] KIDNEY, URETER, BLADDER (KUB):** Normal

Unknown date BLADDER ECHOCARDIOGRAM: NP of bilateral kidney.

[redacted] **20[redacted] CT SCAN:** LEFT LOWER URETERAL OPAQUE STONE

Unknown date KIDNEY SONAR: 0.6 cm tiny nodule.

[redacted] **20[redacted] RBC (URINE):** Positive; 30-49/HPF

[redacted] **20[redacted] SUPINE ABDOMEN (KUB:** KIDNEY, URETER, BLADDER): LEFT LOWER URETERAL OPAQUE STONE

Unknown date URINE SEDIMENT: Microscopic hematuria.

Unknown date WBC (URINE): 0-5/HPF

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
尿管結石症	X			

Treatment Group	Age at Study Start	Sex	Race
P1:PLACEBO /P2:ABT-494 15 MG QD	3[redacted]	MALE	ASIAN

Medical History	Onset Year
AXIAL SPONDYLOARTHRITIS DISEASE HISTORY: AXIAL SPONDYLOARTHRITIS	20[redacted]
MEDICAL HISTORY: BACK PAIN	20[redacted]
MEDICAL HISTORY: HYPERLIPIDEMIA	20[redacted]
MEDICAL HISTORY: FATTY LIVER	20[redacted]
MEDICAL HISTORY: INSOMNIA	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
PLACEBO		ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 98	98
ABT-494	15 mg	ORAL	QD	[redacted]20[redacted] / 99	/	

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
DICLOFENAC SODIUM	75 mg	OTHER: HS	Y-M: 20[redacted]
PREDNISOLONE	10 mg	QD	Y-M: 20[redacted]
ETANERCEPT	25 mg	OTHER: BIW	Y-M: 20[redacted]
ETORICOXIB	60 mg	QD	Y-M: 20[redacted]
SULFASALAZINE	500 mg	BID	Y-M: 20[redacted]
SILYBUM MARIANUM	150 mg	TID	Y-M: 20[redacted]
SECUKINUMAB	150 mg	OTHER: Q4W	Y-M: 20[redacted]
SULFASALAZINE	500 mg	BID	Y-M: 20[redacted] / -355
LORAZEPAM	0.5 mg	OTHER: HS	Y-M: 20[redacted] / -152
CELECOXIB	NOT REPORTED	BID	Y-M: 20[redacted] / -124

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
SULFASALAZINE	500 MG	BID	Y-M: 20[redacted] / -355	ONGOING
CELECOXIB	NOT REPORTED	BID	Y-M: 20[redacted] / -124	NOT REPORTED
LORAZEPAM	0.5 MG	OTHER: HS	Y-M: 20[redacted] / 127	NOT REPORTED
CEFAZOLIN SODIUM	1000 MG	OTHER: Q8H	Y-M: 20[redacted] / 213	Y-M: 20[redacted] / 217
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	1 G	OTHER: Q12H	Y-M: 20[redacted] / 226	Y-M: 20[redacted] / 233
OXYBUTYNIN	5 MG	OTHER: HS	Y-M: 20[redacted] / 226	Y-M: 20[redacted]2 / 233
SILODOSIN	4 MG	OTHER: HS	Y-M: 20[redacted] / 226	Y-M: 20[redacted] / 233
AMLODIPINE BESILATE	5 MG	QD	Y-M: 20[redacted] / 232	Y-M: 20[redacted] / 246
AMLODIPINE BESILATE	2.5 MG	QD	Y-M: 20[redacted] / 246	NOT REPORTED

Event #1: Serious Adverse Event

Event Description	URETERAL CALCULI
Preferred Term	尿管結石症
AE Onset Date / Rx Day	[redacted]20[redacted] / 213
Age at AE Onset	3[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 213): ALANINE AMINOTRANSFERASE: 176 [5 - 40] U/L; ERYTHROCYTES: 44 [0 - 17] /MICROLITER; [redacted]20[redacted] (RX DAY 215): ALANINE AMINOTRANSFERASE: 97 [5 - 40] U/L; ASPARTATE AMINOTRANSFERASE: 150 [5 - 34] U/L; CREATINE KINASE: 7377 [26 - 245] U/L; [redacted]20[redacted] (RX DAY 217): CREATINE KINASE: 1257 [26 - 245] U/L; [redacted]20[redacted] (RX DAY 219): CREATINE KINASE: 425 [26 - 245] U/L

Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
NOT REPORTED	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	Grade 3
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
Investigator Alternative Etiology	THAT SUBJECT'S UNDERLYING DISEASE WHICH IS NOT RELATED TO STUDY OR STUDY DRUG.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted] 20[redacted] :14:15

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M19-944

治験責任医師からの報告。本被験者は台湾の 3[redacted] 歳男性で，米国アッヴィ社の ABT-494（ウパダシチニブ）の治験で盲検化された治験薬及びウパダシチニブが投与され，尿管結石を発現した。

Event 1 の臨床経過：

関連病歴は，背部痛，軸性脊椎関節炎，非喫煙者及び非飲酒者であった。

被験者は 14 週時までは盲検化プラセボ対照期に参加していた。投与開始から 99 日後，ウパダシチニブの非盲検投与期に移行した。

投与開始から 213 日後，被験者は尿管結石を発現した。

投与開始から 213 日後，被験者は終日持続する腰痛のため入院した。CT 検査で右腎臓周囲脂肪組織濃度上昇，遅延造影像で軽度の水腎症，遠位尿管の炎症性変化から遠位尿管の小結石の存在が疑われた。尿路感染症のため入院時にセファゾリンの投与が開始された。入院中，クレアチンホスフォキナーゼ（CPK）上昇が認められた。被験者には筋力低下も筋肉痛もなく，黄疸の徴候もなかった。水分補給により CPK は改善した。運動が好ましいと勧められた。高血圧（約 150–160 mmHg）のため，ノルバスクの投与が追加された。血圧は安定し側腹部痛も軽減し，被験者は比較的安定した状態であった。投与開始から 217 日後，被験者は退院した。

投与された薬剤は，セファゾリン，curam，シロドシン及び oxybutynin ER であった。

The patient's past medications include:

DICLOFENAC SR for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

PRENISOLONE for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

ETANERCEPT for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

ETORICOXIB for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

SECUKINUMAB for AXIAL SPONDYLOARTHRITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Ureteral calculus (10046383) (Ureterolithiasis (10077989)) [v.24.0] [10046383]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Causality for UPADACITINIB (Open Label)

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1) Ureteral calculus (10046383) (Ureterolithiasis (10077989)) [v.24.0] [10046383]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for UPADACITINIB (Blinded)
