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

Event Description	URINARY TRACT INFECTION
Preferred term	尿路感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 20
Age at AE Onset	5[redacted]
Laboratory Testing	
[redacted]20[redacted] (Rx Day 22): Leukocytes: 17.4 [4 - 10.5] 10^3/uL	
Microbiology	
[redacted]20[redacted] (Rx Day 22): URINE NPTST272-URICULT: POSITIVE-ENTEROCOCCUS FAECALIS IDENTIFIED; [redacted]20[redacted] (Rx Day 35): URINE NPTST272-URICULT: POSITIVE-ENTEROCOCCUS FAECALIS AND E.COLI IDENTIFIED; [redacted]20[redacted] (Rx Day 65): URINE NPTST272-URICULT: NEGATIVE	
SAE Supplemental Procedure	
[redacted]20[redacted] (Rx Day -5): ULTRASONOGRAPHY OF THE UPPER ABDOMEN, KIDNEYS AND LOWER ABDOMEN: THICKENED URINARY BLADDER WALL, ALSO SUSPECTED URINARY TRACT INFECTION;NO EVIDENCE OF BOSNIAK TYPE II CYST LEFTPYELONEPHRITIS;	
AE Stopped Rx Day	66 (1 DAY AFTER LAST TREATMENT)
Duration of AE	47 DAYS
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	BACTERIAL INFECTION
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

オーストリアの治験責任医師からの報告。本被験者は5[redacted]歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，尿路感染の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，クローン病，尿閉，喫煙者（1 日 10 本を 30 年間）及び非飲酒者であった。

投与 20 日後，被験者は尿路感染を発現した。

投与 22 日後，被験者はかかりつけ医により病院に移送され，尿路感染及び発熱を伴う側腹部痛の確認のため入院した。尿検査が行われ，結果からエンテロコッカス・フェカーリスが原因の尿路感染が認められた。被験者は抗生剤の投与を受け始め，反応は良好であった。投与 25 日後，被験者は退院した。投与 66 日後，尿路感染は消失した。

投与された薬剤は，オーグメンチン，セフトリアキソン，シプロフロキサシン，セフロキシム及び Calciduran であった。

Causality for RISANKIZUMAB (Blinded)

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1) Urinary tract infection (10046571) (Urinary tract infection (10046571)) [v.23.0] [10046571]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of URINARY TRACT INFECTION

- Investigator: Bacterial infection.

- AbbVie: Risk factors include pre-existing bladder inability to empty and female gender.

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] ILEOCOLONOSCOPY: Biopsies obtained

[redacted] **20[redacted] ULTRASONOGRAPHY OF THE UPPER ABDOMEN, KIDNEYS AND LOWERABDOMEN:** Thickened urinary bladder wall, also suspected urinary tract infection; no evidence of bosniak type II cyst leftpyelonephritis.

[redacted] **20[redacted] URICULT:** Positive Entercoccus Faecalis.

[redacted] **20[redacted] WHITE BLOOD CELLS:** 17.4 10^3/uL (normal 4 to 10.5)

Subject [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
腸閉塞	X			

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 600 MG IV	3[redacted]	FEMALE	WHITE

Medical History	Onset Year
ASTHMA: ASTHMA BRONCHIALIS	19[redacted]
OTHER: NEURODERMITS	19[redacted]
OTHER: MORBUS BECHTEREW	20[redacted]
CROHN'S DISEASE	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): BIOPSY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
Risankizumab	600 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 56	56

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
AZATHIOPRINE	Not reported.	Not reported.	Y-M: 20[redacted]
INFLIXIMAB	5 mg/kg	Not reported.	Y-M: 20[redacted]
INFLIXIMAB	Not reported.	Not reported.	Y-M: 20[redacted]
ADALIMUMAB	80 mg	Not reported.	Y-M: 20[redacted]

EUGYNON	3 mg	QD	Y-M: 20[redacted]
ADALIMUMAB	Not reported.	Not reported.	Y-M: 20[redacted]
GOLIMUMAB	Not reported.	Not reported.	Y-M: 20[redacted]
GOLIMUMAB	50 mg	Not reported.	Y-M: 20[redacted] / -322
ETORICOXIB	90 mg	QD	Y-M: 20[redacted] / -20
MOVIPREP	NOT APPLICABLE OTHER: NOT APPLICABLE	QD	Y-M: 20[redacted] / -16
MIDAZOLAM	5 mg	OTHER: ONCE	Y-M: 20[redacted] / -15
PROPOFOL	150 mg	OTHER: ONCE	Y-M: 20[redacted] / -15

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
EUGYNON	3 mg	QD	Y-M: 20[redacted]	ONGOING
ETORICOXIB	90 mg	QD	Y-M: 20[redacted] / -20	ONGOING
TOBRADEX	UNK gtt	PRN	Y-M: 20[redacted] / 2	Y-M: 20[redacted] / 9
CIPROFLOXACIN	400 mg	BID	Y-M: 20[redacted] / 13	Y-M: 20[redacted] / 42
METRONIDAZOLE	1500 mg	QD	Y-M: 20[redacted] / 13	Y-M: 20[redacted] / 42
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted] / 32	Y-M: 20[redacted] / 42
PARACETAMOL	500 mg	PRN	Y-M: 20[redacted] / 32	Y-M: 20[redacted] / 42
PASSEDAN	50 g	PRN	Y-M: 20[redacted] / 32	Y-M: 20[redacted] / 42

Event #1: Serious Adverse Event

Event Description	ACUTE BOWEL OBSTRUCTION
Preferred term	腸閉塞
AE Onset Date / Rx Day	[redacted]20[redacted] / 32
Age at AE Onset	3[redacted]

Laboratory Testing

Not reported

Microbiology

Not reported

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 13): SURGERY ILEOCOECAL RESECTION: RESECTED PART OF ILEOCOECUM WITH NON INFLAMMED RESECTION EDGES AND ULCERA IN THE TERMINAL ILEUM.

AE Stopped Rx Day	42
Duration of AE	11 DAYS
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility

Investigator Alternative Etiology	CROHNS DISEASE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

オーストリアの治験責任医師からの報告。本被験者は 3[redacted] 歳女性であり，AbbVie の ABBV-066（リサンキズマブ）の治験で盲検化された治験薬が投与され，急性腸閉塞の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，強直性脊椎炎，クローン病，非喫煙者及び飲酒者（1 日 2 杯未満）であった。

投与 32 日後，被験者は急性腸閉塞を発現した。投与 42 日後，急性腸閉塞は消失した。

投与 32 日後，被験者は腹痛及び発熱の急性発現のため入院した。被験者は，回腸末端に腸閉塞に起因する非炎症性切除縁及び潰瘍を伴う回盲部切除を受けた。投与 42 日後，被験者は退院した。

投与された薬剤は，Mexalen 及び Pantoloc であった。

The patient's past medications include:

INFLIXIMAB for CROHN'S DISEASE (20[redacted] - [redacted] 20[redacted])

ADALIMUMAB for CROHN'S DISEASE (20[redacted] - [redacted] 20[redacted])

GOLIMUMAB for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-066 (Blinded)

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1) Bowel obstruction (10006055) (Intestinal obstruction (10022687)) [v.21.1] [10006055]

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABBV-066 (Blinded)

Event of ACUTE BOWEL OBSTRUCTION

- Investigator: Crohn's disease.

- AbbVie: Event more likely due to pre-existing Crohn's Disease.

Subject [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
クローン病	X			

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 600 MG IV	3[redacted]	MALE	WHITE

Medical History	Onset Year
CROHN'S DISEASE	20[redacted]
OTHER: OBSTRUCTION	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE SURGICAL HISTORY: BOWEL RESECTION	20[redacted]
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): BIOPSY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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)
Risankizumab	600 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 57	57

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
ADALIMUMAB	40 mg	Not reported.	Y-M: 20[redacted]
AZATHIOPRINE	Not reported.	Not reported.	Y-M: 20[redacted]
INFLIXIMAB	400 mg	Not reported.	Y-M: 20[redacted]
INFLIXIMAB	800 mg	Not reported.	Y-M: 20[redacted] / -247

MOVIPREP	UNKNOWN OTHER: UNKNOWN	QD	Y-M: 20[redacted] / -16
MIDAZOLAM	5 mg	OTHER: ONCE	Y-M: 20[redacted] / -15
PROPOFOL	450 mg	OTHER: ONCE	Y-M: 20[redacted] / -15

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
ENOXAPARIN	40 mg	QD	Y-M: 20[redacted] / 26	Y-M: 20[redacted] / 34
PIP/TAZO	4 mg	TID	Y-M: 20[redacted] / 26	Y-M: 20[redacted] / 39
METOCLOPRAMIDE	10 mg	TID	Y-M: 20[redacted] / 28	Y-M: 20[redacted] / 31
METAMIZOLE	1 g	TID	Y-M: 20[redacted] / 28	Y-M: 20[redacted] / 39
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted] / 28	Y-M: 20[redacted] / 39
LACTOBACILLUS ACIDOPHILUS	NA mg	BID	Y-M: 20[redacted] / 31	Y-M: 20[redacted] / 39
IRON	1000 mg	QD	Y-M: 20[redacted] / 34	Y-M: 20[redacted] / 34
ERYTHROPOIETIN HUMAN	30.000 IU	QD	Y-M: 20[redacted] / 36	Y-M: 20[redacted] / 36

Event #1: Serious Adverse Event

Event Description CROHNS DISEASE AGGRAVATION ILEOCOECAL

Preferred term クローン病

AE Onset Date / Rx Day [redacted]20[redacted] / 19

Age at AE Onset 3[redacted]

Laboratory Testing

Not reported

Microbiology

Not reported

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 16): ABDOMINAL ULTRASOUND: INFLAMMATORY MASS INVOLVING THE TERMINAL ILEUM WITH SUSPECT ABSCESS FORMATION.; CLOSTRIDIUM DIFF.: NEGATIV; COLONOSCOPY AND GATROSCOPY: NORMAL; CT-SCAN: 9X11X9CM INFLAMMATORY MASS INVOLVING THE TERMINAL ILEUM 2,2CM ABSCESS FORMATION. DILATATION OF THE RIGHT URETER DUE TO COMPRESSION BY THE IN INFLAMMATORY MASS; ECG: NORMAL; ILEOACENDOSTOMY: ILEOACENDOSTIOMY WAS DONE WITHOUT COMPLICATIONS; PATHOLOGY REPORT: NO DYSPLASIA NO MALIGNANCY; URIN TEST: NEGSTIV

AE Stopped Rx Day 39

Duration of AE 21 DAYS

Severity Severe

Relation to Study Drug by Investigator No Reasonable Possibility

Investigator Alternative Etiology	RELATED TO CROHN'S DISEASE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

オーストリアの治験責任医師からの報告。本被験者は3[redacted]歳男性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，クローン病増悪（回盲部）の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，クローン病，腸切除術，閉塞，非喫煙者及び禁酒であった。

投与 19 日後，被験者はクローン病増悪（回盲部）を発現した。投与 39 日後，クローン病増悪（回盲部）は消失した。

投与 19 日後，被験者は 1 週間前からの腹痛増加及び全身状態低下のため入院した。身体的診察が行われ，右下腹部に筋性防御が認められた。CT スキャンが行われ，炎症性腫瘤及び炎症性腫瘤による圧迫に起因する回腸膿瘍形成及び右尿管拡張が認められた。投与 27 日後，回盲部切除／ileoascendostiomy が行われた。術後の経過に問題はなかった。病理報告書に異形成及び悪性疾患は認められなかった。投与 39 日後，被験者は退院した。

投与された薬剤は，パントプラゾール，メトクロプラミド，Bioflorin，Tazonam，Lovenox，フェインジェクト，erythropoietin 及びメタミゾールであった。

The patient's past medications include:

ADALIMUMAB for CROHN'S DISEASE (20[redacted] - [redacted] 20[redacted])

AZATHIOPRIN for CROHN'S DISEASE (20[redacted] - [redacted] 20[redacted])

REMICADE for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

INFLIXIMAB for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Crohns disease aggravated (10011408) (Crohn's disease (10011401)) [v.22.1] [10011408]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of CROHN'S DISEASE AGGRAVATION ILEOCOECAL

- Investigator: Related to Crohn's disease.

- AbbVie: Event more likely related to pre-existing Crohn's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMINAL ULTRASOUND:** INFLAMMATORY MASS INVOLVING THE TERMINAL ILEUM WITH SUSPECT ABSCESS FORMATION.

[redacted] 20[redacted] C. DIFF: negative

[redacted] 20[redacted] COLONOSCOPY/GASTROSCOPY: Normal

[redacted] 20[redacted] CRP: Not reported

[redacted] **20[redacted] CT SCAN:** 9X11X9CM INFLAMMATORY MASS INVOLVING THE TERMINAL ILEUM 2,2CM ABSCESS FORMATION. DILATATION OF THE RIGHT URETER DUE TO COMPRESSION BY THE IN INFLAMMATORY MASS

[redacted] 20[redacted] ILEOCOLONOSCOPY: Not reported

Subject [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
喘息	X			
下気道感染	X			X

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 600 MG IV	2[redacted]	MALE	WHITE

Medical History	Onset Year
IMMUNE DEFICIENCY DISEASE: GRAVES DISEASE	Not reported.
OTHER: COELIAC DISEASE	Not reported.
CROHN'S DISEASE	20[redacted]
OTHER: ANAEMIA IRON DEFICIENCY	20[redacted]
OTHER: ANAEMIA FOLATE DEFICIENCY	20[redacted]
OTHER: ACNE	20[redacted]
ASTHMA	20[redacted]
OTHER: GENERAL BODY PAIN	20[redacted]
OTHER: COLD SYMPTOMS	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
SURGERY: APPENDECTOMY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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)
Risankizumab	600 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 54	54

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
INFLIXIMAB	10 mg/kg	Not reported.	Y-M: 20[redacted]
ADALIMUMAB	40 mg	Not reported.	Y-M: 20[redacted]
AZATHIOPRINE	Not reported.	Not reported.	Y-M: 20[redacted]
BUDESONIDE W/FORMOTEROL FUMARATE	1-2 OTHER: PUFFS	PRN	Y-M: 20[redacted]
SALBUTAMOL	1-2 OTHER: PUFFS	PRN	Y-M: 20[redacted]
MERCAPTOPURINE	Not reported.	Not reported.	Y-M: 20[redacted]
PARACETAMOL	1 g	PRN	Y-M: 20[redacted]
OMEPRAZOLE	40 mg	QD	Y-M: 20[redacted] / -33
FENTANYL	100 ug	OTHER: ONCE	Y-M: 20[redacted] / -13
MIDAZOLAM	2 mg	OTHER: ONCE	Y-M: 20[redacted] / -13

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	1-2 OTHER: PUFFS	PRN	Y-M: 20[redacted]	ONGOING
PARACETAMOL	1 g	PRN	Y-M: 20[redacted]	ONGOING
FENTANYL	100 ug	OTHER: ONCE	Y-M: 20[redacted] / -13	Y-M: 20[redacted] / -13
MIDAZOLAM	2 mg	OTHER: ONCE	Y-M: 20[redacted] / -13	Y-M: 20[redacted] / -13
AUGMENTIN	625 mg	TID	Y-M: 20[redacted] / 17	Y-M: 20[redacted] / 20
OSELTAMIVIR	75 mg	TID	Y-M: 20[redacted] / 18	Y-M: 20[redacted] / 22
BEKFORM	2 OTHER: PUFFS	BID	Y-M: 20[redacted] / 19	ONGOING
CLARITHROMYCIN	500 mg	BID	Y-M: 20[redacted] / 20	Y-M: 20[redacted] / 24
PREDNISOLONE	20 mg	QD	Y-M: 20[redacted] / 21	Y-M: 20[redacted] / 23

Event #1: Serious Adverse Event

Event Description	EXACERBATION OF ASTHMA
Preferred term	喘息
AE Onset Date / Rx Day	[redacted]20[redacted] / 17
Age at AE Onset	2[redacted]

Laboratory Testing

Not reported

Microbiology

Not reported

SAE Supplemental Procedure
[redacted]20[redacted] (Rx Day -12): ECG: RESTING TACHYCARDIA NOTED OF 128 BPM. STABILISING BY ADMISSION; PEAK FLOW: 230 WCC

AE Stopped Rx Day	21
Duration of AE	5 DAYS
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	RESPIRATORY INFECTION
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

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

Event Description	LOWER RESPIRATORY TRACT INFECTION
Preferred term	下気道感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 17
Age at AE Onset	2[redacted]

Laboratory Testing
Not reported
Microbiology
Not reported
SAE Supplemental Procedure
[redacted]20[redacted] (Rx Day -12): ECG: RESTING TACHYCARDIA NOTED OF 128 BPM. STABILISING BY ADMISSION; PEAK FLOW: 230 WCC

AE Stopped Rx Day	23
Duration of AE	7 DAYS
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	EXACERBATION OF ASTHMA
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

英国の治験責任医師からの報告。本被験者は 2[redacted] 歳男性であり，AbbVie の ABBV-066（リサンキズマブ）の治験で盲検化された治験薬が投与され，喘息増悪及び下気道感染の事象を発現した。

Event 1 及び 2 の臨床経過：
関連する病歴は，クローン病，喘息，鉄欠乏性貧血，感冒症状，グレーブス病，セリアック病，非喫煙者及び非飲酒者であった。

投与 17 日後，被験者は喘息増悪及び下気道感染を発現した。投与 21 日後，喘息増悪は消失した。投与 23 日後，下気道感染は消失した。

入院前の数日間，被験者は緑黄色の痰を伴う息切れ及び湿性咳嗽を発現した。投与 17 日後，被験者は入院した。入院時に検査が行われ，両肺の均等な air entry 及び捻髪音を伴わない両側喘鳴が認められた。被験者によると，胸痛及び悪心はなかった。投与 21 日後，被験者は退院した。

投与された薬剤は，プレドニゾロン，Fostair，タミフル，クラリスロマイシン及びアモキシシリン・クラブラン酸合剤であった。

The patient’s past medications include:

INFLIXIMAB for CROHNS DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ADALIMUMAB for CROHNS DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

SYMBICORT for ASTHMA (20[redacted] - [redacted] 20[redacted])

Causality for ABBV-066 (Blinded)

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1) Exacerbation of asthma (10015575) (Asthma (10003553)) [v.22.0] [10015575]

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

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

Dechallenge: Not Applicable

2) Lower respiratory tract infection (10024968) (Lower respiratory tract infection (10024968)) [v.22.0] [10024968]

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABBV-066 (Blinded)

Event of EXACERBATION OF ASTHMA

- Investigator: Respiratory infection.

- AbbVie: Event more likely related to pre-existing asthma.

Event of LOWER RESPIRATORY TRACT INFECTION

- Investigator: Exacerbation of asthma

- AbbVie: Event is common in the general population. Pre-existing asthma is an additional risk factor.

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] CHEST X-RAY: Pending

[redacted] **20[redacted] ECG:** RESTING TACHYCARDIA NOTED OF 128 BPM. STABILISING BY ADMISSION

[redacted] 20[redacted] PEAK FLOW: 230 WCC

Subject [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
クローン病	X	X		

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 600 MG IV	2[redacted]	FEMALE	WHITE

Medical History	Onset Year
OTHER: PILONIDAL SINUS OF NATAL CLEFT	20[redacted]
OTHER: ABDOMINAL PAIN	20
CROHN'S DISEASE	20
OTHER: ABDOMINAL PAIN	20
OTHER: CHEST INFECTION/PNEUMONIA	20
OTHER: NAUSEA	20
OTHER: BENIGN JOINT HEIGHT MOBILITY SYNDROME	20
OTHER: MULTIPLE MECHANICAL ARTHRALGIA	20
OTHER: CONSTIPATION	20
OTHER: FACIAL RASH	20
OTHER: FLARE OF TENNIS ELBOW	20
OTHER: ILEAC FOSSA PAIN	20
OTHER: LOOSE STOOL	20
GASTROINTESTINAL BLEED: RECTAL BLEEDING	20
OTHER: ABDOMINAL PAIN	20
OTHER: COUGH	20
OTHER: FLU LIKE SYMPTOMS	20
OTHER: LYMPHADENOPATHY	20
OTHER: MOOD DISORDER	20
OTHER: VIRAL UPPER RESPIRATORY TRACT INFECTION	20
OTHER: PYREXIA	20

Prior Procedures	Procedure Year
SURGERY: BILATERAL MAXILLARY OSTEOTOMY	20[redacted]
CROHN'S DISEASE HISTORY: COLONOSCOPY	20
ENDOSCOPY (SCREENING): BIOPSY	20
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	20

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CIGARETTES	FORMER	1 CIGARETTE	3	20[redacted]
CHEWING TOBACCO	NEVER			
CIGARS	NEVER			

E-CIGARETTES	NEVER
PIPES	NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
Risankizumab	600 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 54	54

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
HYDROCORTISONE	100 mg	OTHER: STAT	Y-M: 20[redacted]-
PREDNISOLONE	40 mg	QD	Y-M: 20[redacted]-
PREDNISOLONE	35 mg	QD	Y-M: 20[redacted]-
PREDNISOLONE	30 mg	QD	Y-M: 20[redacted]-
PREDNISOLONE	20 mg	QD	Y-M: 20[redacted]-
PREDNISOLONE	15 mg	QD	Y-M: 20[redacted]-
PREDNISOLONE	10 mg	QD	Y-M: 20[redacted]-
PREDNISOLONE	5 mg	QD	Y-M: 20[redacted]-
PREDNISOLONE	25 mg	QD	Y-M: 20[redacted]-
PREDNISOLONE	15 mg	QD	Y-M: 20[redacted]-
PREDNISOLONE	40 mg	QD	Y-M: 20[redacted]-
PREDNISOLONE	10 mg	QD	Y-M: 20[redacted]-
PREDNISOLONE	5 mg	QD	Y-M: 20[redacted]-
HYDROCORTISONE	100 mg	OTHER: STAT	Y-M: 20[redacted]-
SPEKTRAMOX	625 mg	TID	Y-M: 20[redacted]-
COLECALCIFEROL	20000 OTHER: UNITS	OTHER: MONTHLY	Y-M: 20[redacted]-
HYOSCINE	10 - 20 mg	PRN	Y-M: 20[redacted]-
INFLIXIMAB	5 mg/kg	OTHER: 8 WEEKLY	Y-M: 20[redacted]-
LANSOPRAZOLE	30 mg	BID	Y-M: 20[redacted]-
PREDNISOLONE	30 mg	QD	Y-M: 20[redacted]-
PREDNISOLONE	25 mg	QD	Y-M: 20[redacted]-
PREDNISOLONE	20 mg	QD	Y-M: 20[redacted]-
PREDNISOLONE	15 mg	QD	Y-M: 20[redacted]-
PREDNISOLONE	10 mg	QD	Y-M: 20[redacted]-
PREDNISOLONE	5 mg	QD	Y-M: 20[redacted]-
MESALAZINE	2 g	QD	Y-M: 20[redacted]-
PARACETAMOL	1 g	QID	Y-M: 20[redacted]-
CHLORPHENAMINE	10 mg	OTHER: STAT	Y-M: 20[redacted]-
HYDROCORTISONE	200 mg	OTHER: STAT	Y-M: 20[redacted]-
AZATHIOPRINE	200 mg	BID	Y-M: 20[redacted]-
ADALIMUMAB	160 mg	OTHER: STAT	Y-M: 20[redacted]-

ADALIMUMAB	80 mg	OTHER: 4WEEKLY	Y-M: 20[redacted]
ADALIMUMAB	40 mg	OTHER: EIGHT WEEKLY	Y-M: 20[redacted]
MOVICOL	2 OTHER: SACHETS	BID	Y-M: 20[redacted]
VEDOLIZUMAB	300 mg	OTHER: 8WKLY	Y-M: 20[redacted] / -90

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
IRON	200 mg	QD	Y-M: 20[redacted] / 26	Y-M: 20[redacted] / 65
RINGER-LACTATE	1000 OTHER: 1000 ONCE ONLY	PRN	Y-M: 20[redacted] / 64	Y-M: 20[redacted] / 68
CAFFEINE W/CARBOHYDRATES NOS/CHOLIN	200 mL	QID	Y-M: 20[redacted] / 65	ONGOING
OXYCODONE	2.5 - 5 mg	PRN	Y-M: 20[redacted] / 65	ONGOING
OXYGEN	4 OTHER: L/MINUTE	PRN	Y-M: 20[redacted] / 65	ONGOING
NALOXONE	100 OTHER: MICROGRAM	PRN	Y-M: 20[redacted] / 65	Y-M: 20[redacted] / 65
ONDANSETRON	4 mg	PRN	Y-M: 20[redacted] / 65	Y-M: 20[redacted] / 65
HYDROCORTISONE	100 mg	QID	Y-M: 20[redacted] / 65	Y-M: 20[redacted] / 66
ENOXAPARIN	40 mg	QD	Y-M: 20[redacted] / 65	Y-M: 20[redacted] / 78

Event #1: Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Event Description WORSENING OF CROHNS DISEASE

Preferred term クローン病

AE Onset Date / Rx Day [redacted]20[redacted] / 63 (9 DAYS AFTER LAST TREATMENT)

Age at AE Onset 2[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 64): Basophils: 0.07 [0 - 0.1] 10^9/L; Erythrocytes: 4.78 [3.8 - 5.8] 10^9/L; Hemoglobin: 119 [115 - 160] g/L; Leukocytes: 15.11 [4 - 15.11] 10^9/L; NPTST070-CRP: 12.3 [10 - 10] mg/L; Platelets: 461 [150 - 400] 10^9/L; [redacted]20[redacted] (Rx Day 70): Leukocytes: 11.55 [4 - 11] 10^9/L

Microbiology

Not reported

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 35): CT ABDOMEN AND PELVIS SC WITH ILEOSTOMY AND HARTMANN POUCH AND ILEORECTAL ANASTOMOSIS: NO EVIDENCE OF BOWEL PERFORATION OR OBSTRUCTION BOWEL IS COLLPSED

AE Stopped Rx Day 65 (11 DAYS AFTER LAST TREATMENT)

Duration of AE 3 DAYS

Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	WORSENING OF THE PRESENT CONDITION
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Generated: [redacted] 20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

英国の治験責任医師からの報告。本被験者は 2[redacted] 歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，クローン病悪化の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，腹痛，軟便，直腸出血，クローン病及び便秘であった。

投与 63 日後，被験者はクローン病悪化を発現した。投与 65 日後，クローン病悪化は消失した。

投与 64 日後，被験者はクローン病悪化のため入院した。血塊を伴う便の増加などの徴候及び症状があった。被験者は回腸瘻造設，並びにハルトマン手術及び回腸直腸吻合を受けた。投与 76 日後，被験者は退院した。

投与された薬剤は，オンダンセトロン，オキシコドン，コデインリン酸塩，paracetamol，酸素，オキシコドン塩酸塩，Fresubin energy liquid，ヒドロコルチゾン及びエノキサパリンであった。

The patient’s past medications include:

HYDROCORTISONE for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

PREDNISOLONE for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

AZATHIOPRINE for CROHN'S DISEASE (Stopped [redacted] 20[redacted])

VEDOLICIMAB for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Crohns disease aggravated (10011408) (Crohn's disease (10011401)) [v.22.0] [10011408]

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 RISANKIZUMAB (Blinded)

Event of WORSENING OF CROHNS DISEASE

- Investigator: WORSENING OF THE PRESENT CONDITION.

- AbbVie: Event more likely related to pre-existing Crohn's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CRP:** 12.3 X10**9/L (normal <10)

[redacted] **20[redacted] CT ABDOMEN AND PELVIS:** No evidence of bowel perforation or obstruction bowel is collapsed.

[redacted] **20[redacted] HEMOGLOBIN:** 119 G/L (normal 115 to 160)

[redacted] 20[redacted] ILEOCOLONOSCOPY: Screening

[redacted] **20[redacted] PLATELET:** 461 X10**9/L (normal 150 to 400)

[redacted] **20[redacted] RED BLOOD CELLS:** 4.78 X10**9/L (normal 3.80 to 5.80)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 15.11 X10**9/L (normal 4 to 15.11)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 11.55 X10**9/L (normal 4 to 15.11)

Subject [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
クローン病	X	X		

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 1200 MG IV	2[redacted]	MALE	WHITE

Medical History	Onset Year
DIABETES MELLITUS: TYPE 1	19[redacted]
CROHN'S DISEASE	20[redacted]
INFLAMMATORY BOWEL DISEASE: CROHNS	20[redacted]
OTHER: FATIGUE SYNDROM	20[redacted]
INFLAMMATORY BOWEL DISEASE: DISEASE FLARE	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): BIOPSY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CIGARETTES	FORMER	1 CIGARETTE	0	20[redacted]
CHEWING TOBACCO	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
Risankizumab	1200 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 30	30

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
INSULIN HUMAN	UNKNOWN OTHER: IU/ML	QD	Y-M: 20[redacted]-[redacted]
AZATHIOPRINE	200 mg	QD	Y-M: 20[redacted]-[redacted]

INFLIXIMAB	400 mg	OTHER: MONTHLY	Y-M: 20[redacted]
USTEKINUMAB	90 mg	OTHER: 8 WEEKS	Y-M: 20[redacted]
VEDOLIZUMAB	300 mg	OTHER: MONTHLY	Y-M: 20[redacted]
BUDESONIDE	6 mg	QD	Y-M: 20[redacted] / -63
MOVIPREP	2 OTHER: DOSE UNITS	BID	Y-M: 20[redacted] / -20
ALFENTANIL	2.5 mg	OTHER: AS NEEDED	Y-M: 20[redacted] / -19
MIDAZOLAM	3 mg	OTHER: AS NEEDED	Y-M: 20[redacted] / -19

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
INSULIN HUMAN	UNKNOWN OTHER: IU/ML	QD	Y-M: 20[redacted]	ONGOING
AZATHIOPRINE	200 mg	QD	Y-M: 20[redacted]	ONGOING
BUDESONIDE	6 mg	QD	Y-M: 20[redacted] / -63	ONGOING
BETAMETHASONE	4 mg	BID	Y-M: 20[redacted] / 59	Y-M: 20[redacted] / 63
PREDNISONE	45 mg	QD	Y-M: 20[redacted] / 64	ONGOING

Event #1: Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Event Description WORSENING OF CROHNS DISEASE

Preferred term クローン病

AE Onset Date / Rx Day [redacted]20[redacted] / 48 (18 DAYS AFTER LAST TREATMENT)

Age at AE Onset 3[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 59): Albumin: 37 [36 - 48] g/L; Bilirubin: 10 [0 - 26] umol/L; C Reactive Protein: 9 [0 - 3] mg/L; Creatinine: 90 [0 - 100] umol/L; Ery. Mean Corpuscular Hemoglobin: 34 [27 - 33] pg; Ery. Mean Corpuscular Volume: 97 [82 - 98] fL; Erythrocytes: 4.3 [4.2 - 5.7] 10^12/L; Glucose: 13.6 [4 - 6] mmol/L; Hematocrit: 0.42 [0.39 - 0.5] Unit not reported; Hemoglobin: 148 [134 - 170] g/L; Leukocytes: 6.7 [3.5 - 8.8] 10^9/L; Platelets: 390 [145 - 348] 10^9/L; Potassium: 4.3 [3.5 - 4.6] mmol/L; Sodium: 137 [137 - 145] mmol/L

Microbiology

[redacted]20[redacted] (Rx Day 62): STOOL NPTST008-AEROMONAS: NEGATIVE; STOOL NPTST057-CAMPYLOBACTER: NEGATIVE; STOOL NPTST061-CLOSTRIDIOIDES DIFFICILE: NEGATIVE; STOOL NPTST071-CRYPTOSPORIDIUM SPECIES: NEGATIVE; STOOL NPTST075-CYSTS AND WORM EGGS: NEGATIVE; STOOL NPTST086-ENTAMOEBA HISTOLYTICA: NEGATIVE; STOOL NPTST116-GIARDIA INTESTINALIS: NEGATIVE; STOOL NPTST197-PLESIOMONAS: NEGATIVE; STOOL NPTST238-SALMONELLA: NEGATIVE; STOOL NPTST245-SHIGELLA: NEGATIVE; STOOL NPTST287-YERSINIA: NEGATIVE

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 29): ABDOMINAL CT-SCAN: ON LEFT SIDE OF THE UPPER ABDOMINAL THERE WERE SIGNS OF FREE GAS. AND THERE WERE ALSO SIGNS OF COLITIS IN BOTH ILEUM AND COLON.; SIGMOIDEOSCOPY: SEVERE INFLAMMATION UP TO ABOUT HALF OF TRANSVERSUM.

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	Severe
Relation to Study Drug by Investigator	Reasonable Possibility
Investigator Alternative Etiology	Not reported
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

スウェーデンの治験責任医師からの報告。本被験者は3[redacted]歳男性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，クローン病悪化の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，1 型糖尿病，元喫煙者（1 日 1 本），クローン病，疲労症候群，クローン病フレア，炎症性腸疾患及び現飲酒者（1 日 2 杯未満）であった。

投与 48 日後，被験者はクローン病悪化を発現した。

投与 59 日後，被験者は 2 週間にわたる重度のクローン病フレアの徴候増加のため入院した。腹痛，悪心，1 日 15～20 回の排便及び毎晩 4 回の排便などの徴候及び症状があった。腸管穿孔が疑われた。投与 59 日後，被験者は治験参加の同意を撤回した。コルチゾンによる治療開始から数日後，状態に改善が認められた。投与 69 日後，被験者は退院した。

投与された薬剤は，Betapred，コルチゾン及び prednisone であった。

The patient's past medications include:

REMICADE for CROHN'S DISEASE ([redacted]20[redacted] - [redacted]20[redacted])

USTEKINUMAB for CROHN'S DISEASE ([redacted]20[redacted] - [redacted]20[redacted])

ENTYVIO for CROHN'S DISEASE ([redacted]20[redacted] - [redacted]20[redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Crohns disease aggravated (10011408) (Crohn's disease (10011401)) [v.23.0] [10011408]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of WORSENING OF CROHNS DISEASE

- Investigator: Not applicable

- AbbVie: Event more likely related to pre-existing Crohn's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMINAL CT:** Signs of free gas left upper abdomen; signs of colitis in both ileum and colon

[redacted] **20[redacted] CRP:** 9 MG/L (normal 0 to 3)

[redacted] **20[redacted] HCT:** 0.42 no unit (normal 0.39 to 0.50)

[redacted] **20[redacted] HGB:** 148 G/L (normal 134 to 170)

[redacted] **20[redacted] ILEOCOLONOSCOPY:** Screening: 8 Biopsies taken

[redacted] **20[redacted] RBC:** 4.3 X10**12/L (normal 4.2 to 5.7)

[redacted] **20[redacted] SIGMOIDEOSCOPY:** Severe inflammation up to about half of transversum

[redacted] **20[redacted] SODIUM:** 137 MMOL/L (normal 137 to 145)

[redacted] 20[redacted] STOOL AEROMONAS: Negative

[redacted] 20[redacted] STOOL C DIFF: Negative

[redacted] 20[redacted] STOOL CAMPYLOBACTER: Negative

[redacted] 20[redacted] STOOL CRYPTOSPORIDIUM SPECIES: Negative

[redacted] 20[redacted] STOOL CYSTS AND WORM EGGS: Negative

[redacted] 20[redacted] STOOL ENTAMOEBA HISTOLYTICA: Negative

[redacted] 20[redacted] STOOL GIARDIA INTESTINALIS: Negative

[redacted] 20[redacted] STOOL PLESIOMONAS: Negative

[redacted] 20[redacted] STOOL SALMONELLA: Negative

[redacted] 20[redacted] STOOL SHIGELLA: Negative

[redacted] 20[redacted] STOOL YERSINIA: Negative

[redacted] **20[redacted] WBC:** 6.7 X10**9/L (normal 3.5 to 8.8)

Subject [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
関節痛	X	X		

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 600 MG IV	2[redacted]	MALE	WHITE

Medical History	Onset Year
ASTHMA: ASTHMA AS A CHILD	Not reported.
OTHER: SEASONAL ALLERGY	Not reported.
CROHN'S DISEASE	20[redacted]
OTHER: ARTHRALGIA - EXTRAINTESTINAL MANIFESTATION OF CROHN'S DISEASE	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): BIOPSY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
Risankizumab	600 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 31	31

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
LOPERAMIDE	2 mg	PRN	Y-M: 20[redacted]
PARACETAMOL	500 mg	PRN	Y-M: 20[redacted]
AZATHIOPRINE	150 mg	QD	Y-M: 20[redacted]-[redacted]

METHOTREXATE	25 mg	OTHER: ONCE A WEEK	Y-M: 20[redacted]
DESLORATADINE	5 mg	PRN	Y-M: 20[redacted]
PREDNISOLONE	20 mg	QD	Y-M: 20[redacted] / -147
PREDNISOLONE	40 mg	QD	Y-M: 20[redacted] / -125
ADALIMUMAB	80 mg	OTHER: EVERY 2 WEEKS	Y-M: 20[redacted] / -41
BETAMETHASONE	4 mg	QD	Y-M: 20[redacted] / -25
MOVICOL	1 OTHER: SACHET	BID	Y-M: 20[redacted] / -6
MOVPREP	2 L	OTHER: ONCE	Y-M: 20[redacted] / -6
ALFENTANIL	0.25 mg	OTHER: ONCE	Y-M: 20[redacted] / -5
MIDAZOLAM	2 mg	OTHER: ONCE	Y-M: 20[redacted] / -5

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
LOPERAMIDE	2 mg	PRN	Y-M: 20[redacted]	ONGOING
PARACETAMOL	500 mg	PRN	Y-M: 20[redacted]	ONGOING
DESLORATADINE	5 mg	PRN	Y-M: 20[redacted]	ONGOING
OMEPRAZOLE	20 mg	QD	Y-M: 20[redacted] / 31	ONGOING
LEKOVIT CA	500/800 OTHER: MG+IE	QD	Y-M: 20[redacted] / 44	ONGOING
PREDNISOLONE	40 mg	QD	Y-M: 20[redacted] / 44	ONGOING
GOLIMUMAB	200 mg	OTHER: INDUCTION DOSE	Y-M: 20[redacted] / 65	ONGOING

Event #1: AE Leading to Discontinuation of Study Drug

Event Description	EXACERBATION OF ARTHRALGIA
Preferred term	関節痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 28
Age at AE Onset	2[redacted]
Laboratory Testing	
Not Applicable	
Microbiology	
Not Applicable	
SAE Supplemental Procedure	
Not Applicable	
AE Stopped Rx Day	67 (36 DAYS AFTER LAST TREATMENT)
Duration of AE	40 DAYS
Severity	Moderate
Relation to Study Drug by Investigator	Reasonable Possibility

Investigator Alternative Etiology	Not Applicable
Discontinued Study Drug Due to the Event	YES
SAE Criteria	None

Event #2: Serious Adverse Event

Event Description	MIGRATING PERIPHERAL ARTHRALGIA
Preferred term	関節痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 67 (36 DAYS AFTER LAST TREATMENT)
Age at AE Onset	2[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 75): Alanine Aminotransferase: 0.33 [0 - 1.1] ukat/L; Albumin: 37 [36 - 48] g/L; Aspartate Aminotransferase: <0.22 [0 - 0.76] ukat/L; Basophils: <0.1 [0 - 0.1] 10^9/L; Bilirubin: 16 [0 - 26] umol/L; C Reactive Protein: <1 [0 - 3] mg/L; Calcium: 2.32 [2.15 - 2.5] mmol/L; Creatine Kinase: 0.8 [0.8 - 6.7] ukat/L; Creatinine: 97 [0 - 100] umol/L; Eosinophils: 0.1 [0 - 0.5] 10^9/L; Ery. Mean Corpuscular Hemoglobin: 31 [27 - 33] pg; Ery. Mean Corpuscular Volume: 91 [82 - 98] fL; Erythrocytes: 4.4 [4.2 - 5.7] 10^12/L; Hematocrit: 0.40 [0.39 - 0.5] fraction of 1; Hemoglobin: 136 [134 - 170] g/L; Leukocytes: 10 [3.5 - 8.8] 10^9/L; Lymphocytes: 4.6 [1.1 - 3.5] 10^9/L; Monocytes: 0.8 [0.2 - 0.8] 10^9/L; NPTST085-EGFR(CREA) REL: 80 [80 - Not reported] Unit not reported; NPTST089-ERYTHROCYTE SEDIMENTATION RATE: 3 [0 - 10] Unit not reported; NPTST150-LACTATE DEHYDROGENASE: 2.3 [0 - 3.5] ukat/L; Neutrophils: 4.4 [1.6 - 5.9] 10^9/L; Platelets: 295 [145 - 348] 10^9/L; Potassium: 3.6 [3.5 - 4.6] mmol/L; Sodium: 141 [137 - 145] mmol/L; Urate: 395 [230 - 480] umol/L

Microbiology

Not reported

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 55): ULTRASOUND BILATERAL FEET AND ANKLES: NO SIGN OF ARTHRITIS, SYNOVITIS, TENOSYVITIS, ENTESITIS; XR BILATERAL FEET: NO FRACTURE NO MALALIGNMENT

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	Severe
Relation to Study Drug by Investigator	Reasonable Possibility
Investigator Alternative Etiology	Not reported
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

スウェーデンの治験責任医師からの報告。本被験者は2[redacted]歳男性であり，AbbVieのリサンキズマブの治験で盲検化された治験薬が投与され，遊走性末梢性関節痛の事象を発現した。

Event 2 の臨床経過：

関連する病歴は，クローン病，関節痛（クローン病の腸管外徴候），非喫煙者及び飲酒者（1日2杯未満）であった。

投与67日後，被験者は遊走性末梢性関節痛を発現した。

本事象発現前の投与28日後から投与67日後まで，被験者は非重篤な関節痛悪化を発現した。本事象により治験薬の投与は中止された。

投与67日後，被験者は運動中に両足に灼熱痛及び刺すような疼痛を発現した。運動をしていない間の疼痛はなかった。感覚消失及び筋力喪失はなかった。発赤及び腫脹もなかった。投与74日後，被験者は入院した。身体的診察の結果に異常は認められなかった。投与76日後，疼痛は自然消失し，その後被験者は退院した。本事象に対してその他追加の医療介入は必要とされなかった。

The patient’s past medications include:

IMUREL for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

METOJECT for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

HUMIRA for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

BETAPRED for ALLERGY ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Arthralgia (10003239) (Arthralgia (10003239)) [v.22.0] [10003239]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of MIGRATING PERIPHERAL ARTHRALGIA

- Investigator: Not applicable

- AbbVie: Risk factor includes pre-existing history of arthralgia-extraintestinal manifestation of Crohn's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] ALANINE AMINO TRANSFERASE: 0.33 ukat/L (normal 0 to 1.1)

[redacted] **20[redacted] ALBUMIN:** 37 G/L (normal 36 to 48)

[redacted] 20[redacted] ASPARTATE AMINO TRANSFERASE: 0.22 ukat/L (normal 0 to 0.76)

[redacted] **20[redacted] BASOPHILS ABS:** 0.1 X10**9/L (normal 0 to 0.1)

[redacted] **20[redacted] BILIRUBIN:** 16 MCMOL/L (normal 0 to 26)

[redacted] **20[redacted] CALCIUM:** 2.32 MMOL/L (normal 2.15 to 2.5)

[redacted] **20[redacted] CREATINE KINASE:** 0.8 ukat/L (normal 0.8 to 6.7)

[redacted] **20[redacted] CREATININE:** 97 MCMOL/L (normal 0 to 100)

[redacted] **20[redacted] EGFR(CREA) REL:** 80 ML/MIN/1.7 (normal >80)

[redacted] **20[redacted] EOSINOPHILS ABS:** 0.1 X10**9/L (normal 0 to 0.5)

[redacted] 20[redacted] ERYTHROCYTE SEDIMENTATION RATE: 3 MM (normal 0 to 10)

[redacted] **20[redacted] HEMATOCRIT:** 0.40 NO UNIT (normal 0.39 to 0.5)

[redacted] **20[redacted] HEMOGLOBIN:** 136 G/L (normal 134 to 170)

[redacted] **20[redacted] HIGH-SENSITIVITY C REACTIVE PROTEIN:** Results: <1mg/L Normal value low: 0mg/L Normal value high: 3mg/L

[redacted] 20[redacted] LACTATE DEHYDROGENASE: 2.3 ukat/L (normal 0 to 3.5)

[redacted] **20[redacted] LYMPHOCYTES ABS:** 4.6 X10**9/L (normal 1.1 to 3.5)

[redacted] **20[redacted] MCH:** 31 PG (normal 27 to 33)

[redacted] **20[redacted] MCV:** 91 FL (normal 82 to 98)

[redacted] **20[redacted] MONOCYTES ABS:** 0.8 X10**9/L (normal 0.2 to 0.8)

[redacted] **20[redacted] NEUTROPHILS ABS:** 4.4 X10**9/L (normal 1.6 to 5.9)

[redacted] **20[redacted] PLATELET COUNT:** 295 X10**9/L (normal 145 to 348)

[redacted] **20[redacted] POTASSIUM:** 3.6 MMOL/L (normal 3.5 to 4.6)

[redacted] **20[redacted] RED BLOOD CELLS:** 4.4 X10**12/L (normal 4.2 to 5.7)

[redacted] **20[redacted] SODIUM:** 141 MMOL/L (normal 137 to 145)

[redacted] **20[redacted] ULTRASOUND BILATERAL FEET AND ANKLES:** NO SIGN OF ARTHRITIS, SYNOVITIS, TENOSYVITIS, ENTHESITIS

[redacted] **20[redacted] URIC ACID:** 395 MCMOL/L (normal 230 to 480)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 10 X10**9/L (normal 3.5 to 8.8)

[redacted] 20[redacted] X-RAY BILATERAL FEET: NO FRACTURE. NO MALALIGNMENT.

Subject [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
アラニンアミノトランスフェラーゼ増加				X
クローン病	X	X		

Treatment Group	Age at Study Start	Sex	Race
P1:PLACEBO	3[redacted]	FEMALE	WHITE

Medical History	Onset Year
OTHER: ALLERGY	19[redacted]
OTHER: PCOS	20[redacted]
CROHN'S DISEASE	20[redacted]
OTHER: ATHRALGIA INTERMITTENT	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): BIOPSY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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	FORMER	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
Placebo		IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 26	26

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]
DESLORATADINE	5 mg	PRN	Y-M: 20[redacted]
MESALAZINE	800 mg	QD	Y-M: 20[redacted]

MESALAZINE	1 g	QD	Y-M: 20[redacted]
BUDESONIDE	9 mg	QD	Y-M: 20[redacted]
AZATHIOPRINE	250 mg	QD	Y-M: 20[redacted]
BUDESONIDE	9 mg	QD	Y-M: 20[redacted]
ADALIMUMAB	40 mg	OTHER: EVERY 2 WEEKS	Y-M: 20[redacted]
PREDNISONE	30 mg	QD	Y-M: 20[redacted]
BUDESONIDE	2 mg	QD	Y-M: 20[redacted]
VEDOLIZUMAB	300 mg	OTHER: WEEK 0-2-6-10	Y-M: 20[redacted]
PICO-SALAX	1 OTHER: BAG	BID	Y-M: 20[redacted] / -35
ALFENTANIL	0.75 mg	QID	Y-M: 20[redacted] / -34
MIDAZOLAM	2.5 mg	QD	Y-M: 20[redacted] / -34
PICO-SALAX	1 OTHER: DOSEBAGS	BID	Y-M: 20[redacted] / -13
ALFENTANIL	1 mg	QD	Y-M: 20[redacted] / -12
MIDAZOLAM	2.5 mg	QD	Y-M: 20[redacted] / -12
LOPERAMIDE	2 mg	PRN	Y-M: 20[redacted] / -1

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
BCG Vaccine	Not reported.	Not reported.	Y-M: 19[redacted]	Not reported.
DESLORATADINE	5 mg	PRN	Y-M: 20[redacted]	ONGOING
PICO-SALAX	1 OTHER: DOSEBAGS	BID	Y-M: 20[redacted] / -13	Y-M: 20[redacted] / -13
ALFENTANIL	1 mg	QD	Y-M: 20[redacted] / -12	Y-M: 20[redacted] / -12
MIDAZOLAM	2.5 mg	QD	Y-M: 20[redacted] / -12	Y-M: 20[redacted] / -12
LOPERAMIDE	2 mg	PRN	Y-M: 20[redacted] / -1	Y-M: 20[redacted] / 54
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted] / 9	Y-M: 20[redacted] / 12
PIP/TAZO	1.5 g	TID	Y-M: 20[redacted] / 9	Y-M: 20[redacted] / 12
DALTEPARIN	5000 IU	QD	Y-M: 20[redacted] / 9	Y-M: 20[redacted] / 14
POTASSIUM	750 mg	QD	Y-M: 20[redacted] / 10	Y-M: 20[redacted] / 14
RINGER	1000 L	PRN	Y-M: 20[redacted] / 11	Y-M: 20[redacted] / 14
CIPROFLOXACIN	500 mg	BID	Y-M: 20[redacted] / 12	Y-M: 20[redacted] / 16
METRONIDAZOLE	400 mg	TID	Y-M: 20[redacted] / 12	Y-M: 20[redacted] / 16

PARACETAMOL	1 g	PRN	Y-M: 20[redacted] / 27	Y-M: 20[redacted] / 60
SODIUM CHLORIDE	1000 L	QD	Y-M: 20[redacted] / 31	Y-M: 20[redacted] / 32
BUDESONIDE	9 mg	QD	Y-M: 20[redacted] / 32	Y-M: 20[redacted] / 121
CIPROFLOXACIN	500 mg	BID	Y-M: 20[redacted] / 36	Y-M: 20[redacted] / 46
METRONIDAZOLE	400 mg	BID	Y-M: 20[redacted] / 36	Y-M: 20[redacted] / 46
HYDROCORTISONE	100 mg	PRN	Y-M: 20[redacted] / 39	Y-M: 20[redacted] / 39
INFLIXIMAB	700 mg	OTHER: WEEK 0 - 2	Y-M: 20[redacted] / 39	Y-M: 20[redacted] / 51
COLECALCIFEROL	2000 IU	QD	Y-M: 20[redacted] / 54	ONGOING
INFLIXIMAB	350 mg	OTHER: EVERY 6 WEEKS	Y-M: 20[redacted] / 80	ONGOING
METHYLPREDNISOLONE	20 mg	PRN	Y-M: 20[redacted] / 80	ONGOING
HEPATITIS A VACCINE INACT W/HEPATITIS B VACCI	1 OTHER: ML	OTHER: ONCE	Y-M: 20[redacted] / 91	Y-M: 20[redacted] / 121
HEPATITIS VACCINES	UN OTHER: UNKNOWN	OTHER: ONCE	Y-M: 20[redacted] / 122	Y-M: 20[redacted] / 152

Event #1: Serious Adverse Event

Event Description	WORSENING CROHNS DISEASE
Preferred term	クローン病
AE Onset Date / Rx Day	[redacted]20[redacted] / 5
Age at AE Onset	3[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 9): C Reactive Protein: 320 [0 - 5] mg/L; [redacted]20[redacted] (Rx Day 10): C Reactive Protein: 400 [0 - 5] mg/L; [redacted]20[redacted] (Rx Day 11): C Reactive Protein: 250 [0 - 5] mg/L; [redacted]20[redacted] (Rx Day 12): C Reactive Protein: 190 [0 - 5] mg/L; [redacted]20[redacted] (Rx Day 13): C Reactive Protein: 90 [0 - 5] mg/L; [redacted]20[redacted] (Rx Day 25): C Reactive Protein: 6 [0 - 5] mg/L

Microbiology

[redacted]20[redacted] (Rx Day 9): BLOOD NPTST043-BLOOD CULTURE: NEGATIVE; STOOL NPTST062-CLOSTRIDIUM: NEGATIVE; STOOL NPTST109-GENERAL MICROBIOLOGY: NEGATIVE; OTHER SPUTUM NPTST251-SPUTUM FROM NASOPAHRYNX: NEGATIVE

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day -1): CT ABDOMEN: WALL THICKENING AS WITH ACTIVE INFLAMMATION IN THE LEFT PART OF THE COLON; THORAX RADIOGRAPHY: NOT PNEUMONIA SUSPECTED

AE Stopped Rx Day	25
Duration of AE	21 DAYS
Severity	Moderate
Relation to Study Drug by Investigator	Reasonable Possibility
Investigator Alternative Etiology	Not reported

Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #2: AE Leading to Discontinuation of Study Drug

Event Description	WORSENING CROHNS DISEASE
Preferred term	クローン病
AE Onset Date / Rx Day	[redacted]20[redacted] / 27 (1 DAY AFTER LAST TREATMENT)
Age at AE Onset	3[redacted]
Laboratory Testing	
Not Applicable	
Microbiology	
Not Applicable	
SAE Supplemental Procedure	
Not Applicable	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	Moderate
Relation to Study Drug by Investigator	Reasonable Possibility
Investigator Alternative Etiology	Not Applicable
Discontinued Study Drug Due to the Event	YES
SAE Criteria	None

Event #3: Event of Interest - Hepatic Events

Event Description	HIGH ALT - 260 U/L
Preferred term	アラニンアミノトランスフェラーゼ増加
AE Onset Date / Rx Day	[redacted]20[redacted] / 124 (98 DAYS AFTER LAST TREATMENT)
Age at AE Onset	3[redacted]
Laboratory Testing	
Not Applicable	
Microbiology	
Not Applicable	
SAE Supplemental Procedure	
Not Applicable	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	Mild
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	Not Applicable
Discontinued Study Drug Due to the Event	NO
SAE Criteria	None

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ノルウェーの治験責任医師からの報告。本被験者は3[redacted]歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，クローン病悪化の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，クローン病，非喫煙者及び元飲酒者（2 杯未満）であった。

投与 5 日後，被験者はクローン病悪化を発現した。投与 25 日後，クローン病悪化は消失した。

投与 9 日後，被験者は排便回数増加，直腸出血，発熱（体温は未報告），悪寒，筋肉痛，肩息，全身状態低下，腹痛増加及び CRP 上昇のため入院した。臨床検査及び診断が行われた。投与 15 日後，被験者はより良好な状態で退院した。

投与された薬剤は Tazocin，フラジール及び Ciproxin であった。

The patient’s past medications include:

ENTOCORT for CROHN'S DISEASE ([redacted]20[redacted] - [redacted]20[redacted], [redacted]20[redacted] - [redacted]20[redacted], [redacted]20[redacted] - [redacted]20[redacted])

IMUREL for CROHN'S DISEASE ([redacted]20[redacted] - [redacted]20[redacted])

HUMIRA for CROHN'S DISEASE ([redacted]20[redacted] - [redacted]20[redacted])

PREDNISONE for CROHN'S DISEASE ([redacted]20[redacted] - [redacted]20[redacted])

ENTYVIO for CROHN'S DISEASE ([redacted]20[redacted] - [redacted]20[redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Crohn's disease aggravated (10011403) (Crohn's disease (10011401)) [v.22.1] [10011403]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of WORSENING CROHN'S DISEASE

- Investigator: Not applicable

- AbbVie: Reported event more likely related to pre-existing Crohn's disease

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] BLOOD CULTURE: Negative

[redacted] 20[redacted] CLOSTRIDIUM STOOL CULTURE: Negative

[redacted] **20[redacted] CRP:** 320 MG/L (normal 0 to 5)

[redacted] **20[redacted] CRP:** 400 MG/L (normal 0 to 5)

[redacted] **20[redacted] CRP:** 250 MG/L (normal 0 to 5)

[redacted] **20[redacted] CRP:** 190 MG/L (normal 0 to 5)

[redacted] **20[redacted] CRP:** 90 MG/L (normal 0 to 5)

[redacted] **20[redacted] CRP:** 6 MG/L (normal 0 to 5)

[redacted] **20[redacted] CT ABDOMEN:** WALL THICKENING AS WITH ACTIVE INFLAMMATION IN THE LEFT PART OF THE COLON

[redacted] 20[redacted] GENERAL MICROBIOLOGY STOOL: Negative

[redacted] 20[redacted] SPUTUM CULTURE (NASOPHARYNX): Negative

[redacted] 20[redacted] THORAX RADIOGRAPHY: NO PNEUMONIA SUSPECTED

Subject [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
クローン病	X			

Treatment Group	Age at Study Start	Sex	Race
P1:PLACEBO	1[redacted]	MALE	WHITE

Medical History	Onset Year
OTHER: ACNE	Not reported.
OTHER: APHTHOUS STOMATITIS	Not reported.
OTHER: SCARS AFTER SURGIERES	20[redacted]
CROHN'S DISEASE	20[redacted]
OTHER: APHTOSIS	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE SURGICAL HISTORY: BOWEL RESECTION	20[redacted]
CROHN'S DISEASE SURGICAL HISTORY: RECONSTRUCTION OF DIGESTIVE TRACT	20[redacted]
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): BIOPSY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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)
Placebo		IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 28	28

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: 20[redacted]
MESALAZINE	1.5 g	QD	Y-M: 20[redacted]
AZATHIOPRINE	50 mg	TID	Y-M: 20[redacted]
NUTRIENTS NOS	2000 mL	QD	Y-M: 20[redacted]
BLINDED THERAPY	50 mg	TID	Y-M: 20[redacted] / -182
CALCIUM CARBONATE	1000 mg	QD	Y-M: 20[redacted] / -98
COLECALCIFEROL	1000 IU	QD	Y-M: 20[redacted] / -98
OMEPRAZOLE	20 mg	QD	Y-M: 20[redacted] / -98
POTASSIUM	1 OTHER: TABLET	QD	Y-M: 20[redacted] / -98
PREDNISONE	40 mg	QD	Y-M: 20[redacted] / -98
FOLIC ACID	5 mg	OTHER: 6 TIMES PER WEEK	Y-M: 20[redacted] / -70
METHOTREXATE	20 mg	OTHER: WEEKLY	Y-M: 20[redacted] / -70
CALCIUM	1000 mg	QD	Y-M: 20[redacted] / -66
PREDNISONE	35 mg	QD	Y-M: 20[redacted] / -66
PREDNISONE	30 mg	QD	Y-M: 20[redacted] / -59
PREDNISONE	25 mg	QD	Y-M: 20[redacted] / -52
PREDNISONE	20 mg	QD	Y-M: 20[redacted] / -45
PICO-SALAX	1 DF	BID	Y-M: 20[redacted] / -16
ELECTROLYTE SOLUTIONS	500 mL	QD	Y-M: 20[redacted] / -15
FENTANYL	0.1 mg	QD	Y-M: 20[redacted] / -15
PARACETAMOL	1 g	QD	Y-M: 20[redacted] / -15
PROPOFOL	160 mg	QD	Y-M: 20[redacted] / -15

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
BCG Vaccine	Not reported.	Not reported.	Y-M: 20[redacted]	Not reported.
MESALAZINE	1.5 g	QD	Y-M: 20[redacted]	ONGOING
COLECALCIFEROL	1000 IU	QD	Y-M: 20[redacted] / -98	ONGOING
OMEPRAZOLE	20 mg	QD	Y-M: 20[redacted] / -98	ONGOING
POTASSIUM	1 OTHER: TABLET	QD	Y-M: 20[redacted] / -98	ONGOING
FOLIC ACID	5 mg	OTHER: 6 TIMES PER WEEK	Y-M: 20[redacted] / -70	ONGOING
METHOTREXATE	20 mg	OTHER: WEEKLY	Y-M: 20[redacted] / -70	ONGOING
CALCIUM	1000 mg	QD	Y-M: 20[redacted] / -66	ONGOING

PREDNISONE	20 mg	QD	Y-M: 20[redacted]-[redacted] / - 45	ONGOING
ANALGESICS	NOT APPLICABLE DF	OTHER: NA	Y-M: 20[redacted]-[redacted] / 19	ONGOING
AZATHIOPRINE	50 mg	BID	Y-M: 20[redacted]-[redacted] / 19	ONGOING
HEPARIN	NOT APPLICABLE %	OTHER: NA	Y-M: 20[redacted]-[redacted] / 19	ONGOING
METRONIDAZOLE	NOT APPLICABLE DF	OTHER: NA	Y-M: 20[redacted]-[redacted] / 19	ONGOING
PIP/TAZO	NOT APPLICABLE DF	OTHER: NA	Y-M: 20[redacted]-[redacted] / 19	ONGOING
SOLUTIONS FOR PARENTERAL NUTRITION	NA DF	OTHER: NA	Y-M: 20[redacted]-[redacted] / 19	ONGOING
CEFUROXIME	500 mg	BID	Y-M: 20[redacted]-[redacted] / 48	ONGOING
COLECALCIFEROL	750 IU	QD	Y-M: 20[redacted]-[redacted] / 48	ONGOING
METRONIDAZOLE	500 mg	TID	Y-M: 20[redacted]-[redacted] / 48	ONGOING
SACCHAROMYCES BOULARDII	1 DF	QD	Y-M: 20[redacted]-[redacted] / 48	ONGOING

Event #1: Serious Adverse Event

Event Description	CROHN DISEASE EXACERBATION
Preferred term	クローン病
AE Onset Date / Rx Day	[redacted]20[redacted] / 37 (9 DAYS AFTER LAST TREATMENT)
Age at AE Onset	1[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 38): Albumin: 3.8 [3.9 - 4.9] g/dL; Hemoglobin: 10.5 [11 - 18] g/dL; NPTST050-C REACTIVE PROTEIN: 5.7 [0 - 0.8] mg/dL; [redacted]20[redacted] (Rx Day 42): NPTST204-PROKALCITONINE: 3.58 [0 - 0.046] ng/mL; [redacted]20[redacted] (Rx Day 44): NPTST276-URINE CULTURE: NEGATIVE [Not reported - Not reported] Unit not reported

Microbiology

Not reported

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 19): ABDOMINAL AND PELVIS TOMOGRAPHY: INFLAMMATORY CHANGES IN LOWER RIGHT ABDOMINAL; LIVER CYSTS AND CHOLECYSTOLITHIASIS; ABDOMINAL ULTRASOUND: INFLAMMATORY CHANGES IN LOWER RIGHT ABDOMINAL;; ABDOMINAL ULTRASOUND: INFLAMMATORY CHANGES IN LOWER RIGHT ABDOMINAL;; ABDOMINAL ULTRASOUND: INFLAMMATORY CHANGES IN LOWER RIGHT ABDOMINAL;; ABDOMINAL X-REY: SUBILEUS; PLAIN ABDOMINAL RADIOGRAPHY: SUBILEUS; PLAIN ABDOMINAL RADIOGRAPHY: SUBILEUS; PLAIN ABDOMINAL RADIOGRAPHY: SUBILEUS

AE Stopped Rx Day NOT REPORTED

Duration of AE	NOT REPORTED
Severity	Moderate
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	ONLY UNDERLYING DIAGNOSIS
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ポーランドの治験責任医師からの報告。本被験者は 1[redacted] 歳男性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，クローン病増悪の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，腸切除，消化管再建，クローン病，アフタ性口内炎，非喫煙者及び非飲酒者であった。

投与 37 日後，被験者はクローン病増悪を発現した。

投与 37 日後，被験者は亜イレウスの疑いのため入院した。被験者に胃痛，おくび及び体重減少が認められた。臨床検査及び画像検査が行われた。入院中，肝嚢胞及び胆嚢結石症（非重篤）と診断された。被験者は非経口栄養及び鎮痛剤による治療を定期的に受けた。投与 48 日後，被験者は退院した。

投与された薬剤は，メトロニダゾール，ピペラシリン／タゾバクタム，アザチオプリン VIS，Xorimax，Enterol，Devikap 及び低分子ヘパリンであった。

Causality for RISANKIZUMAB (Blinded)

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1) Crohn's disease aggravated (10011403) (Crohn's disease (10011401)) [v.22.0] [10011403]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of CROHN DISEASE EXACERBATION

- Investigator: Only underlying diagnosis.

- AbbVie: Event more likely related to pre-existing Crohn's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABD ULTRASOUND:** INFLAMMATORY CHANGES IN LOWER RIGHT ABDOMINAL;

[redacted] 20[redacted] ABD XRAY: subileus

[redacted] **20[redacted] ABDOMINAL AND PELVIS TOMOGAPHY:** INFLAMMATORY CHANGES IN LOWER RIGHT ABDOMINAL; LIVER CYSTS AND CHOLECYSTOLITHIASIS

[redacted] **20[redacted] ALBUMIN:** 3.8 G/DL (normal 3.9 to 4.9)

[redacted] **20[redacted] C REACTIVE PROTEIN:** 5.7 mg/dL (normal 0 to 0.8)

[redacted] **20[redacted] HEMOGLOBIN:** 10.5 G/DL (normal 11.0 to 18.0)

[redacted] **20[redacted] PROKALCITONINE:** 3.58 NG/ML (normal 0 to 0.046)

Subject [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
ヘモグロビン減少	X			

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 1200 MG IV	2[redacted]	MALE	WHITE

Medical History	Onset Year
CROHN'S DISEASE	20[redacted]
ANEMIA: N/A	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): BIOPSY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
Risankizumab	1200 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 63	63

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: 20[redacted]
AZATHIOPRINE	150 mg	QD	Y-M: 20[redacted] / -121
PREDNISONE	20 mg	QD	Y-M: 20[redacted] / -30
FORTRANS	2 OTHER: SACHETS	QD	Y-M: 20[redacted] / -8
MACROGOL	2 OTHER: SACHET	QD	Y-M: 20[redacted] / -8

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
BCG Vaccine	Not reported.	Not reported.	Y-M: 20[redacted]	Not reported.
AZATHIOPRINE	150 mg	QD	Y-M: 20[redacted] / -121	ONGOING
PREDNISONE	20 mg	QD	Y-M: 20[redacted] / -30	ONGOING
IRON	100 mg	TID	Y-M: 20[redacted] / 28	ONGOING
CYANOCOBALAMIN	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 70	Y-M: 20[redacted] / 100
IRON	1500 mg	OTHER: UNKNOWN	Y-M: 20[redacted] / 70	Y-M: 20[redacted] / 100

Event #1: Serious Adverse Event

Event Description	DECREASED VALUE OF HEMOGLOBIN
Preferred term	ヘモグロビン減少
AE Onset Date / Rx Day	[redacted]20[redacted] / 73 (10 DAYS AFTER LAST TREATMENT)
Age at AE Onset	2[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 73): Hemoglobin: 6.1 [13.5 - 17.2] g/dL; [redacted]20[redacted] (Rx Day 74): Hemoglobin: 7.6 [13.5 - 17.2] g/dL

Microbiology

Not reported

SAE Supplemental Procedure

Not reported

AE Stopped Rx Day	75 (12 DAYS AFTER LAST TREATMENT)
Duration of AE	3 DAYS
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	ANEMIA DUE TO IRON DEFICIENCY
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ポーランドの治験責任医師からの報告。本被験者は 2[redacted] 歳男性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，ヘモグロビン値減少の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，クローン病，非喫煙者及び飲酒者（1 日 2 杯未満）であった。

投与 73 日後，被験者はヘモグロビン値減少を発現した。投与 75 日後，ヘモグロビン値減少は消失した。

投与 73 日後，被験者はヘモグロビンの臨界値まで鉄剤の静脈内投与及び輸血を受けるため入院した。投与 75 日後，被験者は退院した。

入院中の本事象の臨床経過に関する詳細は提供されなかった。

投与された薬剤は，KOBALAMINA，血液及び iron (III) isomaltoside であった。

Causality for RISANKIZUMAB (Blinded)

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1) Decreased hemoglobin (10011964) (Haemoglobin decreased (10018884)) [v.22.1] [10011964]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of DECREASED VALUE OF HEMOGLOBIN

- Investigator: Anemia due to Crohn's disease

- AbbVie: Risk factors include pre-existing anemia and Crohn's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] HEMATOCRIT:** 37 % (normal 39 to 54)

[redacted] **20[redacted] HEMATOCRIT:** 33 % (normal 39 to 54)

[redacted] **20[redacted] HEMATOCRIT:** 33 % (normal 39 to 54)

[redacted] **20[redacted] HEMATOCRIT:** 26 % (normal 39 to 54)

[redacted] **20[redacted] HEMATOCRIT:** 34 % (normal 39 to 54)

[redacted] **20[redacted] HEMOGLOBIN:** 10.7 G/DL (normal 12.7 to 18.1)

[redacted] **20[redacted] HEMOGLOBIN:** 9.5 G/DL (normal 12.7 to 18.1)

[redacted] **20[redacted] HEMOGLOBIN:** 9.1 G/DL (normal 12.7 to 18.1)

[redacted] **20[redacted] HEMOGLOBIN:** 7.6 G/DL (normal 12.7 to 18.1)

[redacted] **20[redacted] HEMOGLOBIN:** 6.1 G/DL (normal 13.5 to 17.2)

[redacted] **20[redacted] HEMOGLOBIN:** 7.6 G/DL (normal 13.5 to 17.2)

[redacted] **20[redacted] HEMOGLOBIN:** 9.5 G/DL (normal 12.7 to 18.1)

Subject [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
貧血	X			

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 1200 MG IV / P2:RZB 360 mg SC	2[redacted]	FEMALE	WHITE

Medical History	Onset Year
ASTHMA	20[redacted]
CROHN'S DISEASE	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): BIOPSY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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)
Risankizumab	1200 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 57	57
Risankizumab	360 mg	SC	Every 8 Weeks	[redacted]20[redacted] / 85	[redacted]20[redacted] / 142	58

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
RUPATADINE	10 mg	QD	Y-M: 20[redacted]
MESALAZINE	1 g	BID	Y-M: 20[redacted]
AZATHIOPRINE	100 mg	QD	Y-M: 20[redacted] / -260
MESALAZINE	1 g	QD	Y-M: 20[redacted] / -259
BEKFORM	2 OTHER: BREATHS	PRN	Y-M: 20[redacted] / -254

LACTOBACILLUS ACIDOPHILUS	1 OTHER: SPRAY APPLICATION	PRN	Y-M: 20[redacted] / -254
MOMETASONE	50 ug	BID	Y-M: 20[redacted] / -254
CYANOCOBALAMIN	400 ug	QD	Y-M: 20[redacted] / -68
TRIMEBUTINE	100 mg	BID	Y-M: 20[redacted] / -68
FOLIC ACID	4 mg	QD	Y-M: 20[redacted] / -30
AIDA	3,02 mg	OTHER: EVERY THREE WEEKS IN A MONTH	Y-M: 20[redacted] / -26
FORTRANS	2 OTHER: SACHETS	QD	Y-M: 20[redacted] / -15

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
RUPATADINE	10 mg	QD	Y-M: 20[redacted]	ONGOING
MESALAZINE	1 g	BID	Y-M: 20[redacted]	ONGOING
BEKFORM	2 OTHER: BREATHS	PRN	Y-M: 20[redacted] / -254	ONGOING
LACTOBACILLUS ACIDOPHILUS	1 OTHER: SPRAY APPLICATION	PRN	Y-M: 20[redacted] / -254	ONGOING
MOMETASONE	50 ug	BID	Y-M: 20[redacted] / -254	ONGOING
TRIMEBUTINE	100 mg	BID	Y-M: 20[redacted] / -68	ONGOING
FOLIC ACID	4 mg	QD	Y-M: 20[redacted] / -30	ONGOING
AIDA	3,02 mg	OTHER: EVERY THREE WEEKS IN A MONTH	Y-M: 20[redacted] / -26	ONGOING
FORTRANS	2 OTHER: SACHETS	QD	Y-M: 20[redacted] / -15	Y-M: 20[redacted] / -14
IRON	1500 mg	OTHER: ONCE	Y-M: 20[redacted] / 10	Y-M: 20[redacted] / 10
METEOSPASMYL	60+300 mg	TID	Y-M: 20[redacted] / 30	ONGOING
BLOOD, WHOLE	2 OTHER: UNITS	OTHER: UNKNOWN	Y-M: 20[redacted] / 34	Y-M: 20[redacted] / 63
IRON	500 mg	OTHER: UNKNOWN	Y-M: 20[redacted] / 34	Y-M: 20[redacted] / 63
IRON	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 34	Y-M: 20[redacted] / 63
METAMIZOLE	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 34	Y-M: 20[redacted] / 63

PAPAVERINE	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 34	Y-M: 20[redacted] / 63

Event #1: Serious Adverse Event

Event Description	ANEMIA
Preferred term	貧血
AE Onset Date / Rx Day	[redacted]20[redacted] / 10
Age at AE Onset	2[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 10): Hemoglobin: 8.0 [12 - 15.4] g/dL; NPTST100-FERRITIN: 17.45 [10 - 204] ng/mL; NPTST216-RDW-CV: 14.3 [11.5 - 15] %; NPTST217-RDW-SD: 47.9 [39 - 51] fL; NPTST263-TRANSERIN SATURATION: 4 [25 - 50] Unit not reported; NPTST283-VITAMIN B12: 293 [155 - 355] pg; [redacted]20[redacted] (Rx Day 14): NPTST101-FERRUM: 15 [60 - 180] ug/dL

Microbiology

Not reported

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 3): ECG: DIAGNOSTIC PROCEDURE- RESULT NORMAL

AE Stopped Rx Day	11
Duration of AE	2 DAYS
Severity	Moderate
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	IRON DEFICIENCY
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #2: Serious Adverse Event

Event Description	WORSENING OF ANEMIA
Preferred term	貧血
AE Onset Date / Rx Day	[redacted]20[redacted] / 35
Age at AE Onset	2[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 35): Hemoglobin: 8.2 [12 - 15.4] g/dL; [redacted]20[redacted] (Rx Day 36): Hemoglobin: 11.0 [12 - 15.4] g/dL; NPTST080-DIMER-D: 0.14 [0 - 0.5] Unit not reported; [redacted]20[redacted] (Rx Day 37): Hemoglobin: 11.3 [12 - 15.4] g/dL

Microbiology

Not reported

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 34): ECG: NORMAL (DIAGNOSTIC PROCEDURE); ECHO: NORMAL

AE Stopped Rx Day	37
Duration of AE	3 DAYS
Severity	Moderate
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	CROHN'S DISEASE

Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ポーランドの治験責任医師からの報告。本被験者は2[redacted]歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，貧血の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，クローン病，非喫煙者及び非飲酒者であった。

投与 10 日後，被験者は貧血を発現した。投与 11 日後，貧血は消失した。

投与 10 日後，被験者は鉄剤の静脈内投与のため入院した。投与 11 日後，被験者は退院した。

投与された薬剤は，Monover であった。

The patient's past medications include:

AZATHIOPRINUM for CROHN'S DISEASE ([redacted]20[redacted] - [redacted]20[redacted])

B12 VITAMIN for CROHN'S DISEASE ([redacted]20[redacted] - [redacted]20[redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Anemia (10002272) (Anaemia (10002034)) [v.23.0] [10002272]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of ANEMIA

- Investigator: Iron Deficiency

- AbbVie: Risk factor includes pre-existing Crohn's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] HEMATOCRIT:** 36 % (normal 34 to 48)

[redacted] **20[redacted] HEMATOCRIT:** 33 % (normal 34 to 48)

[redacted] **20[redacted] HEMATOCRIT:** 30 % (normal 34 to 48)

[redacted] **20[redacted] HEMOGLOBIN:** 11.8 G/DL (normal 11.6 to 16.4)

[redacted] **20[redacted] HEMOGLOBIN:** 10.5 G/DL (normal 11.6 to 16.4)

[redacted] **20[redacted] HEMOGLOBIN:** 8.0 G/DL (normal 12.0 to 15.4)

[redacted] **20[redacted] HEMOGLOBIN:** 8.8 G/DL (normal 11.6 to 16.4)

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ポーランドの治験責任医師からの報告。本被験者は 2[redacted] 歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，貧血増悪の事象を発現した。

Event 2 の臨床経過：

関連する病歴は，喘息，クローン病，非喫煙者及び非飲酒者であった。

投与 35 日後，被験者は貧血増悪を発現した。投与 37 日後，貧血増悪は消失した。

投与 35 日後，被験者は貧血のため入院した。被験者のヘモグロビンは 8.8 であった。治験責任医師によると，被験者は投与 10 日後同様の事象を発現していた。被験者は血液及び鉄剤 2 単

位による治療を受けた。投与 37 日後，被験者は良好な状態で退院した。

投与された薬剤は，メタミゾール，血液，パパベリン塩酸塩，Tardyferon 及び iron isomaltoside 1000 であった。

The patient’s past medications include:

MONOVER for ANEMIA ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Anemia aggravated (10054309) (Anaemia (10002034)) [v.23.0] [10054309]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of WORSENING OF ANEMIA

- Investigator: CROHNS DISEASE

- AbbVie: more likely related to pre-existing crohn's disease with recent event of anemia. In addition, subject's Hemoglobin was already decreasing from screening to baseline visit.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] FERRUM:** 15 MCG/DL (normal 60 to 180)

[redacted] **20[redacted] HEMATOCRIT:** 36 % (normal 34 to 48)

[redacted] **20[redacted] HEMATOCRIT:** 33 % (normal 34 to 48)

[redacted] **20[redacted] HEMATOCRIT:** 30 % (normal 34 to 48)

[redacted] **20[redacted] HEMOGLOBIN:** 11.8 G/DL (normal 11.6 to 16.4)

[redacted] **20[redacted] HEMOGLOBIN:** 10.5 G/DL (normal 11.6 to 16.4)

[redacted] **20[redacted] HEMOGLOBIN:** 8.8 G/DL (normal 12 to 15.4)

[redacted] **20[redacted] HEMOGLOBIN:** 8.2 G/DL (normal 12 to 15.4)

[redacted] **20[redacted] HEMOGLOBIN:** 11 G/DL (normal 12 to 15.4)

[redacted] **20[redacted] HEMOGLOBIN:** 11.3 G/DL (normal 12 to 15.4)

[redacted] 20[redacted] TRANSERIN SATURATION: 4 % (normal 25 to 50)

Subject [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
帯状疱疹				X
大腸穿孔	X			
腹膜炎	X			X

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 600 MG IV / P2:RZB 360 mg SC	3[redacted]	FEMALE	WHITE

Medical History	Onset Year
OTHER: HYPERPLASTIC POLYP OF DUODENUM	Not reported.
OTHER: SURGICAL SCAR	20[redacted]
OTHER: HEMORRHOIDS	20[redacted]
CROHN'S DISEASE	20[redacted]
GASTROESOPHAGEAL REFLUX DISEASE: LOS ANGELES A	20[redacted]
ANEMIA: ANEMIA IN COURSE OF CROHN'S DISEASE	20[redacted]
OTHER: HYPERPLASTIC POLYP OF DUODENUM	20[redacted]
OTHER: SIGMOIDAL CURVATURE OF THE THORACOLUMBAR SPINE	20[redacted]

Prior Procedures	Procedure Year
SURGERY: APPENDECTOMY	20[redacted]
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): BIOPSY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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)
Risankizumab	600 mg	IV	Every 4 Weeks	[redacted] / 1	[redacted] / 57	57
Risankizumab	360 mg	SC	Every 8 Weeks	[redacted] / 85	[redacted] / 149	65

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
PANTOPRAZOLE	40 mg	QD	Y-M: [redacted]
AZATHIOPRINE	50 mg	QD	Y-M: [redacted]
MESALAZINE	1 g	QD	Y-M: [redacted]
AZATHIOPRINE	100 mg	QD	Y-M: [redacted] / -213
INTRAUTERINE CONTRACEPTIVE DEVICE	1 OTHER: DEVICE	OTHER: PERMANENTLY	Y-M: [redacted] / -121
BUDESONIDE	9 mg	QD	Y-M: [redacted] / -92
SIDROS	1 OTHER: TABLET	QD	Y-M: [redacted] / -30
PREDNISONE	20 mg	QD	Y-M: [redacted] / -24
ATROPINE	0.5 mg	OTHER: ONCE	Y-M: [redacted] / -21
FENTANYL	0.1 mg	OTHER: ONCE	Y-M: [redacted] / -21
IRON	1 g	OTHER: ONCE	Y-M: [redacted] / -21
MIDAZOLAM	2 mg	OTHER: ONCE	Y-M: [redacted] / -21
PICO-SALAX	1 OTHER: SACHET	BID	Y-M: [redacted] / -21
PROPOFOL	150 mg	OTHER: ONCE	Y-M: [redacted] / -21
PANTOPRAZOLE	40 mg	QD	Y-M: [redacted] / -20
IRON	1 g	OTHER: ONCE	Y-M: [redacted] / -17
ASCORBIC ACID W/FERROUS BISGLYCINATE/FOLIC AC	1 OTHER: CAPSULE	BID	Y-M: [redacted] / -16

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
BCG Vaccine	Not reported.	Not reported.	Not reported.	Not reported.
MESALAZINE	1 g	QD	Y-M: [redacted]	Y-M: [redacted] / 214
AZATHIOPRINE	100 mg	QD	Y-M: [redacted] / -213	ONGOING
INTRAUTERINE CONTRACEPTIVE DEVICE	1 OTHER: DEVICE	OTHER: PERMANENTLY	Y-M: [redacted] / -121	ONGOING
PREDNISONE	20 mg	QD	Y-M: [redacted] / -24	Y-M: [redacted] / 128
PANTOPRAZOLE	40 mg	QD	Y-M: [redacted] / -20	ONGOING
ASCORBIC ACID W/FERROUS BISGLYCINATE/FOLIC AC	1 OTHER: CAPSULE	BID	Y-M: [redacted] / -16	ONGOING

ACICLOVIR	400 mg	OTHER: FIVE TIMES A DAY	Y-M: 20[redacted] / 33	Y-M: 20[redacted] / 44
ITOPRIDE	50 mg	QD	Y-M: 20[redacted] / 57	ONGOING
HYOSCINE	1 OTHER: AMPULE	OTHER: ONCE	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 128
CEFUROXIME	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 139
DEXAMETHASONE	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 139
DIAZEPAM	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 139
ELECTROLYTES NOS	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 139
ENOXAPARIN	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 139
MEROPENEM	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 139
METAMIZOLE	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 139
METRONIDAZOLE	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 139
OMEPRAZOLE	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 139
SODIUM CHLORIDE	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 139
TRAMADOL	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 139
OMEPRAZOLE	40 mg	BID	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 149
AMINO ACIDS NOS W/FATS NOS/GLUCOSE	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 129	Y-M: 20[redacted] / 136
CERNEVIT	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 129	Y-M: 20[redacted] / 136

TRACUTIL	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted]-[redacted] / 129	Y-M: 20[redacted]-[redacted] / 136
PREDNISONE	15 mg	QD	Y-M: 20[redacted]-[redacted] / 139	Y-M: 20[redacted]-[redacted] / 176

Event #1: Event of Interest - Herpes Zoster

Event Description	HERPES ZOSTER
Preferred term	帯状疱疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 33
Age at AE Onset	3[redacted]
Laboratory Testing	
Not Applicable	
Microbiology	
Not Applicable	
SAE Supplemental Procedure	
Not Applicable	
AE Stopped Rx Day	42
Duration of AE	10 DAYS
Severity	Mild
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 Description	PERFORATION OF THE CECUM, PERITONITIS
Preferred term	大腸穿孔
AE Onset Date / Rx Day	[redacted]20[redacted] / 128
Age at AE Onset	3[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 128): Activated Partial Thromboplastin Time: 31.7 [Not reported - Not reported] Unit not reported; Amylase: 54 [Not reported - Not reported] U/L; C Reactive Protein: 66.53 [0 - 9.99999] mg/L; Creatinine: 0.67 [0.5995 - 1.0972] mg/dL; Erythrocytes: 3.63 [Not reported - Not reported] Unit not reported; Hemoglobin: 9.6 [Not reported - Not reported] Unit not reported; Leukocytes: 11.21 [Not reported - Not reported] Unit not reported; NPTST146-INR: 1.4 [Not reported - Not reported] Unit not reported; Platelets: 453 [Not reported - Not reported] U/L; Potassium: 3.91 [3.4 - 4.4] mmol/L; Sodium: 138 [136 - 145] mmol/L; [redacted]20[redacted] (Rx Day 129): Alanine Aminotransferase: 17 [Not reported - Not reported] IU/L; Albumin: 31 [34 - 49] g/L; Alkaline Phosphatase: 79.9 [Not reported - Not reported] U/L; Aspartate Aminotransferase: 11 [Not reported - Not reported] IU/L; Bilirubin: 0.91 [0.2923 - 1.2278] mg/dL; Calcium: 8.4 [8.6169 - 10.0196] mg/dL; Cholesterol: 94 [130.302 - 230.445] mg/dL; NPTST165-MAGNESIUM: 0.64 [Not reported - Not reported] mmol/L; NPTST244-SERUM CHLORIDES: 110 [Not reported - Not reported] mmol/L; NPTST270-UREA IN SERUM: 19 [Not reported - Not reported] mg/dL; Protein: 5.12 [6.4 - 8.3] g/dL; Triglycerides: 43 [38.9381 - 150.4425] mg/dL; [redacted]20[redacted] (Rx Day 130): Glucose: 5.9 [4.1 - 5.9] mmol/L; [redacted]20[redacted] (Rx Day 135): Activated Partial Thromboplastin Time: 38.6 [Not reported - Not reported] Unit not reported; Alanine Aminotransferase: 12 [Not reported - Not reported] IU/L; Albumin: 31 [34 - 49] g/L; Alkaline Phosphatase:

121.8 [Not reported - Not reported] U/L; Aspartate Aminotransferase: 9 [Not reported - Not reported] IU/L; Bilirubin: 0.34 [0.2923 - 1.2278] mg/dL; C Reactive Protein: 83.38 [0 - 9.99999] mg/L; Calcium: 8.2 [8.6169 - 10.0196] mg/dL; Cholesterol: 165 [130.302 - 230.445] mg/dL; Creatinine: 0.52 [0.5995 - 1.0972] mg/dL; Erythrocytes: 3.21 [Not reported - Not reported] Unit not reported; Hemoglobin: 8.4 [Not reported - Not reported] Unit not reported; Leukocytes: 7.97 [Not reported - Not reported] Unit not reported; NPTST108-GAMMA-GLUTAMYLTRANSPEPTIDASE: 293 [Not reported - Not reported] U/L; NPTST146-INR: 1.31 [Not reported - Not reported] Unit not reported; NPTST165-MAGNESIUM: 0.78 [Not reported - Not reported] mmol/L; NPTST244-SERUM CHLORIDES: 105 [Not reported - Not reported] mmol/L; NPTST270-UREA IN SERUM: 27 [Not reported - Not reported] mg/dL; Platelets: 401 [Not reported - Not reported] U/L; Potassium: 4.06 [3.4 - 4.4] mmol/L; Protein: 5.33 [6.4 - 8.3] g/dL; Sodium: 137 [136 - 145] mmol/L; Triglycerides: 195 [38.9381 - 150.4425] mg/dL; [redacted]20[redacted] (Rx Day 137): Glucose: 7.4 [4.1 - 5.9] mmol/L

Microbiology

[redacted]20[redacted] (Rx Day 128): OTHER TISSUE NPTST138-HISTOPATHOLOGY: -RESULT: ABUNDANT, CHRONIC INFLAMMATORY INFILTRATES WITH THE PRESENCE OF SINGLE COCCI, MUCOSA WITH EROSIONS AND ULCERATIONS WITH GRANULATION, PURULENT EXUDATE ON THE INSIDE; [redacted]20[redacted] (Rx Day 129): OTHER PERITONEAL FLUID NPTST007-AEROBIC CULTURE SWAB: POSITIVE-ESCHERICHIA COLI VERY NUMEROUS

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 123): ABDOMINAL CAVITY RADIOGRAPHY: RADIOLOGICAL FEATURES OF GASTROINTESTINAL PERFORATION; CHEST RADIOGRAPHY [redacted] 20[redacted]: RADIOLOGICAL FEATURES OF GASTROINTESTINAL PERFORATION, PULMONARY FIELDS WITHOUT VISIBLE PATHOLOGICAL DENSITIES, SILHOUETTE OF THE HEART NOT WIDENED LATERALLY; CHEST RADIOGRAPHY [redacted] 20[redacted]: PULMONARY FIELDS WITHOUT VISIBLE PATHOLOGICAL DENSITIES; HEMICOLECTOMY: EXCISION OF THE RIGHT HALF OF THE COLON WAS MADE WITH AN ILEO-TRANSVERSE ANASTOMOSIS END-TO-END

AE Stopped Rx Day	139
Duration of AE	12 DAYS
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	CROHN'S DISEASE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, LIFE THREATENING

Event #3: Serious Adverse Event, Event of Interest - Serious Infections

Event Description	PERFORATION OF THE CECUM, PERITONITIS
Preferred term	腹膜炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 128
Age at AE Onset	3[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 128): Activated Partial Thromboplastin Time: 31.7 [Not reported - Not reported] Unit not reported; Amylase: 54 [Not reported - Not reported] U/L; C Reactive Protein: 66.53 [0 - 9.99999] mg/L; Creatinine: 0.67 [0.5995 - 1.0972] mg/dL; Erythrocytes: 3.63 [Not reported - Not reported] Unit not reported; Hemoglobin: 9.6 [Not reported - Not reported] Unit not reported; Leukocytes: 11.21 [Not reported - Not reported] Unit not reported; NPTST146-INR: 1.4 [Not reported - Not reported] Unit not reported; Platelets: 453 [Not reported - Not reported] U/L; Potassium: 3.91 [3.4 - 4.4] mmol/L; Sodium: 138 [136 - 145] mmol/L; [redacted]20[redacted] (Rx Day 129): Alanine Aminotransferase: 17 [Not reported - Not reported] IU/L; Albumin: 31 [34 - 49] g/L; Alkaline Phosphatase: 79.9 [Not reported - Not reported] U/L; Aspartate Aminotransferase: 11 [Not

reported - Not reported] IU/L; Bilirubin: 0.91 [0.2923 - 1.2278] mg/dL; Calcium: 8.4 [8.6169 - 10.0196] mg/dL; Cholesterol: 94 [130.302 - 230.445] mg/dL; NPTST165-MAGNESIUM: 0.64 [Not reported - Not reported] mmol/L; NPTST244-SERUM CHLORIDES: 110 [Not reported - Not reported] mmol/L; NPTST270-UREA IN SERUM: 19 [Not reported - Not reported] mg/dL; Protein: 5.12 [6.4 - 8.3] g/dL; Triglycerides: 43 [38.9381 - 150.4425] mg/dL; [redacted] (Rx Day 130): Glucose: 5.9 [4.1 - 5.9] mmol/L; [redacted] (Rx Day 135): Activated Partial Thromboplastin Time: 38.6 [Not reported - Not reported] Unit not reported; Alanine Aminotransferase: 12 [Not reported - Not reported] IU/L; Albumin: 31 [34 - 49] g/L; Alkaline Phosphatase: 121.8 [Not reported - Not reported] U/L; Aspartate Aminotransferase: 9 [Not reported - Not reported] IU/L; Bilirubin: 0.34 [0.2923 - 1.2278] mg/dL; C Reactive Protein: 83.38 [0 - 9.99999] mg/L; Calcium: 8.2 [8.6169 - 10.0196] mg/dL; Cholesterol: 165 [130.302 - 230.445] mg/dL; Creatinine: 0.52 [0.5995 - 1.0972] mg/dL; Erythrocytes: 3.21 [Not reported - Not reported] Unit not reported; Hemoglobin: 8.4 [Not reported - Not reported] Unit not reported; Leukocytes: 7.97 [Not reported - Not reported] Unit not reported; NPTST108-GAMMA-GLUTAMYLTRANSPEPTIDASE: 293 [Not reported - Not reported] U/L; NPTST146-INR: 1.31 [Not reported - Not reported] Unit not reported; NPTST165-MAGNESIUM: 0.78 [Not reported - Not reported] mmol/L; NPTST244-SERUM CHLORIDES: 105 [Not reported - Not reported] mmol/L; NPTST270-UREA IN SERUM: 27 [Not reported - Not reported] mg/dL; Platelets: 401 [Not reported - Not reported] U/L; Potassium: 4.06 [3.4 - 4.4] mmol/L; Protein: 5.33 [6.4 - 8.3] g/dL; Sodium: 137 [136 - 145] mmol/L; Triglycerides: 195 [38.9381 - 150.4425] mg/dL; [redacted] (Rx Day 137): Glucose: 7.4 [4.1 - 5.9] mmol/L

Microbiology

[redacted] (Rx Day 128): OTHER TISSUE NPTST138-HISTOPATHOLOGY: -RESULT: ABUNDANT, CHRONIC INFLAMMATORY INFILTRATES WITH THE PRESENCE OF SINGLE COCCI, MUCOSA WITH EROSIONS AND ULCERATIONS WITH GRANULATION, PURULENT EXUDATE ON THE INSIDE; [redacted] (Rx Day 129): OTHER PERITONEAL FLUID NPTST007-AEROBIC CULTURE SWAB: POSITIVE-ESCHERICHIA COLI VERY NUMEROUS

SAE Supplemental Procedure

[redacted] (Rx Day 123): ABDOMINAL CAVITY RADIOGRAPHY: RADIOLOGICAL FEATURES OF GASTROINTESTINAL PERFORATION; CHEST RADIOGRAPHY [redacted]: RADIOLOGICAL FEATURES OF GASTROINTESTINAL PERFORATION, PULMONARY FIELDS WITHOUT VISIBLE PATHOLOGICAL DENSITIES, SILHOUETTE OF THE HEART NOT WIDENED LATERALLY; CHEST RADIOGRAPHY [redacted]: PULMONARY FIELDS WITHOUT VISIBLE PATHOLOGICAL DENSITIES; HEMICOLECTOMY: EXCISION OF THE RIGHT HALF OF THE COLON WAS MADE WITH AN ILEO-TRANSVERSE ANASTOMOSIS END-TO-END

AE Stopped Rx Day	139
Duration of AE	12 DAYS
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	CROHN'S DISEASE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, LIFE THREATENING

Generated: [redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ポーランドの治験責任医師からの報告。本被験者は 3[redacted] 歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，盲腸穿孔（腹膜炎）の事象を発現した。

Event 2 及び 3 の臨床経過：

関連する病歴は，虫垂切除，手術瘢痕，痔核，クローン病，胃食道逆流性疾患，クローン病の経過中の貧血，十二指腸の過形成性ポリープ，胸腰椎の側弯症，非喫煙者及び非飲酒者であった。投与開始の約 4 か月前から現在まで，被験者は避妊目的で子宮内器具の併用療法を受けている。

本治験では，Week 12 の開始時に，被験者は盲検性を維持する目的で盲検化された IV 製剤及び盲検化された皮下製剤の投与を受ける予定である。

投与 128 日後，被験者は盲腸穿孔（腹膜炎）を発現した。投与 139 日後，盲腸穿孔（腹膜炎）は消失した。投与 128 日後，被験者は重度の腹痛のため入院した。盲腸穿孔（腹膜炎）のため，結腸右半分の半結腸切除及び回腸－横行結腸端端吻合が行われた。投与 139 日後，被験者は退院した。

投与された薬剤は，等張複数電解質生理液，塩化ナトリウム 0.9%，Pyralgina，トラマール，ブスコパン，クレキサン，Dexaven，Biofuroxime，メトロニダゾール，オメプラゾール，Tracutil，Cernevit，Lipoflex Peri，メロペネム及び Relanium であった。

The patient’s past medications include:

ASAMAX for CROHN'S DISEASE ([redacted] 20[redacted] - 20[redacted])

ENTOCORT for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Cecum perforation (10055432) (Large intestine perforation (10023804)) [v.23.0] [10055432]

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

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

Dechallenge: Not Applicable

2) Peritonitis (10034674) (Peritonitis (10034674)) [v.23.0] [10034674]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of PERFORATION OF THE CECUM, PERITONITIS

- Investigator: Crohn's disease

- AbbVie: Cecum perforation is more likely related to pre-existing Crohn's disease with Peritonitis as its complication.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMINAL CAVITY RADIOGRAPHY:** Radiological features of gastrointestinal perforation.

[redacted] 20[redacted] ACTIVATED PARTIAL THROMBOPLASTIN TIME: 31.7 No units

[redacted] 20[redacted] ACTIVATEDPARTIAL THROMBOPLASTIN TIME: 38.6 No units

[redacted] **20[redacted] AEROBIC CULTURE SWAB:** Peritoneal fluid (Positive Escherichia Coli very numerous)

[redacted] 20[redacted] ALANINE AMINO TRANSFERASE: 17 IU/L

[redacted] 20[redacted] ALANINE AMINO TRANSFERASE: 12 IU/L

[redacted] 20[redacted] ALKALINE PHOSPHATASE: 79.9 U/L

[redacted] 20[redacted] ALKALINE PHOSPHATASE: 121.8 U/L

[redacted] 20[redacted] AMYLASE: 54 U/L

[redacted] 20[redacted] ASPARTATE AMINO TRANSFERASE: 11 IU/L

[redacted] 20[redacted] ASPARTATE AMINO TRANSFERASE: 9 IU/L

[redacted] 20[redacted] BILIRUBIN: 0.91 mg/dL

[redacted] 20[redacted] BILIRUBIN: 0.34 mg/dL

[redacted] 20[redacted] BODY WEIGHT: 4[redacted] KG

[redacted] **20[redacted] CHEST RADIOGRAPHY:** Radiological features of gastrointestinal perforation, pulmonary fields without visible pathological densities, silhouette of the heart not widened laterally.

[redacted] **20[redacted] CHEST RADIOGRAPHY:** Pulmonary fields without visible pathological densities.

[redacted] 20[redacted] CREATININE: 453 mg/dL

[redacted] 20[redacted] CREATININE: 401 mg/dL

[redacted] 20[redacted] HEMOGLOBIN: 9.6 G

[redacted] 20[redacted] HEMOGLOBIN: 8.4 G

[redacted] **20[redacted] INR:** 1.4 No units

[redacted] **20[redacted] INR:** 1.31 No units

[redacted] 20[redacted] PLATELET COUNT: 453 U/L

[redacted] 20[redacted] PLATELET COUNT: 401 U/L

[redacted] 20[redacted] RED BLOOD CELLS: 3.63 T/L

[redacted] 20[redacted] RED BLOOD CELLS: 3.21 T/L

[redacted] 20[redacted] WHITE BLOOD CELLS: 11.21 G/L

[redacted] 20[redacted] WHITE BLOOD CELLS: 7.97 G/L

NON SERIOUS EVENTS and **OTHER AREAS OF SAFETY INTEREST

Herpes zoster: One dermatome was affected and located at the left arm.

Subject [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
クローン病	X	X		
低アルブミン血症				X

Treatment Group	Age at Study Start	Sex	Race
P1:PLACEBO	1[redacted]	FEMALE	WHITE

Medical History	Onset Year
OTHER: SCOLIOSIS	20[redacted]
INFLAMMATORY BOWEL DISEASE: ULCERATIVE COLITIS	20[redacted]
CROHN'S DISEASE	20[redacted]
OTHER: FOCAL SPLENIC LESION	20[redacted]
ANEMIA: ANEMIA REQUIRING TREATMENT	20[redacted]

Prior Procedures	Procedure Year
SURGERY: SURGICAL TREATMENT OF SCOLIOSIS	20[redacted]
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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)
Placebo		IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 24	24

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: 20[redacted]
MESALAZINE	2 g	BID	Y-M: 20[redacted]

METHYLPREDNISOLONE	48 mg	QD	Y-M: 20[redacted]
AZATHIOPRINE	75 mg	QD	Y-M: 20[redacted]
MESALAZINE	1 g	QD	Y-M: 20[redacted]
METHYLPREDNISOLONE	40 mg	QD	Y-M: 20[redacted]
AZATHIOPRINE	50 mg	QD	Y-M: 20[redacted] / -363
PICO-SALAX	1 DF	BID	Y-M: 20[redacted] / -16
FENTANYL	80 ug	OTHER: ONCE	Y-M: 20[redacted] / -15
METAMIZOLE	800 mg	OTHER: ONCE	Y-M: 20[redacted] / -15
PROPOFOL	200 mg	OTHER: ONCE	Y-M: 20[redacted] / -15

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
BCG Vaccine	Not reported.	Not reported.	Y-M: 20[redacted]	Not reported.
MESALAZINE	2 g	BID	Y-M: 20[redacted]	ONGOING
AZATHIOPRINE	50 mg	QD	Y-M: 20[redacted] / -363	Y-M: 20[redacted] / 24
PICO-SALAX	1 DF	BID	Y-M: 20[redacted] / -16	Y-M: 20[redacted] / -16
FENTANYL	80 ug	OTHER: ONCE	Y-M: 20[redacted] / -15	Y-M: 20[redacted] / -15
METAMIZOLE	800 mg	OTHER: ONCE	Y-M: 20[redacted] / -15	Y-M: 20[redacted] / -15
PROPOFOL	200 mg	OTHER: ONCE	Y-M: 20[redacted] / -15	Y-M: 20[redacted] / -15
ALBUMIN HUMAN	50 mL	QD	Y-M: 20[redacted] / 10	Y-M: 20[redacted] / 10
CALCIUM CARBONATE	500 mg	TID	Y-M: 20[redacted] / 10	Y-M: 20[redacted] / 14
CIPROFLOXACIN	500 mg	BID	Y-M: 20[redacted] / 10	Y-M: 20[redacted] / 17
METRONIDAZOLE	500 mg	BID	Y-M: 20[redacted] / 10	Y-M: 20[redacted] / 20
FUROSEMIDE	40 mg	QD	Y-M: 20[redacted] / 10	Y-M: 20[redacted] / 30
ALBUMIN HUMAN	50 mL	BID	Y-M: 20[redacted] / 11	Y-M: 20[redacted] / 11
RED BLOOD CELLS	1 DF	QD	Y-M: 20[redacted] / 12	Y-M: 20[redacted] / 12
ALBUMIN HUMAN	100 mL	BID	Y-M: 20[redacted] / 12	Y-M: 20[redacted] / 17
AMINO ACIDS NOS W/CARBOHYDRATES NOS	UNK DF	QD	Y-M: 20[redacted] / 14	Y-M: 20[redacted] / 31
CALCIUM CARBONATE	500 mg	BID	Y-M: 20[redacted] / 15	ONGOING

RED BLOOD CELLS	1 DF	QD	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 16
RED BLOOD CELLS	1 DF	QD	Y-M: 20[redacted] / 18	Y-M: 20[redacted] / 18
ALBUMIN HUMAN	100 mL	BID	Y-M: 20[redacted] / 20	Y-M: 20[redacted] / 22
RED BLOOD CELLS	1 DF	QD	Y-M: 20[redacted] / 22	Y-M: 20[redacted] / 22
ALBUMIN HUMAN	100 mL	QD	Y-M: 20[redacted] / 23	Y-M: 20[redacted] / 31
AZATHIOPRINE	25 MG mg	OTHER: EVERY OTHER DAY	Y-M: 20[redacted] / 25	ONGOING
AZATHIOPRINE	50 mg	QD	Y-M: 20[redacted] / 25	ONGOING
RED BLOOD CELLS	1 DF	QD	Y-M: 20[redacted] / 25	Y-M: 20[redacted] / 25
RED BLOOD CELLS	1 DF	QD	Y-M: 20[redacted] / 26	Y-M: 20[redacted] / 26
INFLIXIMAB	300 mg	OTHER: ONCE	Y-M: 20[redacted] / 27	Y-M: 20[redacted] / 27
RED BLOOD CELLS	1 DF	QD	Y-M: 20[redacted] / 32	Y-M: 20[redacted] / 32
ALBUMIN HUMAN	100 mL	QD	Y-M: 20[redacted] / 34	Y-M: 20[redacted] / 36

Event #1: Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Event Description CD FLARE

Preferred term クローン病

AE Onset Date / Rx Day [redacted]20[redacted] / 10

Age at AE Onset 1[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 10): NPTST070-CRP: 2.58 [0 - 50] mg/dL; Sodium: 132 [136 - 145] mmol/L; [redacted]20[redacted] (Rx Day 12): Hematocrit: 25 [37 - 47] %; Hemoglobin: 7.9 [12 - 16] g/dL; [redacted]20[redacted] (Rx Day 16): Hematocrit: 23 [37 - 47] %; Hemoglobin: 7.4 [12 - 16] g/dL; NPTST098-FECAL CALPROTECTIN: 3436 [0 - 50] Unit not reported; [redacted]20[redacted] (Rx Day 33): Hematocrit: 30 [37 - 47] %; Hemoglobin: 9.6 [12 - 16] g/dL; [redacted]20[redacted] (Rx Day 36): Hematocrit: 27 [37 - 47] %; Hemoglobin: 8.6 [12 - 16] g/dL; NPTST070-CRP: 0.10 [0 - 5] mg/dL; Sodium: 140 [136 - 145] mmol/L

Microbiology

[redacted]20[redacted] (Rx Day 11): BLOOD NPTST202-PROCALCITONIN: -RESULT EQUAL TO 0.51; [redacted]20[redacted] (Rx Day 16): STOOL NPTST062-CLOSTRIDIUM: NEGATIVE

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 15): ABDOMINAL USG: SIGMOID COLON AND RECTUM WITH THICKENED WALL UP TO 7 MM WITH INCREASED VASCULAR FLOW. IN THE VICINITY OF THE INTESTINAL LOOPS VISIBLE INCREASED ECHOGENICITY OF SURROUNDING TISSUES, WITH NUMEROUS SMALLLYMPH NODES AND DILATED BLOOD VESSELS; X-RAY: PULMONARY PARENCHYMA WITHOUT COMPACTION. PLEURAL FREE. THE SILHOUETTE OF THE HEART IS NOT ENLARGED. 0.46. LUNG VASCULAR DRAWING WITHIN NORMAL LIMITS. DEEP CANNULA IN RA / RV PROJECTION. RIGHT-SIDED CURVATURE OF THE THORACIC SPINE WITH STABILIZATION.

CHEST DEFORMITY. LINEAR CALCIFICATIONS ARE VISIBLE ALONG THE RIGHT OUTLINE OF THE BODY OF THE TH7-TH10 VERTEBRAE

AE Stopped Rx Day	36 (12 DAYS AFTER LAST TREATMENT)
Duration of AE	27 DAYS
Severity	Moderate
Relation to Study Drug by Investigator	Reasonable Possibility
Investigator Alternative Etiology	NA
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #2: Event of Interest - Hepatic Events

Event Description	HYPOALBUMINEMIA
Preferred term	低アルブミン血症
AE Onset Date / Rx Day	[redacted]20[redacted] / 10
Age at AE Onset	1[redacted]

Laboratory Testing
Not Applicable

Microbiology
Not Applicable

SAE Supplemental Procedure
Not Applicable

AE Stopped Rx Day	36 (12 DAYS AFTER LAST TREATMENT)
Duration of AE	27 DAYS
Severity	Moderate
Relation to Study Drug by Investigator	Reasonable Possibility
Investigator Alternative Etiology	Not Applicable
Discontinued Study Drug Due to the Event	NO
SAE Criteria	None

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ポーランドの治験責任医師からの報告。本被験者は 1[redacted] 歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，クローン病フレアの事象を発現した。

Event 1 の臨床経過：

関連する病歴は，潰瘍性大腸炎，クローン病，限局性脾臓病変，貧血，非喫煙者及び非飲酒者であった。

投与 10 日後，被験者はクローン病フレアを発現した。投与 36 日後，クローン病フレアは消失した。

投与 10 日後，被験者はクローン病増悪のため入院した。被験者には皮膚蒼白，四肢腫脹，粘膜乾燥及び貧血があった。被験者は薬剤，TPN 及び赤血球濃厚液による治療を受けた。症状は改善し，投与 36 日後，被験者は退院した。

本事象により治験薬の投与は完全に中止された。

投与された薬剤は，インフリキシマブ，イムラン，中心静脈栄養，メトロニダゾール，赤血球濃厚液，Cipronex，Calperos，アルブミン及びフロセミドであった。

The patient’s past medications include:

METYPRED for CROHN'S DISEASE and ULCERATIVE COLITIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Crohn's disease aggravated (10011403) (Crohn's disease (10011401)) [v.23.1] [10011403]

Causality as per reporter (Drug/Vaccine): 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 RISANKIZUMAB (Blinded)

Event of CROHN'S DISEASE FLARE

- Investigator: Not applicable

- AbbVie: Event is more likely related to pre-existing Crohn's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMINAL ULTRASOUND:** Sigmoid colon and rectum with thickened wall up to 7 mm with increased vascular flow. In the vicinity of the intestinal loops visible increased echogenicity of surrounding tissues, with numerous small lymph nodes and dilated blood vessels

[redacted] 20[redacted] BLOOD PROCALCTONIN: 0.51 no unit

[redacted] **20[redacted] CRP:** 2.58 mg/dL (normal <50)

[redacted] **20[redacted] CRP:** 0.10 mg/dL (normal <50)

[redacted] **20[redacted] HCT:** 25 % (normal 37 to 47)

[redacted] 20[redacted] HCT: 27 %

[redacted] **20[redacted] HGB:** 7.9 G/DL (normal 12.0 to 16.0)

[redacted] 20[redacted] HGB: 8.6 G/DL

[redacted] **20[redacted] SODIUM:** 132 MMOL/L (normal 136 to 145)

[redacted] **20[redacted] SODIUM:** 140 MMOL/L (normal 136 to 145)

[redacted] 20[redacted] STOOL CLOSTRIDIUM: NEGATIVE

[redacted] 20[redacted] STOOL FECAL CALPROTECTIN: 3436 mcg/g (normal 0 to 50)

[redacted] **20[redacted] X-RAY:** PULMONARY PARENCHYMA WITHOUT COMPACTION. PLEURAL FREE. THE SILHOUETTE OF THE HEART IS NOTENLARGED. 0.46. LUNG VASCULAR DRAWING WITHIN NORMAL LIMITS. DEEP CANNULA IN RA / RV PROJECTION. RIGHT-SIDED CURVATURE OF THE THORACIC SPINE WITH STABILIZATION. CHEST DEFORMITY. LINEAR CALCIFICATIONS ARE VISIBLE ALONG THE RIGHT OUTLINE OF THE BODY OF THE TH7-TH10 VERTEBRAE

Subject [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
転倒	X			
前腕骨折	X			

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 600 MG IV	1[redacted]	FEMALE	WHITE

Medical History	Onset Year
CROHN'S DISEASE	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): BIOPSY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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)
Risankizumab	600 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 57	57

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: 20[redacted]
AZATHIOPRINE	50 mg	BID	Y-M: 20[redacted]
MESALAZINE	1 g	QD	Y-M: 20[redacted]
NUTRIENTS NOS	2200 mL	QD	Y-M: 20[redacted]
AZATHIOPRINE	50 mg	QD	Y-M: 20[redacted]
AZATHIOPRINE	25 mg	QD	Y-M: 20[redacted]

INFLIXIMAB	250 mg	OTHER: ACCORDING TO THE PROTOCOL	Y-M: 20[redacted]
CIPROFLOXACIN	500 mg	BID	Y-M: 20[redacted]
CEFTRIAXONE	1 g	QD	Y-M: 20[redacted] / -285
CEFUROXIME	250 mg	BID	Y-M: 20[redacted] / -279
INFLIXIMAB	300 mg	OTHER: ACCORDING TO THE PROTOCOL	Y-M: 20[redacted] / -264

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
BCG Vaccine	Not reported.	Not reported.	Y-M: 20[redacted]	Not reported.
MESALAZINE	1 g	QD	Y-M: 20[redacted]	ONGOING

Event #1: Serious Adverse Event

Event Description	FOREARM FRACTURE (LEFT FOREARM), FALL DUE TO SPORTS ACTIVITIES
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 11
Age at AE Onset	1[redacted]

Laboratory Testing

Not reported

Microbiology

Not reported

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day -9): SURGERY: WRIST STABILIZATION; X-RAY: WRIST FRACTURE

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	UNFORTUNATELY FALL
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Event #2: Serious Adverse Event

Event Description	FOREARM FRACTURE (LEFT FOREARM), FALL DUE TO SPORTS ACTIVITIES
Preferred term	前腕骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 11
Age at AE Onset	1[redacted]

Laboratory Testing

Not reported

Microbiology
Not reported
SAE Supplemental Procedure
[redacted]20[redacted] (Rx Day -9): SURGERY: WRIST STABILIZATION; X-RAY: WRIST FRACTURE

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	UNFORTUNATELY FALL
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ポーランドの治験責任医師からの報告。本被験者は 1[redacted] 歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，前腕骨折（左腕，運動による転倒）の事象を発現した。

Event 1 及び 2 の臨床経過：

関連する病歴は，クローン病，非喫煙者及び非飲酒者であった。

投与 11 日後，被験者は前腕骨折（左腕，運動による転倒）を発現した。投与 13 日後，前腕骨折（左腕，運動による転倒）は消失した。

投与 11 日後，被験者は運動中の転倒による左前腕骨折のため入院した。被験者は骨折を固定する目的で手術を受けた。投与 12 日後，被験者は退院した。

The patient’s past medications include:

IMURAN for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

MODULEN IBD for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

INFLIXIMAB for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

CIPRONEX for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

CEFTRIAXON for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ZINNAT for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Fall (10016173) (Fall (10016173)) [v.23.1] [10016173]

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

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

Dechallenge: Not Applicable

2) Forearm fracture (10016997) (Forearm fracture (10016997)) [v.23.1] [10016997]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of FOREARM FRACTURE (LEFT FOREARM), FALL DUE TO SPORTS ACTIVITIES

- Investigator: UNFORTUNATELY FALL

- AbbVie: event more likely an unexpected and unintentional incident during sport activity.

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] X-RAY WRIST: Fracture

Subject [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
腸管膿瘍	X			X
クローン病	X			

Treatment Group	Age at Study Start	Sex	Race
P1:PLACEBO	3[redacted]	MALE	WHITE

Medical History	Onset Year
ASTHMA	19[redacted]
CROHN'S DISEASE	20[redacted]
OTHER: ILEORECTAL FISTULA	20[redacted]

Prior Procedures	Procedure Year
SURGERY: TONSILLECTOMY	19[redacted]
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CIGARETTES	FORMER	10 CIGARETTE	12	20[redacted]
CHEWING TOBACCO	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
Placebo		IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 29	29

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
BUDESONIDE	3 mg	TID	Y-M: 20[redacted]
ADALIMUMAB	160 mg	OTHER: WEEKLY	Y-M: 20[redacted]
SALBUTAMOL	2 mg	PRN	Y-M: 20[redacted]
PREDNISOLONE	60 mg	QD	Y-M: 20[redacted] / -52

MOVIPREP	UNKNOWN g	QD	Y-M: 20[redacted] / -11
JONOSTERIL	500 mL	OTHER: ONCE	Y-M: 20[redacted] / -10
PROPOFOL	510 mg	OTHER: ONCE	Y-M: 20[redacted] / -10
HYOSCINE	20 mg	PRN	Y-M: 20[redacted] / -5
METAMIZOLE	500 mg	PRN	Y-M: 20[redacted] / -5

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	2 mg	PRN	Y-M: 20[redacted]	ONGOING
HYOSCINE	20 mg	PRN	Y-M: 20[redacted] / -5	Y-M: 20[redacted] / 31
METAMIZOLE	500 mg	PRN	Y-M: 20[redacted] / -5	Y-M: 20[redacted] / 61
IRON	500 mg	OTHER: ONCE	Y-M: 20[redacted] / 8	Y-M: 20[redacted] / 8
IRON	500 mg	OTHER: ONCE	Y-M: 20[redacted] / 29	Y-M: 20[redacted] / 29
OMEPRAZOLE	40 mg	OTHER: ONCE	Y-M: 20[redacted] / 31	Y-M: 20[redacted] / 31
PIP/TAZO	4/0.5 g	TID	Y-M: 20[redacted] / 32	Y-M: 20[redacted] / 37
ENOXAPARIN	40 mg	QD	Y-M: 20[redacted] / 32	Y-M: 20[redacted] / 38
HYOSCINE	20 mg	TID	Y-M: 20[redacted] / 32	Y-M: 20[redacted] / 61
SPEKTRAMOX	875/125 mg	BID	Y-M: 20[redacted] / 38	ONGOING

Event #1: Serious Adverse Event

Event Description WORSENING OF CROHN DISEASE

Preferred term クローン病

AE Onset Date / Rx Day [redacted]20[redacted] / 30 (1 DAY AFTER LAST TREATMENT)

Age at AE Onset 3[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 31): Alkaline Phosphatase: 236 [40 - 129] U/L; C Reactive Protein: 20.7 [0 - 0.5] mg/dL; Creatine Kinase: 27 [39 - 308] U/L; Glucose: 110 [70 - 100] mg/dL; Hematocrit: 38 [40 - 53] %; Hemoglobin: 11.7 [14 - 18] g/dL; Leukocytes: 20.6 [4.3 - 10] 10^9/L; Lymphocytes/Leukocytes: 14.4 [22.4 - 47.9] %; Monocytes: 2.29 [0.9 - 1.04] 10^3/uL; NPTST042-BLOOD: + [0 - 0] Unit not reported; NPTST115-GGT: 370 [8 - 61] U/L; Neutrophils: 15.16 [1.8 - 7] 10^3/uL; Neutrophils/Leukocytes: 74 [50 - 70] %; Platelets: 469 [150 - 300] g/L; Sodium: 129 [135 - 145] mmol/L

Microbiology

[redacted]20[redacted] (Rx Day 31): BLOOD NPTST180-NOROVIRUS: NEGATIVE

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 24): ABDOMINAL ULTRASOUND: SPLENOMEGALIE; GASTROSCOPY: GASTRITIS; [redacted]20[redacted] (Rx Day 55): MRT ABDOMEN: CONGLOMERATE TUMOR

AE Stopped Rx Day 72 (43 DAYS AFTER LAST TREATMENT)

Duration of AE	43 DAYS
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	VOMITTING
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

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

Event Description	ABSCESS TERMINALES ILEUM
Preferred term	腸管膿瘍
AE Onset Date / Rx Day	[redacted] / 32 (3 DAYS AFTER LAST TREATMENT)
Age at AE Onset	[redacted]

Laboratory Testing

[redacted] (Rx Day 32): Alkaline Phosphatase: 284 [40 - 130] U/L; C Reactive Protein: 167.5 [0 - 5] mg/L; Ery. Mean Corpuscular Hemoglobin: 24.1 [27 - 33] pg; Ery. Mean Corpuscular Volume: 76.7 [81 - 98] fL; Hematocrit: 35.6 [39 - 51] %; Hemoglobin: 11.2 [13.5 - 17.5] g/dL; Leukocytes: 14.02 [4 - 10] 10^9/L; NPTST115-GGT: 334 [0 - 60] U/L; NPTST167-MCHC: 31.5 [32 - 36] g/L; Platelets: 494 [140 - 350] 10^9/L; [redacted] (Rx Day 36): Bilirubin: 0.3 [0 - 1.1] mg/dL; C Reactive Protein: 32.2 [0 - 5] mg/L; Ery. Mean Corpuscular Hemoglobin: 24.7 [27 - 33] pg; Ery. Mean Corpuscular Volume: 78.1 [81 - 98] fL; Hematocrit: 37.9 [39 - 51] %; Hemoglobin: 12.0 [13.5 - 17.5] g/dL; Leukocytes: 11.68 [4 - 10] 10^9/L; NPTST011-ALT: 26 [0 - 50] U/L; NPTST115-GGT: 259 [0 - 60] U/L; NPTST167-MCHC: 31.7 [32 - 36] g/L; Platelets: 470 [140 - 350] 10^9/L

Microbiology

[redacted] (Rx Day 32): BLOOD NPTST043-BLOOD CULTURE: NEGATIVE

SAE Supplemental Procedure

[redacted] (Rx Day 24): ABDOMINAL ULTRASOUND: ABSCESS TERMINALES ILEUM; [redacted] (Rx Day 55): MRT ABDOMEN: CONGLOMERATE TUMOR

AE Stopped Rx Day	72 (43 DAYS AFTER LAST TREATMENT)
Duration of AE	41 DAYS
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	NO MORE INFORMATIONS ARE AVAILABLE AT THIS MOMENT
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ドイツの治験責任医師からの報告。本被験者は3[redacted]歳男性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，回腸末端膿瘍及びクローン病悪化の事象を発現した。

Event 1 及び 2 の臨床経過：

関連する病歴は，クローン病，元喫煙者（1 日 10 本を 12 年間），回腸直腸瘻及び現飲酒者（1 日 2 杯未満）であった。

投与 30 日後，被験者はクローン病悪化を発現した。投与 32 日後，被験者は回腸末端膿瘍を発現した。投与 72 日後，回腸末端膿瘍及びクローン病悪化は消失した。

投与 30 日後，被験者は入院した。過去 7 日間，被験者には嘔吐，腹部圧痛及び発熱があった。投与 31 日後，被験者は退院した。

投与 31 日後，被験者は非重篤な胃炎を発現したと報告された。

投与 32 日後，被験者は腹部圧痛，発熱，CRP 増加及び初期感染のため再入院した。入院中，症状は減少した。投与 38 日後，被験者は退院した。

投与された薬剤は，Amoxiclav，ピペラシリン／タゾバクタム，ブスコパン及びクレキサンであった。

The patient’s past medications include:

BUDENOFALK for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ADALIMUMAB for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PREDNISOLON for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Abscess intestinal (10000285) (Abscess intestinal (10000285)) [v.22.0] [10000285]

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

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

Dechallenge: Not Applicable

2) Crohns disease aggravated (10011408) (Crohn's disease (10011401)) [v.22.0] [10011408]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of ABSCESS TERMINALES ILEUM

- Investigator: NO MORE INFORMATIONS ARE AVAILABLE AT THIS MOMENT

- AbbVie: Event is more likely related to pre-existing Crohn's disease.

Event of WORSENING OF CROHN DISEASE

- Investigator: VOMITTING

- AbbVie: Event is more likely related to pre-existing Crohn's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] ABDOMINAL ULTRASOUND: SPLENOMEGALIE

[redacted] 20[redacted] ABDOMINAL ULTRASOUND: abscess terminales ileum

[redacted] 20[redacted] ALKALINE PHOSPHATASE: 236 U/L (normal 40 to 129)

[redacted] 20[redacted] ALKALINE PHOSPHATASE: 284 u/l (normal 40 to 130)

[redacted] **20[redacted] ALT:** 26 U/L (normal 0 to 50)

[redacted] **20[redacted] BILIRUBIN:** 0.3 mg/dL (normal 0 to 1.1)

[redacted] 20[redacted] BLOOD CULTURE: negative

[redacted] **20[redacted] CREATINE KINASE:** 27 U/L (normal 39 to 308)

[redacted]y 2[redacted]9 GASTROSCOPY: GASTRITIS

[redacted] **20[redacted] GGT:** 370 U/L (normal 8 to 61)

[redacted] **20[redacted] GLUCOSE:** 110 mg/dL (normal 70 to 100)

[redacted] **20[redacted] HEMATOCRIT:** 38 % (normal 40 to 53)

[redacted] **20[redacted] HEMATOCRIT:** 37.9 % (normal 39 to 51)

[redacted] **20[redacted] HEMOGLOBIN:** 11.7 G/DL (normal 14.0 to 18.0)

[redacted] **20[redacted] HEMOGLOBIN:** 12.0 G/DL (normal 13.5 to 17.5)

[redacted] 20[redacted] HIGH SENSITIVITY C REACTIVE PROTEIN: 20.7 mg/dL (normal 0 to .5)

[redacted] **20[redacted] NEUTROPHIL ABS:** 15.16 ¥10^3/mikrol) (normal 1.8 to 7.0)

[redacted] 20[redacted] NEUTROPHIL PERCENT: 74 % (normal 50 to 70)

[redacted] 20[redacted] NOROVIRUS: negative

[redacted] **20[redacted] PLATELET COUNT:** 469 G/L (normal 150 to 300)

[redacted] **20[redacted] SODIUM:** 129 MMOL/L (normal 135 to 145)

[redacted] **20[redacted] WBC:** 20.6 G/L (normal 4.3 to 10.0)

[redacted] **20[redacted] WBC:** 11.68 10^3/MIKROL (normal 4 to 10)

Subject [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
イレウス	X			

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 600 MG IV	2[redacted]	MALE	WHITE

Medical History	Onset Year
CROHN'S DISEASE	20[redacted]
OTHER: SINUSBRADYCARDIA	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE SURGICAL HISTORY: BOWEL RESECTION	20[redacted]
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
Risankizumab	600 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 57	57

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
LEKOVIT CA	500 mg	QD	Y-M: 20[redacted]
MESALAZINE	500 mg	BID	Y-M: 20[redacted]
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted]
PREDNISOLONE	60 mg	QD	Y-M: 20[redacted]
AZATHIOPRINE	UNKNOWN mg	QD	Y-M: 20[redacted]
MERCAPTOPURINE	UNKNOWN mg	QD	Y-M: 20[redacted]

INFLIXIMAB	650 mg	OTHER: EVERY 4 WEEKS	Y-M: 20[redacted]
ADALIMUMAB	40 mg	OTHER: WEEKLY	Y-M: 20[redacted]
VEDOLIZUMAB	300 mg	OTHER: EVERY 8 WEEKS	Y-M: 20[redacted]
PARACETAMOL	500 mg	PRN	Y-M: 20[redacted]
USTEKINUMAB	90 mg	OTHER: EVERY 8 WEEKS	Y-M: 20[redacted]
ADALIMUMAB	40 mg	OTHER: EVERY 2 WEEKS	Y-M: 20[redacted] / -255
FOLIC ACID	5 mg	OTHER: EVERY WEEK	Y-M: 20[redacted] / -255
METHOTREXATE	25 mg	OTHER: EVERY WEEK	Y-M: 20[redacted] / -255
DIMETICONE	45 gtt	PRN	Y-M: 20[redacted] / -56
JONOSTERIL	500 mL	OTHER: ONCE	Y-M: 20[redacted] / -8
MIDAZOLAM	2 mg	OTHER: ONCE	Y-M: 20[redacted] / -8
PROPOFOL	180 mg	OTHER: ONCE	Y-M: 20[redacted] / -8
JONOSTERIL	500 mL	QD	Y-M: 20[redacted] / -7
PROPOFOL	120 mg	OTHER: ONCE	Y-M: 20[redacted] / -7
PROPOFOL	260 mg	OTHER: ONCE	Y-M: 20[redacted] / -6

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
LEKOVIT CA	500 mg	QD	Y-M: 20[redacted]	ONGOING
MESALAZINE	500 mg	BID	Y-M: 20[redacted]	ONGOING
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted]	ONGOING
PARACETAMOL	500 mg	PRN	Y-M: 20[redacted]	ONGOING
DIMETICONE	45 gtt	PRN	Y-M: 20[redacted] / -56	ONGOING
METAMIZOLE	500 mg	TID	Y-M: 20[redacted] / 152	ONGOING
PREDNISOLONE	7.5 mg	QD	Y-M: 20[redacted] / 152	ONGOING

Event #1: Serious Adverse Event

Event Description	ILEUS
Preferred term	イレウス
AE Onset Date / Rx Day	[redacted]20[redacted] / 135 (78 DAYS AFTER LAST TREATMENT)
Age at AE Onset	2[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 135): C Reactive Protein: 5.7 [0 - 5] mg/L; Potassium: 3.2 [3.6 - 4.8] mmol/L; [redacted]20[redacted] (Rx Day 137): Hemoglobin: 6.6 [14 - 17] g/dL; [redacted]20[redacted] (Rx Day 140): C Reactive Protein: 343.3 [0 - 5] mg/L; [redacted]20[redacted] (Rx Day 147): Albumin: 19.1 [35 - 55] g/L; [redacted]20[redacted] (Rx Day 150): C Reactive Protein: 78.8 [0 - 5] mg/L; Platelets: 674 [160 - 400] 10^3/uL

Microbiology
Not reported
SAE Supplemental Procedure
[redacted]20[redacted] (Rx Day 102): MRI: ILEUS; [redacted]20[redacted] (Rx Day 133): ABDOMINAL CT: ILEUS; INTESTINAL ULTRASOUND: ILEUS; LAPAROTOMY;　RESECTION OF A PART OF JEJUNUM 40 CM;HEMYCOLECTOMY: RESOLVED

AE Stopped Rx Day	152 (95 DAYS AFTER LAST TREATMENT)
Duration of AE	18 DAYS
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	LAPAROTOMY;　RESECTION OF A PART OF JEJUNUM 40 CM;HEMYCOLECTOMY
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ドイツの治験責任医師からの報告。本被験者は 2[redacted] 歳男性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，イレウスの事象を発現した。

Event 1 の臨床経過：

関連する病歴は，クローン病（回腸・結腸，上部消化管に関連する合併症，狭窄型），非喫煙者及び現飲酒者（1 日 2 杯未満）であった。

投与 135 日後，被験者はイレウスを発現した。投与 152 日後，イレウスは消失した。

投与 135 日後，被験者は間欠性嘔吐（投与初日から）のため入院した。被験者は開腹及び半結腸切除を受けることとなった。空腸が 40 cm 切除された。投与 152 日後，被験者は退院した。

投与された薬剤は，プレドニゾロン及び Novalgin であった。

The patient's past medications include:

PREDNISOLON for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

AZATHIOPRIN for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

6-MERCAPTOPURIN for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

INFLIXIMAB for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ADALIMUMAB for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

VEDOLIZUMAB for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

USTEKINUMAB for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

AMGEVITA for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

METHOTREXAT for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Ileus (10021328) (Ileus (10021328)) [v.23.1] [10021328]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of ILEUS

- Investigator: Laparotomy; resection of a part of jejunum 40 cm; hemycolectomy

- AbbVie: Event more likely related to pre-existing Crohn's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] ABDOMINAL CT: Ileus

[redacted] **20[redacted] ALBUMIN:** 19.1 G/L (normal 35 to 55)

[redacted] **20[redacted] HEMOGLOBIN:** 6.6 G/DL (normal 14 to 17)

[redacted] 20[redacted] HIGH SENSITIVITY C REACTIVE PROTEIN: 5.7 MG/L (normal 0 to 5)

[redacted] 20[redacted] HIGH SENSITIVITY C REACTIVE PROTEIN: 343.3 MG/L (normal 0 to 5)

[redacted] 20[redacted] HIGH SENSITIVITY C REACTIVE PROTEIN: 78.8 MG/L (normal 0 to 5)

[redacted] 20[redacted] INTESTINAL ULTRASOUND: Ileus

[redacted] 20[redacted] MRI: Ileus

[redacted] **20[redacted] PLATELET COUNT:** 674 X10**3/MCL (normal 160 to 400)

[redacted] **20[redacted] POTASSIUM:** 3.2 MMOL/L (normal 3.6 to 4.8)

Subject [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
尿路結石	X			

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 600 MG IV / P2:RZB 180 mg SC	5[redacted]	MALE	WHITE

Medical History	Onset Year
OTHER: PERIPHERAL ARTHROPATHY	Not reported.
OTHER: QTCF PROLONGATION	Not reported.
EYE DISEASE/DISORDER: DYSCHROMATOPSIA	19[redacted]
CROHN'S DISEASE	19[redacted]
OTHER: INTOLERANCE TO INFLIXIMAB	20[redacted]
ANEMIA: IRON DEFICIENCY ANAEMIA	20[redacted]
HYPERTENSION	20[redacted]
OTHER: AUTOLOGOUS HEMATOPOETIC STEM CELL TRANSPLANTATION	20[redacted]
OTHER: ENTHESITIS ACHILLES TENDON	20[redacted]
OTHER: FOLIC ACID DEFICIENCY ANAEMIA	20[redacted]
OTHER: INTOLERANCE AMPLODIPIN	20[redacted]
OTHER: INTOLERANCE DICLOFENAK	20[redacted]
OTHER: INTOLERANCE DOXAZOSIN	20[redacted]
OTHER: INTOLERANCE FERRINJECT	20[redacted]
OTHER: INTOLERANCE FERRO SANOL DUODENAL	20[redacted]
OTHER: INTOLERANCE IBUPROFEN	20[redacted]
OTHER: INTOLERANCE MONOFER	20[redacted]
OTHER: INTOLERANCE RAMIPRIL	20[redacted]
OTHER: LYMPHOPENIA	20[redacted]
OTHER: PYODERMA GANGRAENOSUM	20[redacted]
OTHER: SLEEP DISORDERS	20[redacted]
OTHER: INTOLERANCE TO COTRIMOXAZOL	20[redacted]
OTHER: KIDNEY STONES	20[redacted]
OTHER: ABDOMINAL SPASMS	20[redacted]
OTHER: SHORTNESS OF BREATH	20[redacted]
OTHER: STIFF MUSCLES	20[redacted]
OTHER: VERTIGO	20[redacted]
OTHER: BASALIOMA	20[redacted]
MIGRAINE HEADACHE	20[redacted]
OTHER: ABDOMINAL PAIN	20[redacted]
OTHER: ACHING MUSCLES	20[redacted]

OTHER: BACK PAIN	20[redacted]
OTHER: COUGH	20[redacted]
OTHER: FITS OF DIZZINESS	20[redacted]
OTHER: PRURITUS	20[redacted]
OTHER: RESPIRATORY APNEA	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE SURGICAL HISTORY: BOWEL RESECTION	19[redacted]
SURGERY: APPENDECTOMY	19[redacted]
SURGERY: ILEUS OPERATION	19[redacted]
CROHN'S DISEASE SURGICAL HISTORY: BOWEL RESECTION	19[redacted]
SURGERY: ILEOCECAL RESECTION	19[redacted]
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
Risankizumab	600 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 57	57
Risankizumab	180 mg	SC	Every 8 Weeks	[redacted]20[redacted] / 90	[redacted]20[redacted] / 148	59

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]
MESALAZINE	1200 mg	QD	Y-M: 19[redacted]
AZATHIOPRINE	50 mg	QD	Y-M: 19[redacted]
HYOSCINE	10/500 mg	PRN	Y-M: 19[redacted]
LOPERAMIDE	2 mg	PRN	Y-M: 19[redacted]
METHOTREXATE	30 mg	QD	Y-M: 20[redacted]
INFLIXIMAB	10 OTHER: MG PER BODY WEIGHT)	OTHER: EVERY 8 WEEK	Y-M: 20[redacted]
ADALIMUMAB	40 mg/kg	OTHER: EVERY 2 WEEKS	Y-M: 20[redacted]
COLECALCIFEROL	20000 IU	OTHER: EVERY TWO WEEKS	Y-M: 20[redacted]

DAPSONE	50 mg	OTHER: TWICE PRO WEEK	Y-M: 20[redacted]
FOLIC ACID	5 mg	OTHER: TWICE PRO WEEK	Y-M: 20[redacted]
PANTOPRAZOLE	20 mg	QD	Y-M: 20[redacted]
PYRIMETHAMINE	25 mg	OTHER: TWICE PRO WEEK	Y-M: 20[redacted]
IRON	62,5 mg	PRN	Y-M: 20[redacted]
METAMIZOLE	500 mg	PRN	Y-M: 20[redacted]
PARACETAMOL	500 mg	PRN	Y-M: 20[redacted]
ADALIMUMAB	160 mg	OTHER: WEEKLY	Y-M: 20[redacted]
MYCOPHENOLIC ACID	1 g	QD	Y-M: 20[redacted]
USTEKINUMAB	390 mg	OTHER: EVERY 8 WEEKS	Y-M: 20[redacted]
PREDNISOLONE	15 mg	QD	Y-M: 20[redacted] / -135
CANDESARTAN	8 mg	QD	Y-M: 20[redacted] / -32
CHLORTALIDONE	25 mg	QD	Y-M: 20[redacted] / -32
PICO-SALAX	1 L	QD	Y-M: 20[redacted] / -22
PROPOFOL	220 mg	QD	Y-M: 20[redacted] / -21

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
BCG Vaccine	Not reported.	Not reported.	Y-M: 19[redacted]	Not reported.
HYOSCINE	10/500 mg	PRN	Y-M: 19[redacted]	ONGOING
LOPERAMIDE	2 mg	PRN	Y-M: 19[redacted]	ONGOING
COLECALCIFEROL	20000 IU	OTHER: EVERY TWO WEEKS	Y-M: 20[redacted]	ONGOING
DAPSONE	50 mg	OTHER: TWICE PRO WEEK	Y-M: 20[redacted]	ONGOING
FOLIC ACID	5 mg	OTHER: TWICE PRO WEEK	Y-M: 20[redacted]	ONGOING
PANTOPRAZOLE	20 mg	QD	Y-M: 20[redacted]	ONGOING
PYRIMETHAMINE	25 mg	OTHER: TWICE PRO WEEK	Y-M: 20[redacted]	ONGOING
IRON	62,5 mg	PRN	Y-M: 20[redacted]	ONGOING
METAMIZOLE	500 mg	PRN	Y-M: 20[redacted]	ONGOING
PARACETAMOL	500 mg	PRN	Y-M: 20[redacted]	ONGOING
PREDNISOLONE	15 mg	QD	Y-M: 20[redacted] / -135	Y-M: 20[redacted] / 170
METAMIZOLE	1 g	QID	Y-M: 20[redacted] / 123	Y-M: 20[redacted] / 125
HYOSCINE	20 mg	QD	Y-M: 20[redacted] / 124	Y-M: 20[redacted] / 124

JONOSTERIL	1000 mL	OTHER: ONCE	Y-M: 20[redacted] / 124	Y-M: 20[redacted] / 124
PARACETAMOL	1 g	OTHER: ONCE	Y-M: 20[redacted] / 124	Y-M: 20[redacted] / 124
PROPOFOL	3020 mg	OTHER: ONCE	Y-M: 20[redacted] / 124	Y-M: 20[redacted] / 124
SUFENTANIL	5 mg	OTHER: ONCE	Y-M: 20[redacted] / 124	Y-M: 20[redacted] / 124
TINZAPARIN	3500 IU	QD	Y-M: 20[redacted] / 124	Y-M: 20[redacted] / 126
SPEKTRAMOX	875/125 mg	TID	Y-M: 20[redacted] / 143	Y-M: 20[redacted] / 146
LEVOFLOXACIN	500 mg	TID	Y-M: 20[redacted] / 149	Y-M: 20[redacted] / 156
DEXPANTHENOL	10 mg	QD	Y-M: 20[redacted] / 152	ONGOING
EPHEDRINE	40 mg	OTHER: ONCE	Y-M: 20[redacted] / 152	Y-M: 20[redacted] / 152
JONOSTERIL	1000 mL	OTHER: ONCE	Y-M: 20[redacted] / 152	Y-M: 20[redacted] / 152
ONDANSETRON	4 mg	PRN	Y-M: 20[redacted] / 152	Y-M: 20[redacted] / 152
PARACETAMOL	1 g	OTHER: ONCE	Y-M: 20[redacted] / 152	Y-M: 20[redacted] / 152
PROPOFOL	300 mg	OTHER: ONCE	Y-M: 20[redacted] / 152	Y-M: 20[redacted] / 152
SUFENTANIL	10 mg	OTHER: ONCE	Y-M: 20[redacted] / 152	Y-M: 20[redacted] / 152
TINZAPARIN	3500 IU	TID	Y-M: 20[redacted] / 152	Y-M: 20[redacted] / 153

Event #1: Serious Adverse Event

Event Description	UROLITHIASIS
Preferred term	尿路結石
AE Onset Date / Rx Day	[redacted]20[redacted] / 122
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 123): C Reactive Protein: 24.2 [0 - 5] mg/L; Creatinine: 1.65 [0.67 - 1.17] mg/dL; Leukocytes: 10.80 [3.9 - 9.8] Unit not reported; [redacted]20[redacted] (Rx Day 152): Hemoglobin: POSITIVE [Not reported - Not reported] Unit not reported; NPTST253-STONE ANALYSIS: 70% CALCIUMOXALAT-MO [Not reported - Not reported] Unit not reported; Protein: POSITIVE [Not reported - Not reported] Unit not reported

Microbiology

Not reported

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 108): ABDOMINAL ULTRASOUND: URINARY OBSTRUCTION, KIDNEY STONES; CT ABDOMINAL: URINARY OBSTRUCTION, KIDNEY STONES; DJ URETERAL STENT

LEFT: DECONGESTED KIDNEY; [redacted]20[redacted] (Rx Day 137): DJ URETERAL STENT LEFT EXTRACTION: SUCCESSFUL; KIDNAY ULTRASOUND: KIDNAY(BOTH) NO ECTASIA, RESIDUAL URINE 10 ML; URETERORENOSCOPIC KIDNEY STONE EXCISION LEFT SIDE ON [redacted]-[redacted]-20[redacted]: SUCCESSFUL

AE Stopped Rx Day	154 (6 DAYS AFTER LAST TREATMENT)
Duration of AE	33 DAYS
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	KIDNEY STONE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ドイツの治験責任医師からの報告。本被験者は5[redacted]歳男性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，尿路結石症の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，クローン病，高血圧，壊疽性膿皮症，腎結石，腹部痙縮，背部痛，非喫煙者及び軽度アルコール摂取（1 日 2 杯未満）であった。

投与 122 日後，被験者は尿路結石症を発現した。投与 154 日後，尿路結石症は消失した。

投与 113 日後から投与 114 日後まで，被験者は腎臓痛（非重篤）の事象を発現した。

投与 123 日後，被験者は疼痛の症状を呈した。腹部の超音波検査及び CT 検査が行われ，尿路閉塞及び腎結石が認められた。鎮痙療法が行われた。ダブル J 尿管ステントが左側に留置され，これにより腎臓のうっ滞が除去された。投与 125 日後，被験者は退院した。

投与 152 日後，被験者は投与 122 日後に発現した左腎臓痛のため入院し，左側の腎盂尿管鏡下腎結石除去を受けた。投与 154 日後，左側からダブル J 尿管ステントの除去が成功し，同日，被験者は退院した。

投与された薬剤は，レボフロキサシン，sufentanil，Perfalgan，ブスコパン及び Novalgin であった。

The patient’s past medications include:

MESALAZIN for CROHN'S DISEASE (19[redacted] - 19[redacted])

AZATHIOPRIN for CROHN'S DISEASE (19[redacted] - 20[redacted])

METHOTREXAT for CROHN'S DISEASE (20[redacted] - 20[redacted])

INFLIXIMAB for CROHN'S DISEASE (20[redacted] - 20[redacted])

ADALIMUMAB for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

MYCOPHENOLAT-MOFETIL for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

USTEKINUMAB for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

FERRO SANOL DUODENAL for UNKNOWN INDICATION

MONOFER for UNKNOWN INDICATION

FERRIN for UNKNOWN INDICATION

DOXAZOSIN for UNKNOWN INDICATION

RAMIPRIL for UNKNOWN INDICATION

AMLODIPIN for UNKNOWN INDICATION

Causality for RISANKIZUMAB (Blinded)

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1) Urolithiasis (10046707) (Calculus urinary (10007027)) [v.23.1] [10046707]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of UROLITHIASIS

- Investigator: Kidney stone.

- AbbVie: Risk factors include pre-existing history of kidney stones and crohn's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMINAL ULTRASOUND:** Urinary obstruction, kidney stones.

[redacted] **20[redacted] CREATININE:** 1.65 mg/dL (normal >0.67)

[redacted] **20[redacted] CT ABDOMEN:** Urinary obstruction, kidney stones.

[redacted] 20[redacted] HEMOGLOBINE (URINE): Positive

[redacted] 20[redacted] HIGH SENSITIVITY C REACTIVE PROTEIN: 24.2 mg/dL (normal 0 to 5)

[redacted] **20[redacted] KIDNEY ULTRASOUND:** Kidney (both) no ectasia, residual urine 10mL

[redacted] **20[redacted] LAB TEST:** STONE ANALYSIS: 70% Calciumoxalat-Mo

[redacted] 20[redacted] PROTEIN (URINE): Positive

[redacted] **20[redacted] WHITE BLOOD CELLS:** 10.80 TSD/microliter (normal >3.9)

Subject [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
腎結石症	X			

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 1200 MG IV	4[redacted]	FEMALE	WHITE

Medical History	Onset Year
OTHER: HYPERCHOLESTEREMIA (INCREASE OF LIPOPROTEIN)	Not reported.
OTHER: NICOTINE ABUSE	Not reported.
OTHER: OSTEOPENIA	Not reported.
OTHER: ARTHRALGIA	20[redacted]
CROHN'S DISEASE	20[redacted]
OTHER: CHOLECYSTOLITHIASIS	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE SURGICAL HISTORY: RESECTION OF PERIANAL FISTULA	20[redacted]
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CIGARETTES	FORMER	7 CIGARETTE	12	19[redacted]
CHEWING TOBACCO	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)
Risankizumab	1200 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 60	60

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
PREDNISOLONE	UNK OTHER: UNK	OTHER: INTERMITTEND	Y-M: 20[redacted]-[redacted]

MESALAZINE	UNK OTHER: UNK	OTHER: INTERMITTEND	Y-M: 20[redacted]
AZATHIOPRINE	UNKNOWN mg	QD	Y-M: 20[redacted]
METHOTREXATE	25 mg	OTHER: WEEKLY	Y-M: 20[redacted]
INFLIXIMAB	5 mg/kg	OTHER: EVERY 8 WEEKS	Y-M: 20[redacted]
BUDESONIDE	9 mg	QD	Y-M: 20[redacted] / -73
COLECALCIFEROL	1000 IU	QD	Y-M: 20[redacted] / -73
BUDESONIDE	9 mg	QD	Y-M: 20[redacted] / -43
CIMICIFUGA RACEMOSA	1 OTHER: TABLET	QD	Y-M: 20[redacted] / -31
IBUPROFEN	400 mg	TID	Y-M: 20[redacted] / -22
NITROXOLINE	250 mg	TID	Y-M: 20[redacted] / -22
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted] / -22
TAMSULOSIN	0.4 mg	QD	Y-M: 20[redacted] / -22

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
COLECALCIFEROL	1000 IU	QD	Y-M: 20[redacted] / -73	ONGOING
BUDESONIDE	9 mg	QD	Y-M: 20[redacted] / -43	ONGOING
CIMICIFUGA RACEMOSA	1 OTHER: TABLET	QD	Y-M: 20[redacted] / -31	ONGOING
IBUPROFEN	400 mg	TID	Y-M: 20[redacted] / 75	Y-M: 20[redacted] / 80
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted] / 75	Y-M: 20[redacted] / 80
CEFPODOXIME	250 mg	BID	Y-M: 20[redacted] / 75	Y-M: 20[redacted] / 81

Event #1: Serious Adverse Event

Event Description NEPHROLITHIASIS

Preferred term 腎結石症

AE Onset Date / Rx Day [redacted]20[redacted] / 75 (15 DAYS AFTER LAST TREATMENT)

Age at AE Onset 4[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 75): Leukocytes: 16.52 [4.4 - 11.3] 10^3/uL; Potassium: 2.97 [3.5 - 5.1] mmol/L

Microbiology

Not reported

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 75): DOUBLE J CATHETER REIGHT WAS INJECTED: LITHOTRIPSY IS PLANED; LOW-DOSE CT WITHOUT CONTRAST AGENT: 4.5X3.0X7.2 MM CONCREMENTIN PROXIMAL URETER

AE Stopped Rx Day 76 (16 DAYS AFTER LAST TREATMENT)

Duration of AE	2 DAYS
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	UNKNOWN
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ドイツの治験責任医師からの報告。本被験者は 4[redacted] 歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，腎結石症の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，元喫煙者（1 日 7 本を 12 年間），クローン病（回腸・結腸，穿通型，肛門周囲瘻切除），胆嚢結石症，高コレステロール血症（リポ蛋白の増加），ニコチン乱用及び非飲酒者であった。

投与 75 日後，被験者は腎結石症を発現した。投与 76 日後，腎結石症は消失した。

本事象発現前の投与 21 日前，被験者は腎結石症を発現し，AER #[redacted] に報告された。また，投与 18 日後，被験者は膀胱炎（非重篤）を発現した。

投与 75 日後，被験者は重度の仙痛性疼痛及び悪心の急性発現のため入院した。投与 76 日後，右側にダブル J カテーテルが挿入された。投与 76 日後，被験者は退院した。投与 89 日後に砕石が予定された。

投与された薬剤は，nitroxoline，イブプロフェン，パントプラゾール及びセフポドキシムであった。

The patient's past medications include:

PREDNISOLONE for CROHNS DISEASE ([redacted] 20[redacted] - 20[redacted])

MESALAZINE for CROHNS DISEASE ([redacted] 20[redacted] - 20[redacted])

AZATHIOPRINE for CROHNS DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

METHOTREXAT for CROHNS DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

INFLIXIMAB for CROHNS DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

BUDESONIDE for CROHNS DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

IBUPROFEN for COLICKY PAIN ([redacted] 20[redacted] - [redacted] 20[redacted])

NITROXOLIN for NEPHROLITHIASIS ([redacted] 20[redacted] - [redacted] 20[redacted])

TAMSULOSIN for NEPHROLITHIASIS ([redacted] 20[redacted] - [redacted] 20[redacted])

MONURIL for CYSTITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Nephrolithiasis (10029148) (Nephrolithiasis (10029148)) [v.22.1] [10029148]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of NEPHROLITHIASIS

- Investigator: Unknown.

- AbbVie: Event is more likely related to prior event of nephrolithiasis, which occurred prior to first dose of study drug. Pre-existing Crohn's disease is an additional risk factor.

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] CT SCAN: LOW DOSE STONE.

[redacted] 20[redacted] LOW-DOSE CT WITHOUT CONTRAST AGENT: 4.5x3.0x7.2 mm concrementin proximal ureter

[redacted] **20[redacted] POTASSIUM:** 2.97 MMOL/L (normal 3.5 to 5.1)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 16.52 10^3/uL (normal 4.4 to 11.3)

ChangeHistory

On [redacted] 20[redacted], received updates to event information, suspect drug information, treatment drug information, laboratory/diagnostic procedures and narrative description.

On [redacted] 20[redacted], received updates to company alternative etiology, suspect drug information, laboratory/diagnostic procedures and narrative description.

Subject [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
食物アレルギー	X			

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 600 MG IV	2[redacted]	FEMALE	WHITE

Medical History	Onset Year
OTHER: NEURODERMATITIS	19[redacted]
CROHN'S DISEASE	20[redacted]
OTHER: ALLERGY BIRCH POLLEN	20[redacted]
OTHER: ALLERGY HOUSE DUST MITES	20[redacted]
OTHER: SKIN FUNGUS	20[redacted]
OTHER: ALLERGIC TO MUGWORT	20[redacted]
HYPOTHYROIDISM	20[redacted]
OTHER: ERYSIPELAS	20[redacted]
OTHER: ABCESS PERIANAL	20[redacted]
OTHER: PERIANAL ABCESS	20[redacted]
OTHER: PERIANAL FISTULA	20[redacted]
DEPRESSION: DEPRESSION	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE SURGICAL HISTORY: ABCESS INCISION	20[redacted]
CROHN'S DISEASE SURGICAL HISTORY: DRAINAGE OF FISTULA	20[redacted]
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
Risankizumab	600 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 57	57

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
AZATHIOPRINE	150 mg	QD	Y-M: 20[redacted]
PREDNISOLONE	UNKNOWN mg	QD	Y-M: 20[redacted]
INFLIXIMAB	300 mg/kg	OTHER: EVERY 8 WEEKS	Y-M: 20[redacted]
BUDESONIDE	6 mg	QD	Y-M: 20[redacted]
CERTOSTAT	1 OTHER: PILL	QD	Y-M: 20[redacted]
USTEKINUMAB	390 mg	OTHER: ONCE	Y-M: 20[redacted]
USTEKINUMAB	90 mg	OTHER: EVREY 8 WEEKS	Y-M: 20[redacted] / -330
PAROXETINE	10 mg	QD	Y-M: 20[redacted] / -151

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
CERTOSTAT	1 OTHER: PILL	QD	Y-M: 20[redacted]	ONGOING
PROPOFOL	UN mg	OTHER: ONE TIME	Y-M: 20[redacted] / 29	Y-M: 20[redacted] / 29
METAMIZOLE	4 g	OTHER: ON DEMAND	Y-M: 20[redacted] / 29	Y-M: 20[redacted] / 30
DIMETINDENE	4 mg	OTHER: ONCE	Y-M: 20[redacted] / 37	Y-M: 20[redacted] / 37
PREDNISOLONE	250 mg	OTHER: ONCE	Y-M: 20[redacted] / 37	Y-M: 20[redacted] / 37
RANITIDINE	50 mg	OTHER: ONCE	Y-M: 20[redacted] / 37	Y-M: 20[redacted] / 38
CETIRIZINE	10 mg	OTHER: DAILY	Y-M: 20[redacted] / 38	Y-M: 20[redacted] / 38
PREDNISOLONE	50 mg	OTHER: ONCE	Y-M: 20[redacted] / 38	Y-M: 20[redacted] / 38

Event #1: Serious Adverse Event

Event Description	ALLERGIC REACTION DUE TO MUSTARD PLANTS CELERY, SUBJECT HAS A TO MUSTARD PLANTS
Preferred term	食物アレルギー
AE Onset Date / Rx Day	[redacted]20[redacted] / 37
Age at AE Onset	2[redacted]

Laboratory Testing
Not reported
Microbiology
Not reported
SAE Supplemental Procedure
[redacted]20[redacted] (Rx Day 34): ECG: NORMAL

AE Stopped Rx Day	38
Duration of AE	2 DAYS
Severity	Moderate
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	SUBJECT ATE SOUP WITH CELERY AND GOT SWOLLEN LIPS, SUBJECT KNOWN ALLERGY TO MUGWORT. SUBJECT WENT TO THE HOSPITAL AND STAYED THERE FOR SURVEILLANCE.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ドイツの治験責任医師からの報告。本被験者は2[redacted]歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，青梗菜（チンゲンサイ）によるアレルギー反応（被験者はカラシナアレルギーがある）の事象を発現した。

Event 1 の臨床経過：
関連する病歴は，クローン病，甲状腺機能低下症，うつ病，非喫煙者及び現飲酒者（1 日 2 杯未満）であった。

投与 37 日後，被験者は青梗菜によるアレルギー反応（被験者はカラシナアレルギーがある）を発現した。投与 38 日後，青梗菜によるアレルギー反応（被験者はカラシナアレルギーがある）は消失した。

投与 37 日後，被験者は，青梗菜への口接触後の上下口唇及び舌の口囲腫脹，並びに顔面腫脹のため入院した。紅斑，膨疹，そう痒，循環障害及び息切れは認められなかった。救急治療室で被験者は覚醒しており，見当識があり，自立していた。被験者は観察目的で 1 晩入院した。投

与 38 日後，被験者は退院した。

リスク因子は既知のヨモギアレルギーであった。

投与された薬剤は，セチリジン，Ranitic，プレドニゾロン及び Histakut であった。

The patient’s past medications include:

INFLIXIMAB for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

BUDENOFALK for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

USTEKINUMAB for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Food allergy (10016946) (Food allergy (10016946)) [v.23.1] [10016946]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of ALLERGIC REACTION DUE TO MUSTARD PLANTS CELERY, SUBJECT HAS A TO MUSTARD PLANTS

- Investigator: SUBJECT ATE SOUP WITH CELERY AND GOT SWOLLEN LIPS, SUBJECT KNOWN ALLERGY TO MUGWORT. SUBJECT WENT TO THE HOSPITAL AND STAYED THERE FOR SURVEILLANCE.

- AbbVie: Risk factor includes known allergy to mugwort as reported by PI.

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] ECG: normal

Subject [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
強直性脊椎炎	X			

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 600 MG IV	5[redacted]	FEMALE	WHITE

Medical History	Onset Year
HYPOTHYROIDISM: DUE TO THYREODECTOMY	19[redacted]
OTHER: SARCOIDOSE	19[redacted]
ASTHMA	20[redacted]
OSTEOARTHRITIS	20[redacted]
OTHER: AXIAL ARTHROPATHY	20[redacted]
OTHER: MORBUS BECHTEREW	20[redacted]
OTHER: PERIPHERAL ARTHROPATHY	20[redacted]
CROHN'S DISEASE	20[redacted]
DIABETES MELLITUS: CORTISON INDUCED	20[redacted]

Prior Procedures	Procedure Year
SURGERY: THYREODECTOMY	19[redacted]
SURGERY: INGUEN HERNIA	20[redacted]
SURGERY: RESECTION EYELID TUMOR	20[redacted]
SURGERY: VAGINALE HYSTERECTOMY	20[redacted]
SURGERY: GASTRIC EXTIRPATION	20[redacted]
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
CROHN'S DISEASE SURGICAL HISTORY: BOWEL RESECTION	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CIGARETTES	CURRENT	10 CIGARETTE	30	Not reported.
CHEWING TOBACCO	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
Risankizumab	600 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 56	56

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
LEVOTHYROXINE	125 ug	QD	Y-M: 19[redacted]
ADALIMUMAB	160 mg	OTHER: ONCE	Y-M: 20[redacted]
ADALIMUMAB	40 mg	OTHER: ALL 2 WEEKS	Y-M: 20[redacted]
ADALIMUMAB	80 mg	OTHER: ONCE	Y-M: 20[redacted]
FENOTEROL W/IPRATROPIUM	1 OTHER: STROKE	QD	Y-M: 20[redacted]
METAMIZOLE	4 g	QD	Y-M: 20[redacted]
METHOTREXATE	UNKNOWN mg	OTHER: WEEKLY	Y-M: 20[redacted]
AZATHIOPRINE	50 mg	OTHER: ONCE	Y-M: 20[redacted]-[redacted]
PANTOPRAZOLE	40 mg	OTHER: AS NEEDED	Y-M: 20[redacted]
INFLIXIMAB	300 mg/kg	OTHER: ALL 8 WEEKS	Y-M: 20[redacted]
PLANTAGO OVATA	1-2 OTHER: TEASPOON	QD	Y-M: 20[redacted]
USTEKINUMAB	390 mg	OTHER: ONCE	Y-M: 20[redacted]-[redacted]
USTEKINUMAB	90 mg	OTHER: ALL 8 WEEKS	Y-M: 20[redacted]-[redacted]
PREDNISOLONE	20 mg	QD	Y-M: 20[redacted]-[redacted] / -105
PREDNISOLONE	60 mg	QD	Y-M: 20[redacted]-[redacted] / -103
PREDNISOLONE	60 mg	QD	Y-M: 20[redacted]-[redacted] / -102
PREDNISOLONE	50 mg	QD	Y-M: 20[redacted]-[redacted] / -97
PREDNISOLONE	40 mg	QD	Y-M: 20[redacted]-[redacted] / -91
PREDNISOLONE	40 mg	QD	Y-M: 20[redacted]-[redacted] / -40
PREDNISOLONE	30 mg	QD	Y-M: 20[redacted]-[redacted] / -24
PREDNISOLONE	20 mg	QD	Y-M: 20[redacted]-[redacted] / -17

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
LEVOTHYROXINE	125 ug	QD	Y-M: 19[redacted]	ONGOING
FENOTEROL W/IPRATROPIUM	1 OTHER: STROKE	QD	Y-M: 20[redacted]	ONGOING
METAMIZOLE	4 g	QD	Y-M: 20[redacted]	ONGOING
PANTOPRAZOLE	40 mg	OTHER: AS NEEDED	Y-M: 20[redacted]	ONGOING
PLANTAGO OVATA	1-2 OTHER: TEASPOON	QD	Y-M: 20[redacted]	ONGOING
PREDNISOLONE	20 mg	QD	Y-M: 20[redacted]-[redacted] / -17	Y-M: 20[redacted]-[redacted] / 88

VALORON N	50/4 mg	TID	Y-M: 20[redacted] / 39	Y-M: 20[redacted] / 44
ZOPICLONE	7,5 mg	OTHER: AS NEEDED	Y-M: 20[redacted] / 39	Y-M: 20[redacted] / 47

Event #1: Serious Adverse Event

Event Description	WORSENING MORBUS BECHTEREW
Preferred term	強直性脊椎炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 39
Age at AE Onset	5[redacted]
Laboratory Testing	
Not reported	
Microbiology	
Not reported	
SAE Supplemental Procedure	
[redacted]20[redacted] (Rx Day 23): MRT LUMBAR SPINE: NO FRACTURE	
AE Stopped Rx Day	44
Duration of AE	6 DAYS
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	THE SUBJECT HAD SEVERE PAIN IN THE ILEOSACRAL AREA AND WAS ADMITTED TO THE HOSPITAL IN UELZEN FOR FURTHER DIAGNOSIS. SUBJECT HAS RECEIVED NOVALGIN AND WAS DISCHARGED ON [redacted]. [redacted] 20[redacted] IN GOOD CONDITION
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ドイツの治験責任医師からの報告。本被験者は 5[redacted] 歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，強直性脊椎炎悪化の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，サルコイドーシス，強直性脊椎炎，変形性関節症，クローン病，コルチゾン誘発性糖尿病，喫煙者（1 日 10 本を 10 年間）及び飲酒者（1 日 2 杯未満）であった。

投与 39 日後，被験者は強直性脊椎炎悪化を発現した。投与 44 日後，強直性脊椎炎悪化は消失した。

被験者は数日間で中等度から重度に悪化した背部痛を発現した。投与 39 日後，被験者には仙腸部に重度の疼痛があり，追加診断のため入院した。投与の約 1 か月後，腰椎の MR が行われ，脊椎すべり症（骨折なし）が認められた。被験者は Novalgin の投与を受け，投与 44 日後に良好な状態で退院した。

投与された薬剤は，Novalgin であった。

The patient’s past medications include:

ADALIMUMAB for CROHN'S DISEASE (20[redacted] - 20[redacted], 201[redacted] - 20[redacted], 20[redacted] - 20[redacted])

AZATHIOPRIN for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

INFLIXIMAB for CROHN'S DISEASE (20[redacted] - [redacted] 20[redacted])

STELARA for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Spondylitis ankylosing aggravated (10048398) (Ankylosing spondylitis (10002556)) [v.22.1] [10048398]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of WORSENING MORBUS BECHTEREW

- Investigator: The subject had severe pain in the ileosacral area and was admitted to the hospital in Uelzen for further diagnosis. Subject has received Novalgin and was discharged on [redacted]. [redacted] 20[redacted] in good condition.

- AbbVie: Recurring flare of pre-existing morbus bechterew (Ankylosing spondylitis).

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] MRI: not reported

Subject [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
悪心	X			
嘔吐	X			

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 600 MG IV	5[redacted]	FEMALE	WHITE

Medical History	Onset Year
DRUG ABUSE: NICOTINE ABUSE	19[redacted]
CROHN'S DISEASE	20[redacted]
DEPRESSION: DEPRESSION	20[redacted]
LIVER DISEASE (EXCLUDING HEPATITIS): SEVERAL HEMANGIOMAS IN BOTH LIVER LOBES	20[redacted]
OTHER: GONARTHROSIS LEFT	20[redacted]
OTHER: HWS SYNDROME	20[redacted]
OTHER: POLYARTHROSIS	20[redacted]
OTHER: SIDE BRANCH IPMN OF THE PANCREAS	20[redacted]
OTHER: OSTEOPENIA	20[redacted]
OTHER: ABDOMINAL WALL HERNIA	20[redacted]
OTHER: NAUSEA	20[redacted]
GASTROESOPHAGEAL REFLUX DISEASE	20[redacted]
OTHER: PERIPHERAL ARTHROPATHY	20[redacted]
HYPERTENSION	20[redacted]
OTHER: INSOMNIA	20[redacted]
OTHER: PANCREATIC LIPOMATOSIS	20[redacted]
OTHER: GASTRITIS	20[redacted]

Prior Procedures	Procedure Year
SURGERY: APPENDECTOMY	19[redacted]
SURGERY: CHOLECYSTECTOMY	19[redacted]
SURGERY: MENISCUS SURGERY	20[redacted]
SURGERY: CRUCIATE LIGAMENT SURGERY	20[redacted]
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CIGARETTES	CURRENT	15 CIGARETTE	30	Not reported.
CHEWING TOBACCO	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)
Risankizumab	600 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 59	59

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
AZATHIOPRINE	UNK mg	QD	Y-M: 20[redacted]
SERTRALINE	100 mg	QD	Y-M: 20[redacted]
METHOTREXATE	25 mg	OTHER: 1QW	Y-M: 20[redacted]
METHOTREXATE	15 mg	OTHER: 1QW	Y-M: 20[redacted]
PREDNISOLONE	20 mg	QD	Y-M: 20[redacted]
INFLIXIMAB	5 mg	OTHER: 8QW	Y-M: 20[redacted]
ADALIMUMAB	160 mg	OTHER: EOW	Y-M: 20[redacted]
ADALIMUMAB	80 mg	OTHER: EOW	Y-M: 20[redacted]
ADALIMUMAB	40 mg	OTHER: EW	Y-M: 20[redacted]
BUDESONIDE	3 mg	TID	Y-M: 20[redacted]
BUDESONIDE	3 mg	BID	Y-M: 20[redacted]
AZATHIOPRINE	UNK mg	QD	Y-M: 20[redacted]
ADALIMUMAB	80 mg	OTHER: EOW	Y-M: 20[redacted]
ADALIMUMAB	40 mg	OTHER: EOW	Y-M: 20[redacted]
BUDESONIDE	3 mg	TID	Y-M: 20[redacted]
METAMIZOLE	500 mg	PRN	Y-M: 20[redacted]
METOCLOPRAMIDE	10 mg	QD	Y-M: 20[redacted]
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted]
BUPROPION	300 mg	QD	Y-M: 20[redacted]
VEDOLIZUMAB	300 mg	OTHER: Q8W	Y-M: 20[redacted]
ZOPICLONE	7,5 mg	PRN	Y-M: 20[redacted]
COLECALCIFEROL	0.50 mg	OTHER: WEEKLY	Y-M: 20[redacted]
CANDESARTAN	8 mg	QD	Y-M: 20[redacted] / -309
MOVIPREP	3350 mg	QD	Y-M: 20[redacted] / -9
RINGER-LACTATIS	1000 mL	QD	Y-M: 20[redacted] / -9
ENOXAPARIN	0,4 mL	QD	Y-M: 20[redacted] / -8
PANTOPRAZOLE	40 mg	BID	Y-M: 20[redacted] / -8
PROPOFOL	130 mg	OTHER: ONCE	Y-M: 20[redacted] / -8
PROPOFOL	320 mg	OTHER: ONCE	Y-M: 20[redacted] / -8

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
SERTRALINE	100 mg	QD	Y-M: 20[redacted]	ONGOING
METAMIZOLE	500 mg	PRN	Y-M: 20[redacted]	ONGOING
METOCLOPRAMIDE	10 mg	QD	Y-M: 20[redacted]	ONGOING
BUPROPION	300 mg	QD	Y-M: 20[redacted]	ONGOING
ZOPICLONE	7,5 mg	PRN	Y-M: 20[redacted]	ONGOING
COLECALCIFEROL	0.50 mg	OTHER: WEEKLY	Y-M: 20[redacted]	ONGOING
CANDESARTAN	8 mg	QD	Y-M: 20[redacted] / -309	ONGOING
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted] / 7	ONGOING
MOVIPREP	3350 mg	QD	Y-M: 20[redacted] / 79	Y-M: 20[redacted] / 80
PROPOFOL	320 mg	OTHER: ONCE	Y-M: 20[redacted] / 80	Y-M: 20[redacted] / 80

Event #1: Serious Adverse Event

Event Description	NAUSEA, VOMITTING
Preferred term	悪心
AE Onset Date / Rx Day	[redacted]20[redacted] / 79 (20 DAYS AFTER LAST TREATMENT)
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 79): Albumin: 40 [35 - 53] g/L; Basophils: 0.02 [0 - 0.1] Unit not reported; Basophils/Leukocytes: 0.3 [0.2 - 1.2] %; Calcium: 2.4 [2.1 - 2.6] mmol/L; Creatinine: 65 [45 - 84] umol/L; Eosinophils: 0.13 [0 - 0.3] Unit not reported; Eosinophils/Leukocytes: 1.6 [0 - 4.4] %; Ery. Mean Corpuscular Hemoglobin: 28.2 [27.5 - 33.2] pg; Ery. Mean Corpuscular Volume: 86.4 [80 - 96] fL; Erythrocytes: 4.5 [4.1 - 5.1] 10^12/L; Hematocrit: 0.39 [0.36 - 0.45] Unit not reported; Hemoglobin: 12.6 [12.3 - 15.3] g/dL; Leukocytes: 7.9 [4.4 - 11.3] 10^9/L; Lymphocytes: 1.9 [1.2 - 3.5] Unit not reported; Lymphocytes/Leukocytes: 23.7 [22.3 - 49.9] %; Monocytes: 0.8 [Not reported - 0.5] 10^9/L; Monocytes/Leukocytes: 9.4 [0.7 - 7.5] %; NPTST055-CALCULATED GFR: 89 [Not reported - Not reported] Unit not reported; NPTST100-FERRITIN: 230 [13 - 651] Unit not reported; NPTST101-FERRUM: 12.5 [5.8 - 34.5] umol/L; NPTST102-FERRUM SATURATION: 20 [16 - 45] %; NPTST115-GGT: 17 [Not reported - 40] U/L; NPTST153-LDH: 168 [Not reported - 250] U/L; NPTST167-MCHC: 32.6 [33.4 - 35.3] g/dL; NPTST177-MPV: 10.3 [6.8 - 10] fL; NPTST190-PARTIAL THROMBOPLASTIN TIME: 36 [26 - 36] sec; NPTST209-QUICK: 95 [70 - 130] %; NPTST215-RDW: 14.0 [Not reported - 15] %; NPTST222-RETICULOCYTE PRODUCTION INDEX: 0.8 [Not reported - Not reported] Unit not reported; NPTST224-RETICULOCYTES %: 1.24 [0.43 - 1.36] %; NPTST225-RETICULOCYTES ABS: 55.4 [17 - 70.1] 10^9/L; NPTST264-TRANSFERRIN: 2.5 [2 - 3.6] g/L; Neutrophils: 5.2 [1.3 - 6.7] Unit not reported; Neutrophils/Leukocytes: 65.0 [45.5 - 73.1] %; Platelets: 308 [150 - 450] Unit not reported; Potassium: 4.9 [3.4 - 4.5] mmol/L; Prothrombin Intl. Normalized Ratio: 1.0 [Not reported - Not reported] Unit not reported; Sodium: 139 [135 - 145] mmol/L; Thyrotropin: 2.620 [0.4 - 3.77] Unit not reported; [redacted]20[redacted] (Rx Day 81): Ery. Mean Corpuscular Hemoglobin: 28.6 [27.5 - 33.2] pg; Ery. Mean Corpuscular Volume: 83.7 [80 - 96] fL; Erythrocytes: 4.7 [4.1 - 5.1] Unit not reported; Hematocrit: 0.40 [0.36 - 0.45] Unit not reported; Hemoglobin: 13.6 [12.3 - 15.3] g/dL; Leukocytes: 9.2 [4.4 - 11.3] 10^9/L; NPTST167-MCHC: 34.1 [33.4 - 35.5] g/dL; NPTST177-MPV: 7.7 [6.8 - 10] fL; NPTST215-RDW: 14.4 [Not reported - 15] %; Platelets: 324 [150 - 450] Unit not reported

Microbiology

Not reported

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 58): COLOSCOPY: NORMAL FINDINGS - PROCTOSCOPY. SINGLE DIVERTICULA. CROHN'S ILEITIS TERMINALIS WITHOUT MACROSCOPIC SIGNS OF ACTIVITY IN THE VISUALIZED AREA (COLON).; GASTROSCOPY: LARGE AXIAL HERNIA. MUCOUS MEMBRANE ERYTHEMA IN THE CORPUS AND ANTRUM

AE Stopped Rx Day	80 (21 DAYS AFTER LAST TREATMENT)
Duration of AE	2 DAYS
Severity	Mild
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	INPATIENT DUE TO COMPLAINTS AORUND BOWEL PREP
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #2: Serious Adverse Event

Event Description	NAUSEA, VOMITTING
Preferred term	嘔吐
AE Onset Date / Rx Day	[redacted]20[redacted] / 79 (20 DAYS AFTER LAST TREATMENT)
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 79): Albumin: 40 [35 - 53] g/L; Basophils: 0.02 [0 - 0.1] Unit not reported; Basophils/Leukocytes: 0.3 [0.2 - 1.2] %; Calcium: 2.4 [2.1 - 2.6] mmol/L; Creatinine: 65 [45 - 84] umol/L; Eosinophils: 0.13 [0 - 0.3] Unit not reported; Eosinophils/Leukocytes: 1.6 [0 - 4.4] %; Ery. Mean Corpuscular Hemoglobin: 28.2 [27.5 - 33.2] pg; Ery. Mean Corpuscular Volume: 86.4 [80 - 96] fL; Erythrocytes: 4.5 [4.1 - 5.1] 10^12/L; Hematocrit: 0.39 [0.36 - 0.45] Unit not reported; Hemoglobin: 12.6 [12.3 - 15.3] g/dL; Leukocytes: 7.9 [4.4 - 11.3] 10^9/L; Lymphocytes: 1.9 [1.2 - 3.5] Unit not reported; Lymphocytes/Leukocytes: 23.7 [22.3 - 49.9] %; Monocytes: 0.8 [Not reported - 0.5] 10^9/L; Monocytes/Leukocytes: 9.4 [0.7 - 7.5] %; NPTST055-CALCULATED GFR: 89 [Not reported - Not reported] Unit not reported; NPTST100-FERRITIN: 230 [13 - 651] Unit not reported; NPTST101-FERRUM: 12.5 [5.8 - 34.5] umol/L; NPTST102-FERRUM SATURATION: 20 [16 - 45] %; NPTST115-GGT: 17 [Not reported - 40] U/L; NPTST153-LDH: 168 [Not reported - 250] U/L; NPTST167-MCHC: 32.6 [33.4 - 35.3] g/dL; NPTST177-MPV: 10.3 [6.8 - 10] fL; NPTST190-PARTIAL THROMBOPLASTIN TIME: 36 [26 - 36] sec; NPTST209-QUICK: 95 [70 - 130] %; NPTST215-RDW: 14.0 [Not reported - 15] %; NPTST222-RETICULOCYTE PRODUCTION INDEX: 0.8 [Not reported - Not reported] Unit not reported; NPTST224-RETICULOCYTES %: 1.24 [0.43 - 1.36] %; NPTST225-RETICULOCYTES ABS: 55.4 [17 - 70.1] 10^9/L; NPTST264-TRANSFERRIN: 2.5 [2 - 3.6] g/L; Neutrophils: 5.2 [1.3 - 6.7] Unit not reported; Neutrophils/Leukocytes: 65.0 [45.5 - 73.1] %; Platelets: 308 [150 - 450] Unit not reported; Potassium: 4.9 [3.4 - 4.5] mmol/L; Prothrombin Intl. Normalized Ratio: 1.0 [Not reported - Not reported] Unit not reported; Sodium: 139 [135 - 145] mmol/L; Thyrotropin: 2.620 [0.4 - 3.77] Unit not reported; [redacted]20[redacted] (Rx Day 81): Ery. Mean Corpuscular Hemoglobin: 28.6 [27.5 - 33.2] pg; Ery. Mean Corpuscular Volume: 83.7 [80 - 96] fL; Erythrocytes: 4.7 [4.1 - 5.1] Unit not reported; Hematocrit: 0.40 [0.36 - 0.45] Unit not reported; Hemoglobin: 13.6 [12.3 - 15.3] g/dL; Leukocytes: 9.2 [4.4 - 11.3] 10^9/L; NPTST167-MCHC: 34.1 [33.4 - 35.5] g/dL; NPTST177-MPV: 7.7 [6.8 - 10] fL; NPTST215-RDW: 14.4 [Not reported - 15] %; Platelets: 324 [150 - 450] Unit not reported

Microbiology

Not reported

SAE Supplemental Procedure
[redacted]20[redacted] (Rx Day 58): COLOSCOPY: NORMAL FINDINGS - PROCTOSCOPY. SINGLE DIVERTICULA. CROHN'S ILEITIS TERMINALIS WITHOUT MACROSCOPIC SIGNS OF ACTIVITY IN THE VISUALIZED AREA (COLON).; GASTROSCOPY: LARGE AXIAL HERNIA. MUCOUS MEMBRANE ERYTHEMA IN THE CORPUS AND ANTRUM

AE Stopped Rx Day	80 (21 DAYS AFTER LAST TREATMENT)
Duration of AE	2 DAYS
Severity	Mild
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	INPATIENT DUE TO COMPLAINTS AORUND BOWEL PREP
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ドイツの治験責任医師からの報告。本被験者は5[redacted]歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，悪心及び嘔吐の事象を発現した。

Event 1 及び 2 の臨床経過：

関連する病歴は，クローン病，悪心，喫煙者（1 日 15 本を 30 年間）及び非飲酒者であった。

投与 79 日後，被験者は悪心及び嘔吐を発現した。投与 80 日後，悪心及び嘔吐は消失した。

投与 79 日後，被験者は間欠性悪心及び腸管前処置時の嘔吐のため入院した。投与 81 日後，被験者は退院した。

Causality for RISANKIZUMAB (Blinded)

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1) Nausea (10028813) (Nausea (10028813)) [v.23.1] [10028813]

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

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

Dechallenge: Not Applicable

2) Vomiting (10047700) (Vomiting (10047700)) [v.23.1] [10047700]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of NAUSEA

- Investigator: Inpatient due to complaints around bowel prep.

- AbbVie: event is more likely related to reaction to bowel preparation as reported by PI, additional risk factor includes pre-existing history of crohn's disease and nausea.

Event of VOMITING

- Investigator: Inpatient due to complaints around bowel prep.

- AbbVie: event is more likely related to reaction to bowel preparation as reported by PI, additional risk factor includes pre-existing history of crohn's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CALCIUM:** 2.4 MMOL/L (normal 2.1 to 2.6)

[redacted] 20[redacted] CALCULATED GFR: 89 ML/Min

[redacted] **20[redacted] COLONOSCOPY:** Normal findings - proctoscopy. Single diverticula. Crohn's ileitis terminalis without macroscopic signs of activity in the visualized area (colon).

[redacted] **20[redacted] CREATININE:** 65 MCMOL/L (normal 45 to 84)

[redacted] **20[redacted] GASTROSCOPY:** Large axial hernia. Mucous membrane erythema in the corpus and antrum.

[redacted] **20[redacted] GGT:** 17 U/L (normal <40)

[redacted] 20[redacted] **HEMATOCRIT:** 0.39 L/L (normal 0.36 to 0.45)

[redacted] 20[redacted] **HEMATOCRIT:** 0.40 L/L (normal 0.36 to 0.45)

[redacted] 20[redacted] **HEMOGLOBIN:** 12.6 G/DL (normal 12.3 to 15.3)

[redacted] 20[redacted] **HEMOGLOBIN:** 13.6 G/DL (normal 12.3 to 15.3)

[redacted] 20[redacted] INTERNATIONAL NORMALIZED RATIO: 1.0 No units

[redacted] 20[redacted] **MCH:** 28.2 PG (normal 27.5 to 33.2)

[redacted] 20[redacted] **MCH:** 28.6 PG (normal 27.5 to 33.2)

[redacted] 20[redacted] **MCV:** 86.4 FL (normal 80.0 to 96.0)

[redacted] 20[redacted] **MCV:** 83.7 FL (normal 80.0 to 96.0)

[redacted] 20[redacted] **PLATELET COUNT:** 308 GIGA/L (normal 150 to 450)

[redacted] 20[redacted] **PLATELET COUNT:** 324 GIGA/L (normal 150 to 450)

[redacted] 20[redacted] **POTASSIUM:** 4.9 MMOL/L (normal 3.4 to 4.5)

[redacted] 20[redacted] **RED BLOOD CELLS:** 4.5 X10**12/L (normal 4.1 to 5.1)

[redacted] 20[redacted] **RED BLOOD CELLS:** 4.7 X10**12/L (normal 4.1 to 5.1)

[redacted] 20[redacted] **SODIUM:** 139 MMOL/L (normal 135 to 145)

[redacted] 20[redacted] **WHITE BLOOD CELLS:** 7.9 X10**9/L (normal 4.4 to 11.3)

[redacted] 20[redacted] **WHITE BLOOD CELLS:** 9.2 X10**9/L (normal 4.4 to 11.3)

Subject [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
末端回腸炎	X			

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 1200 MG IV / P2:RZB 1200 MG IV	5[redacted]	FEMALE	WHITE

Medical History	Onset Year
OTHER: AFTER APPENDECTOMIE	19[redacted]
CROHN'S DISEASE	19[redacted]
ANEMIA: MICROCYTIC HYPOCHROMIC ANEMIA	20[redacted]
OTHER: LEFT BUNDLE BRANCH BLOCK	20[redacted]
OTHER: MILD MITRAL INSUFFICIENCY	20[redacted]
OTHER: STOMATITIS	20[redacted]
OTHER: HYPOTHYREOSE	20[redacted]
OTHER: ILEOCECAL RESECTION	20[redacted]
OTHER: POSTMENOPAUSAL	20[redacted]
OTHER: HYPOKALEMIA	20[redacted]
OTHER: LIVER CYST 10MM	20[redacted]
OTHER: ARTHRITIS	20[redacted]
OTHER: BILE ACID LOSS SYNDROME	20[redacted]
OTHER: IRIDOCYCLITIS	20[redacted]
OTHER: VITAMIN D DEFICIENCY	20[redacted]
OTHER: ANASTOMOSITIS	20[redacted]
OTHER: ZINC DEFICIENCY	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE SURGICAL HISTORY: ILEOCECAL RESECTION	20[redacted]
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): BIOPSY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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)
Risankizumab	1200 mg	IV	Every 4 Weeks	[redacted] / 1	[redacted] / 57	57
Risankizumab	1200 mg	IV	Every 4 Weeks	[redacted] / 78	[redacted] / 155	78

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
AZATHIOPRINE	UNKNOWN OTHER: UNKNOWN	QD	Y-M: [redacted]
METHOTREXATE	20 mg	OTHER: UNKNOWN	Y-M: [redacted]
LEVOTHYROXINE	50 mg	QD	Y-M: [redacted]
INFLIXIMAB	UNKNOWN OTHER: UNKOWN	OTHER: UNKNOWN	Y-M: [redacted]
PROTHYRID	50 mg	QD	Y-M: [redacted]
ADALIMUMAB	90 mg	OTHER: EOW	Y-M: [redacted] / -221
PROPOFOL	250 mg	PRN	Y-M: [redacted] / -177
OSMOTICALLY ACTING LAXATIVES	UNKNOW OTHER: UNKNOW	BID	Y-M: [redacted] / -17
PROPOFOL	300 mg	QD	Y-M: [redacted] / -16

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
LEVOTHYROXINE	50 mg	QD	Y-M: [redacted]	Y-M: [redacted] / 153
PROTHYRID	50 mg	QD	Y-M: [redacted]	Y-M: [redacted] / 153
COLECALCIFEROL	UNKNOWN OTHER: I.E	QD	Y-M: [redacted] / 69	ONGOING
PREDNISOLONE	50 mg	QD	Y-M: [redacted] / 69	Y-M: [redacted] / 70
PREDNISONE	40 mg	QD	Y-M: [redacted] / 71	Y-M: [redacted] / 74
PREDNISONE	30 mg	QD	Y-M: [redacted] / 75	Y-M: [redacted] / 84
OSMOTICALLY ACTING LAXATIVES	UNKNOW OTHER: UNKNOWN	BID	Y-M: [redacted] / 77	Y-M: [redacted] / 78
PROPOFOL	380 mg	QD	Y-M: [redacted] / 78	Y-M: [redacted] / 78

PREDNISONE	10 mg	QD	Y-M: 20[redacted] / 85	Y-M: 20[redacted] / 91
PREDNISONE	5 mg	QD	Y-M: 20[redacted] / 92	Y-M: 20[redacted] / 98
METAMIZOLE	500 mg	PRN	Y-M: 20[redacted] / 117	Y-M: 20[redacted] / 118
METAMIZOLE	500 mg	PRN	Y-M: 20[redacted] / 131	Y-M: 20[redacted] / 138
LEVOTHYROXINE	100 ug	QD	Y-M: 20[redacted] / 154	ONGOING

Event #1: Serious Adverse Event

Event Description	INFLAMMATED NEOTERMINAL ILEUM
Preferred term	末端回腸炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 68
Age at AE Onset	5[redacted]

Laboratory Testing

Not reported

Microbiology

Not reported

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 55): ABDOMINAL SONOGRAPHY ABDOMINAL COMPUTED TOMOGRAPHY: LONGSEGMENT INFLAMMATED BOWEL WALL TERMINAL ILEUM, MINIMAL ASCITES, 2.5CM STENOSIS OF THE ANASTOMOSIS, ALSO INFLAMMATED KOLON BOWEL WALL ADDITIONAL FINDINGS: CT: NEPHROLITHIASIS (LEFT) & SONOGRAPHY: KIDNEY CYST (8 MM, LEFT)

AE Stopped Rx Day	157 (2 DAYS AFTER LAST TREATMENT)
Duration of AE	90 DAYS
Severity	Moderate
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	UNKNOWN
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ドイツの治験責任医師からの報告。本被験者は 5[redacted] 歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，回腸末端部炎の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，クローン病，甲状腺機能低下症，回盲部切除，吻合部炎，非喫煙者及び非飲酒者であった。

投与 68 日後，被験者は回腸末端部炎を発現した。投与 157 日後，回腸末端部炎は消失した。

投与 68 日後，被験者は右側腹痛のため入院した。CT スキャンが行われ，回腸末端部の腸壁に炎症が認められた。被験者は疼痛に対する治療を受けた。投与 70 日後，被験者は退院した。

治験責任医師は，回腸盲腸吻合の狭窄の既往を本事象に関連するリスク因子として報告した。

投与された薬剤は，Decortin であった。

The patient’s past medications include:

METHOTREXAT for CROHN'S DISEASE (20[redacted] - 20[redacted])

AZATHIOPRIN for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

REMICADE for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

IMRALDI for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Terminal ileitis (10043280) (Terminal ileitis (10043280)) [v.23.1] [10043280]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of INFLAMMATED NEOTERMINAL ILEUM

- Investigator: Unknown

- AbbVie: Event more likely related to pre-existing Crohn's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMINAL CT:** LONGSEGMENT INFLAMMATED BOWEL WALL TERMINAL ILEUM, MINIMAL ASCITES, 2.5CM STENOSIS OF THE ANASTOMOSIS, ALSO INFLAMMATED KOLON BOWEL WALL, NEPHROLITHIASIS (left)

[redacted] 20[redacted] ABDOMINAL ULTRASOUND: Kidney cyst

[redacted] 20[redacted] CHEMISTRY: Unknown results

[redacted] 20[redacted] HEMATOLOGY: Unknown results

[redacted] 20[redacted] INR: Unknown results

Subject [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
瘻孔	X	X		
全身性炎症反応症候群	X	X		

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 1200 MG IV	4[redacted]	FEMALE	WHITE

Medical History	Onset Year
OSTEOARTHRITIS: ONGOING IBD-ASSOCIATED ACTIVITY	Not reported.
OTHER: PERIPHERE ARTHROPATHIA	Not reported.
CROHN'S DISEASE	19[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE SURGICAL HISTORY: BOWEL RESECTION	20[redacted]
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CIGARETTES	CURRENT	8 CIGARETTE	11	Not reported.
CHEWING TOBACCO	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
Risankizumab	1200 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 57	57

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
ADALIMUMAB	40 mg	OTHER: EYERY 2 WEEKS	Y-M: 20[redacted]
USTEKINUMAB	90 mg	OTHER: EYERY 8 WEEKS	Y-M: 20[redacted]

HYOSCINE	20 mg	OTHER: COLONOSCOPY CO-MEDICATION	Y-M: 20[redacted] / -40
PROPOFOL	400 mg	OTHER: SEDATION COLONOSCOPY	Y-M: 20[redacted] / -40
CEFUROXIME	500 mg	BID	Y-M: 20[redacted] / -38
LEKOVIT CA	500 / 400 mg	BID	Y-M: 20[redacted] / -38
METAMIZOLE	2000 mg	OTHER: PERFUSOR	Y-M: 20[redacted] / -38
METRONIDAZOLE	1200 mg	TID	Y-M: 20[redacted] / -38
PREDNISOLONE	20 mg	QD	Y-M: 20[redacted] / -38
METAMIZOLE	500 mg	PRN	Y-M: 20[redacted] / -33
RAMIPRIL	2,5 mg	QD	Y-M: 20[redacted] / -3

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
LEKOVIT CA	500 / 400 mg	BID	Y-M: 20[redacted] / -38	ONGOING
PREDNISOLONE	20 mg	QD	Y-M: 20[redacted] / -38	ONGOING
METAMIZOLE	500 mg	PRN	Y-M: 20[redacted] / -33	ONGOING
RAMIPRIL	2,5 mg	QD	Y-M: 20[redacted] / -3	ONGOING
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted] / 3	ONGOING
GENTAMICIN	3 mg	TID	Y-M: 20[redacted] / 55	Y-M: 20[redacted] / 58
CEFTRIAXONE	2 g	QD	Y-M: 20[redacted] / 68	Y-M: 20[redacted] / 72
METRONIDAZOLE	500 mg	TID	Y-M: 20[redacted] / 68	Y-M: 20[redacted] / 72
METAMIZOLE	2,5 g	BID	Y-M: 20[redacted] / 68	Y-M: 20[redacted] / 85
PIRITRAMIDE	7,5 mg	PRN	Y-M: 20[redacted] / 74	Y-M: 20[redacted] / 78
PIP/TAZO	4 / 0,5 g	TID	Y-M: 20[redacted] / 74	Y-M: 20[redacted] / 83

Event #1: Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Event Description	BLIND ENDED FISTULA WITH BEGINNING SIRS
Preferred term	瘻孔
AE Onset Date / Rx Day	[redacted]20[redacted] / 68 (11 DAYS AFTER LAST TREATMENT)
Age at AE Onset	5[redacted]

Laboratory Testing

Not reported

Microbiology

Not reported

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 66): 24H-ECG: NORMAL 24H-ECG; CT ABDOMEN: FISTULA FROM SIGMA TO SMALL BOWEL, POSSIBLE ABSZESS IN THIS REGION; ECHOCARDIOGRAPHY: NORMAL FINDING; ILEOCECAL- AND SIGMARESECTION, PROTECTIVE ILEOSTOMA: ACTIVE CROHN'S DISEASE WITH LOCAL PURULENT PERITONITIS AND TRANSMURAL FISTULATING; ULTRASOUND: PATHOLOGICAL COCKADE LEFT ABDOMEN MIT SUBILEUS

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	Severe
Relation to Study Drug by Investigator	Reasonable Possibility
Investigator Alternative Etiology	Not reported
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Event #2: Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Event Description	BLIND ENDED FISTULA WITH BEGINNING SIRS
Preferred term	全身性炎症反応症候群
AE Onset Date / Rx Day	[redacted]20[redacted] / 68 (11 DAYS AFTER LAST TREATMENT)
Age at AE Onset	5[redacted]

Laboratory Testing

Not reported

Microbiology

Not reported

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 66): 24H-ECG: NORMAL 24H-ECG; CT ABDOMEN: FISTULA FROM SIGMA TO SMALL BOWEL, POSSIBLE ABSZESS IN THIS REGION; ECHOCARDIOGRAPHY: NORMAL FINDING; ILEOCECAL- AND SIGMARESECTION, PROTECTIVE ILEOSTOMA: ACTIVE CROHN'S DISEASE WITH LOCAL PURULENT PERITONITIS AND TRANSMURAL FISTULATING; ULTRASOUND: PATHOLOGICAL COCKADE LEFT ABDOMEN MIT SUBILEUS

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	Severe
Relation to Study Drug by Investigator	Reasonable Possibility
Investigator Alternative Etiology	Not reported
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ドイツの治験責任医師からの報告。本被験者は5[redacted]歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，初期 SIRS を伴う盲端瘻孔の事象を発現した。

Event 1 及び 2 の臨床経過：

関連する病歴は，クローン病，腸切除，末梢性関節障害，紙巻タバコ喫煙者（1 日 8 本を 11 年間），アルコール摂取（1 日 2 杯未満）及び IBD 関連活動であった。

投与 68 日後，被験者は初期 SIRS を伴う盲端瘻孔を発現した。

投与 68 日後，被験者はクローン病に関連する急性腹痛のため入院した。画像診断が行われ，S 状結腸から小腸に瘻孔が認められ，膿瘍の可能性があった。初回の抗生剤療法後，被験者は S 状結腸切除及び回盲部切除を受け，保護的回腸瘻造設が行われた。術後，被験者は活性及び貫壁性瘻孔を伴うクローン病，並びに局所性化膿性腹膜炎を含む、重症ではない全身性炎症反応症候群を発現した。被験者は抗生剤療法の継続目的で ICU に入院した。被験者の臨床反応及び身体の回復は良好であった。投与 90 日後，被験者は退院した。

被験者は本治験の参加を完全に中止した。

投与された薬剤は，Clont，セフトリアキソン，ピペラシリン／タゾバクタム，Dipidolor 及びメタミゾールであった。

The patient’s past medications include:

STELARA for CROHN'S DISEASE ([redacted]20[redacted] - [redacted]20[redacted])

HUMIRA for CROHN'S DISEASE ([redacted]20[redacted] - [redacted]20[redacted])

CEFUROXIM for SUBILEUS ([redacted]20[redacted] - [redacted]20[redacted])

METRONIDAZOLE for SUBILEUS ([redacted]20[redacted] - [redacted]20[redacted])

Causality for RISANKIZUMAB(Blinded)

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1) Fistula (10016717) (Fistula (10016717)) [v.23.0] [10016717]

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

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

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

2) SIRS (10062357) (Systemic inflammatory response syndrome (10051379)) [v.23.0] [10062357]

Causality as per reporter (Drug/Vaccine): 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 RISANKIZUMAB (Blinded)

Event of BLIND ENDED FISTULA WITH BEGINNING SIRS

- Investigator: Not applicable

- AbbVie: Risk factor for event includes pre-existing Crohn's disease and recent bowel resection surgery.

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] 24H-ECG: normal 24h-ECG

[redacted] **20[redacted] CT ABDOMEN:** Fistula from Sigma to small bowel, possible abscess in this region

[redacted] 20[redacted] ECHOCARDIOGRAPHY: Normal

[redacted] **20[redacted] ULTRASOUND:** pathological cockade left abdomen mit subileus

Subject [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
脊椎炎	X			

Treatment Group	Age at Study Start	Sex	Race
P1:PLACEBO / P2:RZB 1200 MG IV	5[redacted]	FEMALE	BLACK OR AFRICAN AMERICAN

Medical History	Onset Year
HYPERTENSION	Not reported.
OTHER: PSORIASIS	Not reported.
OTHER: VARICOSE VEINS	20[redacted]
OTHER: AXIAL ARTHROPATHY	20[redacted]
CROHN'S DISEASE	20[redacted]
OTHER: ESOPHAGITIS	20[redacted]
OTHER: SPONDYLOARTHRITIS	20[redacted]
OTHER: POST MENOPAUSAL STATUS	20[redacted]
TUBERCULOSIS: LATENT TB	20[redacted]
OTHER: ANXIETY	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): BIOPSY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CIGARETTES	FORMER	20 CIGARETTE	26	20[redacted]
CHEWING TOBACCO	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		IV	Every 4 Weeks	[redacted] / 1	[redacted] / 57	57
Risankizumab	1200 mg	IV	Every 4 Weeks	[redacted] / 85	[redacted] / 85	1

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
ATENOLOL	25 mg	QD	Y-M: [redacted]
HYDROCHLOROTHIAZIDE	25 mg	BID	Y-M: [redacted]
SPIRONOLACTONE	25 mg	QD	Y-M: [redacted]
LOSARTAN	50 mg	BID	Y-M: [redacted]
ALL OTHER THERAPEUTIC PRODUCTS	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: [redacted]
AZATHIOPRINE	50 mg	QD	Y-M: [redacted]
OMEPRAZOLE	20 mg	QD	Y-M: [redacted]
SULFASALAZINE	500 mg	QD	Y-M: [redacted]
ISONIAZID	300 mg	QD	Y-M: [redacted]
ADALIMUMAB	40 mg	OTHER: 15 / 15 DAYS	Y-M: [redacted]
BISACODYL	5 mg	QD	Y-M: [redacted] / -29
FENTANYL	0.07 mg	QD	Y-M: [redacted] / -28
MANNITOL	500 mL	QD	Y-M: [redacted] / -28
PROPOFOL	140 mg	OTHER: ONCE	Y-M: [redacted] / -28
CODEINE	30 mg	TID	Y-M: [redacted] / -8

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
ATENOLOL	25 mg	QD	Y-M: [redacted]	ONGOING
HYDROCHLOROTHIAZIDE	25 mg	BID	Y-M: [redacted]	ONGOING
SPIRONOLACTONE	25 mg	QD	Y-M: [redacted]	ONGOING
LOSARTAN	50 mg	BID	Y-M: [redacted]	ONGOING
AZATHIOPRINE	50 mg	QD	Y-M: [redacted]	ONGOING
OMEPRAZOLE	20 mg	QD	Y-M: [redacted]	ONGOING
SULFASALAZINE	500 mg	QD	Y-M: [redacted]	ONGOING
CALCIUM DOBESILATE	500 mg	QD	Y-M: [redacted] / 35	ONGOING
SOLPADEINE	500 mg	QID	Y-M: [redacted] / 57	Y-M: [redacted] / 62
TRAMADOL	100 mg	OTHER: ONCE	Y-M: [redacted] / 58	Y-M: [redacted] / 60
METAMIZOLE	500 mg	QID	Y-M: [redacted] / 58	Y-M: [redacted] / 62

Event #1: Serious Adverse Event

Event Description	SPONDYLITS WORSENING
Preferred term	脊椎炎
AE Onset Date / Rx Day	[redacted] / 57
Age at AE Onset	[redacted]
Laboratory Testing	
Not reported	
Microbiology	
Not reported	
SAE Supplemental Procedure	
Not reported	
AE Stopped Rx Day	60
Duration of AE	4 DAYS
Severity	Moderate
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	MEDICAL HISTORY
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ブラジルの治験責任医師からの報告。本被験者は [redacted] 歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，脊椎炎悪化の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，元喫煙者（1 日 20 本を 26 年間），クローン病，脊椎関節炎，高血圧及び非飲酒者であった。

投与 57 日後，被験者は脊椎炎悪化を発現した。投与 60 日後，脊椎炎悪化は消失した。

本事象発現前の投与から約 2 か月後，被験者は腹痛（非重篤）を発現した。

投与 58 日後，被験者はしばらくの間発現していた腹痛及び歩行制限のため入院した。被験者は鎮痛剤による治療を 48 時間受けた。投与 60 日後，被験者は退院した。

投与された薬剤は，dipyrone，paracetamol 及びコデイン，並びにトラマドールであった。

The patient’s past medications include:

ADALIMUMAB for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Spondylitis (10061371) (Spondylitis (10061371)) [v.23.1] [10061371]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of SPONDYLITS WORSENING

- Investigator: Medical history.

- AbbVie: Event is more likely related to pre-existing spondyloarthritis.

Subject [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
小腸閉塞	X			

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 600 MG IV	4[redacted]	FEMALE	WHITE

Medical History	Onset Year
CROHN'S DISEASE	20[redacted]
OTHER: ABDOMINAL PAIN & VOMITING - SMALL BOWEL OBSTRUCTIVE SYMPTOMS	20[redacted]
OTHER: SMALL BOWEL OBSTRUCTION	20[redacted]
OTHER: IRON DEFICIENCY	20[redacted]
DEPRESSION: ANXIETY AND DEPRESSION	20[redacted]

Prior Procedures	Procedure Year
SURGERY: CHOLECYSTECTOMY	19[redacted]
SURGERY: TONSILLECTOMY	19[redacted]
SURGERY: LETZ PROCEDURE	20[redacted]
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
SURGERY: LEFT HEMITHYROIDECTOMY	20[redacted]
SURGERY: BCC REMOVAL FROM FACE	20[redacted]
ENDOSCOPY (SCREENING): BIOPSY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CIGARETTES	FORMER	10 CIGARETTE	5	20[redacted]
CHEWING TOBACCO	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
Risankizumab	600 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 64	64

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
ADALIMUMAB	40 mg	OTHER: Q2W	Y-M: 20[redacted]
INFLIXIMAB	400 mg	OTHER: Q8W	Y-M: 20[redacted]
VEDOLIZUMAB	300 mg	OTHER: Q8W	Y-M: 20[redacted]
METHOTREXATE	20 mg	OTHER: ONCE A WEEK	Y-M: 20[redacted]
USTEKINUMAB	90 mg	OTHER: EVERY 4 WEEKS	Y-M: 20[redacted]
LEVOTHYROXINE	75 ug	QD	Y-M: 20[redacted]
SERTRALINE	50 mg	QD	Y-M: 20[redacted]
SULFASALAZINE	2.0 g	QD	Y-M: 20[redacted] / -197

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
LEVOTHYROXINE	75 ug	QD	Y-M: 20[redacted]	ONGOING
SERTRALINE	50 mg	QD	Y-M: 20[redacted]	ONGOING
I.V. SOLUTIONS	500 mL	OTHER: BOLUS	Y-M: 20[redacted] / 62	Y-M: 20[redacted] / 62
IRON	1000 mg	PRN	Y-M: 20[redacted] / 71	Y-M: 20[redacted] / 71
METOCLOPRAMIDE	10 OTHER: MG/ML	PRN	Y-M: 20[redacted] / 91	Y-M: 20[redacted] / 94
MORPHINE	10 mg	PRN	Y-M: 20[redacted] / 91	Y-M: 20[redacted] / 94
MORPHINE	5 mg	PRN	Y-M: 20[redacted] / 91	Y-M: 20[redacted] / 94
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted] / 91	Y-M: 20[redacted] / 94
PARACETAMOL	1 g	PRN	Y-M: 20[redacted] / 91	Y-M: 20[redacted] / 94
ENOXAPARIN	40 mg	QD	Y-M: 20[redacted] / 93	Y-M: 20[redacted] / 94
HYDROCORTISONE	100 mg	OTHER: QDS	Y-M: 20[redacted] / 93	Y-M: 20[redacted] / 94
PREDNISONE	50 mg	QD	Y-M: 20[redacted] / 94	ONGOING

Event #1: Serious Adverse Event

Event Description	SMALL BOWEL OBSTRUCTION
Preferred term	小腸閉塞
AE Onset Date / Rx Day	[redacted]20[redacted] / 91 (27 DAYS AFTER LAST TREATMENT)
Age at AE Onset	4[redacted]

Laboratory Testing
[redacted]20[redacted] (Rx Day 94): Alanine Aminotransferase: 160 [0 - 34] U/L; Albumin: 32 [35 - 50] g/L; Alkaline Phosphatase: 182 [30 - 110] U/L; Aspartate Aminotransferase: 50 [0 - 31] U/L; NPTST056-CALPROTECTIN: 350 [0 - 50] Unit not reported; NPTST070-CRP: 10 [0 - 5] mg/L; NPTST106-GAMMA GT: 147 [0 - 38] U/L; NPTST160-LYMPHOCYTES: 0.6 [1 - 4] 10^9/L; NPTST194-PHOSPHATE: 0.49 [0.75 - 1.5] mmol/L; NPTST268-URATE: 0.14 [0.15 - 0.45] mmol/L; NPTST269-UREA: 1.4 [2.1 - 7.1] mmol/L; NPTST271-UREA/CREAT: 24 [40 - 100] umol/L; Protein: 59 [60 - 80] g/L; Sodium: 137 [135 - 145] mmol/L

Microbiology
Not reported

SAE Supplemental Procedure
[redacted]20[redacted] (Rx Day 90): CT ABDOMEN: SMALL BOWEL OBSTRUCTION; NASOGASTRIC INTUBATION: NO RESULTS FROM THIS PROCEDURE, PARTICIPANT WAS KEPT NBM IF SURGERY WAS REQUIRED, NO SURGERY WAS DONE; XR ABDOMEN: NO SIGNIFICANT FAECAL LOADING. GAS BOWEL PATTERN UNREMARKABLE. BOWEL LOOPS ARE NON DISTENDED. NO CONCERNING OSSEOUS LESION.

AE Stopped Rx Day	94 (30 DAYS AFTER LAST TREATMENT)
Duration of AE	4 DAYS
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	CROHN'S DISEASE RELATED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

オーストラリアの治験責任医師からの報告。本被験者は 4[redacted] 歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，小腸閉塞の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，手術（胆嚢切除），クローン病，元喫煙者（1 日 10 本を 5 年間），腹痛及び嘔吐（小腸閉塞症状），小腸閉塞，手術（LETZ 法）及び飲酒者（1 日 2 杯未満）であった。

投与 91 日後，被験者は小腸閉塞を発現した。投与 94 日後，小腸閉塞は消失した。

投与 91 日後，被験者は仙痛性上腹部痛，筋痙攣，腹部膨満感，低血圧，少量の出血，悪心及び嘔吐のため入院した。経鼻胃管が留置され，低血圧に対して 500 mL の輸液のボーラス投与が

行われた。被験者は鎮痛剤及び制吐剤による治療を受けた。投与 92 日後，被験者は GI 管理目的で別の病院に転院した。投与 94 日後，被験者は退院した。

治験責任医師によると，被験者には小腸閉塞の病歴があった。

投与された薬剤は，prednisone，ヒドロコルチゾン，prednisone，メトクロプラミド，モルヒネ，パントプラゾール，paracetamol，paracetamol，オキシコドン，ナロキソン及び prednisone であった。

The patient’s past medications include:

ADALIMUMAB for CROHN'S DISEASE ([redacted])

INFLIXIMAB for CROHN'S DISEASE ([redacted])

VEDOLIZUMAB for CROHN'S DISEASE ([redacted])

METHOTREXATE for CROHN'S DISEASE ([redacted])

USTEKINUMAB for CROHN'S DISEASE ([redacted])

SULFASALAZINE for JOINT PAIN ([redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Small bowel obstruction (10041055) (Small intestinal obstruction (10041101)) [v.23.0] [10041055]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of SMALL BOWEL OBSTRUCTION

- Investigator: Crohn's Disease Related

- AbbVie: Risk factors include pre-existing Crohn's Disease and past history of small bowel obstruction.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMEN X-RAY:** No significant faecal loading. Gas bowel pattern unremarkable. Bowel loops are non-distended. No concerning osseous lesion.

[redacted] 20[redacted] ALANINE AMINOTRANSFERASE: 160 U/L (normal 0 to 34)

[redacted] **20[redacted] ALBUMIN:** 32 G/L (normal 35 to 50)

[redacted] 20[redacted] ALKALINE PHOSPHATASE: 182 U/L (normal 30 to 110)

[redacted] 20[redacted] ASPARTATE AMINOTRANSFERASE: 50 U/L (normal 0 to 31)

[redacted] **20[redacted] CALPROTECTIN:** 350 UG/G (normal 0 to 50)

[redacted] **20[redacted] CRP:** 10 MG/L (normal 0 to 5)

[redacted] **20[redacted] CT ABDOMEN:** small bowel obstruction

[redacted] **20[redacted] GAMMA GT:** 147 U/L (normal 0 to 38)

[redacted] **20[redacted] LYMPHOCYTES:** 0.6 X10**9/L (normal 1 to 4.0)

[redacted] **20[redacted] PHOSPHATE:** 0.49 MMOL/L (normal 0.75 to 1.5)

[redacted] **20[redacted] PROTEIN:** 59 G/L (normal 60 to 80)

[redacted] **20[redacted] SODIUM:** 137 MMOL/L (normal 135 to 145)

[redacted] **20[redacted] URATE:** 0.14 MMOL/L (normal 0.15 to 0.45)

[redacted] **20[redacted] UREA:** 1.4 MMOL/L (normal 2.1 to 7.1)

[redacted] 20[redacted] UREA/CREATININE RATIO: 24 umol/L (normal 40 to 100)

Subject [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			
嘔吐	X			

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 600 MG IV / P2:RZB 1200 MG IV	5[redacted]	MALE	WHITE

Medical History	Onset Year
OTHER: RENAL STONES	Not reported.
ASTHMA	19[redacted]
INFLAMMATORY BOWEL DISEASE: CROHN'S DISEASE	20[redacted]
OTHER: VITAMIN B12 DEFICIENCY	20[redacted]
CROHN'S DISEASE	20[redacted]
INFLAMMATORY BOWEL DISEASE: BOWEL OBSTRUCTION ABSCESS	20[redacted]
INFLAMMATORY BOWEL DISEASE: BOWEL RESECTION	20[redacted]
INFLAMMATORY BOWEL DISEASE: PERFORATED BOWEL	20[redacted]
OTHER: IRON DEFIENCY	20[redacted]
OTHER: SEPTICEMIA	20[redacted]
DEPRESSION	20[redacted]
OTHER: UMBILICAL HERNIA	20[redacted]
OTHER: ENTEROPATHIC ARTHRITIS	20[redacted]
HYPERTENSION	20[redacted]

Prior Procedures	Procedure Year
SURGERY: LEFT KNEE ARTHROSCOPIES X 2	Not reported.
SURGERY: RIGHT KNEE ARTHROSCOPIES X 3	Not reported.
SURGERY: VASECTOMY	Not reported.
CROHN'S DISEASE SURGICAL HISTORY: BOWEL RESECTION	20[redacted]
SURGERY: VASECTOMY	20[redacted]
SURGERY: MICRODISCECTOMY	20[redacted]
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): BIOPSY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CIGARETTES	FORMER	20 CIGARETTE	15	20[redacted]
CHEWING TOBACCO	NEVER			
CIGARS	NEVER			

E-CIGARETTES	NEVER
PIPES	NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
Risankizumab	600 mg	IV	Every 4 Weeks	[redacted] / 1	[redacted] / 57	57
Risankizumab	1200 mg	IV	Every 4 Weeks	[redacted] / 85	[redacted] / 141	57

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
CYANOCOBALAMIN	1000 OTHER: MCG/ML	PRN	Y-M: [redacted]
IRON	100 mg	PRN	Y-M: [redacted]
TELMISARTAN	40 mg	QD	Y-M: [redacted]
PREDNISOLONE	20 mg	QD	Y-M: [redacted] / -188
SULFASALAZINE	500 mg	QD	Y-M: [redacted] / -188
PREDNISOLONE	17.5 mg	QD	Y-M: [redacted] / -181
SULFASALAZINE	500 mg	BID	Y-M: [redacted] / -181
PREDNISOLONE	15 mg	QD	Y-M: [redacted] / -174
PREDNISOLONE	12.5 mg	QD	Y-M: [redacted] / -167
SULFASALAZINE	1 g	QD	Y-M: [redacted] / -167
SULFASALAZINE	500 mg	QD	Y-M: [redacted] / -167
PREDNISOLONE	10 mg	QD	Y-M: [redacted] / -160
SULFASALAZINE	1 g	BID	Y-M: [redacted] / -153
PREDNISOLONE	7.5 mg	QD	Y-M: [redacted] / -96
SULFASALAZINE	1.5 g	BID	Y-M: [redacted] / -96
PREDNISOLONE	5 mg	QD	Y-M: [redacted] / -82
PREDNISOLONE	2.5 mg	QD	Y-M: [redacted] / -54
FENTANYL	75 ug	OTHER: STAT	Y-M: [redacted] / -9
MIDAZOLAM	2.5 mg	OTHER: STAT	Y-M: [redacted] / -9
PROPOFOL	200 mg	OTHER: STAT	Y-M: [redacted] / -9

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
BCG Vaccine	Not reported.	Not reported.	Not reported.	Not reported.
TELMISARTAN	40 mg	QD	Y-M: [redacted]	ONGOING
SULFASALAZINE	1.5 g	BID	Y-M: [redacted] / -96	ONGOING

BENZATROPINE	1 mg	OTHER: STAT	Y-M: 20[redacted] / 104	Y-M: 20[redacted] / 104
DROPERIDOL	0.625 mg	OTHER: STAT	Y-M: 20[redacted] / 104	Y-M: 20[redacted] / 104
MORPHINE	2.5 mg	PRN	Y-M: 20[redacted] / 104	Y-M: 20[redacted] / 104
ONDANSETRON	4 mg	OTHER: STAT	Y-M: 20[redacted] / 104	Y-M: 20[redacted] / 104
OXYCODONE	5 mg	PRN	Y-M: 20[redacted] / 104	Y-M: 20[redacted] / 104
PANADEINE CO	500/30 mg	PRN	Y-M: 20[redacted] / 104	Y-M: 20[redacted] / 104
ONDANSETRON	4 mg	OTHER: ONCE	Y-M: 20[redacted] / 104	Y-M: 20[redacted] / 105
PARACETAMOL	1 g	PRN	Y-M: 20[redacted] / 104	Y-M: 20[redacted] / 105
CEFAZOLIN	2 g	OTHER: ONCE	Y-M: 20[redacted] / 105	Y-M: 20[redacted] / 105
DEXAMETHASONE	8 mg	OTHER: ONCE	Y-M: 20[redacted] / 105	Y-M: 20[redacted] / 105
FENTANYL	50 ug	OTHER: ONCE	Y-M: 20[redacted] / 105	Y-M: 20[redacted] / 105
MIDAZOLAM	2 mg	OTHER: ONCE	Y-M: 20[redacted] / 105	Y-M: 20[redacted] / 105
OXYCODONE	2 mg	OTHER: ONCE	Y-M: 20[redacted] / 105	Y-M: 20[redacted] / 105
OXYCODONE	3 mg	PRN	Y-M: 20[redacted] / 105	Y-M: 20[redacted] / 105
PROPOFOL	160 mg	OTHER: ONCE	Y-M: 20[redacted] / 105	Y-M: 20[redacted] / 105
SODIUM LACTATE	1 L	PRN	Y-M: 20[redacted] / 105	Y-M: 20[redacted] / 105
SODIUM BICARBONATE	1 OTHER: SACHET	PRN	Y-M: 20[redacted] / 105	Y-M: 20[redacted] / 110
INDOMETACIN	100 mg	OTHER: ONCE	Y-M: 20[redacted] / 110	Y-M: 20[redacted] / 110
ONDANSETRON	4 mg	PRN	Y-M: 20[redacted] / 111	Y-M: 20[redacted] / 111
SODIUM CHLORIDE	1000 mL	OTHER: ONCE	Y-M: 20[redacted] / 111	Y-M: 20[redacted] / 111
PROCHLORPERAZINE	5 mg	PRN	Y-M: 20[redacted] / 111	Y-M: 20[redacted] / 112

Event #1: Serious Adverse Event

Event Description	LEFT SIDED URETERIC CALCULI
Preferred term	尿管結石症
AE Onset Date / Rx Day	[redacted]20[redacted] / 104

Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 104): Alanine Aminotransferase: 30 [5 - 40] IU/L; Albumin: 38 [34 - 47] g/L; Alkaline Phosphatase: 68 [30 - 110] IU/L; Basophils: 0.09 [0.02 - 0.1] 10^9/L; Bilirubin: 14 [0 - 20] umol/L; C Reactive Protein: 8.2 [Not reported - 5] mg/L; Chloride: 106 [95 - 110] mmol/L; Creatinine: 188 [60 - 110] umol/L; Eosinophils: 0.06 [0.02 - 0.5] 10^9/L; Ery. Mean Corpuscular Hemoglobin: 29.6 [27 - 32] pg; Ery. Mean Corpuscular Volume: 85 [83 - 101] fL; Erythrocytes: 4.79 [4.5 - 5.5] 10^12/L; Hematocrit: 0.41 [0.4 - 0.5] L/L; Hemoglobin: 142 [130 - 170] g/L; Leukocytes: 9.5 [4 - 10] 10^9/L; Lipase: 152 [13 - 60] IU/L; Lymphocytes: 1.24 [1 - 3] 10^9/L; Monocytes: 0.75 [0.2 - 1] 10^9/L; NPTST013-ANION GAP: 16 [7 - 17] mmol/L; NPTST040-BICARBONATE: 22 [22 - 32] mmol/L; NPTST083-EGFR: 35 [90 - Not reported] Unit not reported; NPTST115-GGT: 35 [10 - 71] IU/L; NPTST167-MCHC: 351 [315 - 360] g/L; NPTST269-UREA: 6.8 [2.8 - 8.1] mmol/L; Neutrophils: 7.40 [2 - 7] 10^9/L; Platelets: 217 [150 - 410] 10^9/L; Potassium: 4.4 [3.5 - 5.2] mmol/L; Protein: 66 [60 - 80] g/L; Sodium: 139 [135 - 145] mmol/L

Microbiology

Not reported

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 74): KUB CT (NON CONTRAST): HIGH-GRADE HYDROURETERONEPHROSIS OF THE LEFT KIDNEY DUE TO MULTIPLE CALCULI (2 5MM CALCULI IN DISTAL URETER AND A 1MM CALCULI IN THE PROXIMAL URETER. INFLAMMATORY CHANGES OF THE LEFT KIDNEY WITH ENLARGEMENT. HEPATOSTEATOSIS IS PRESENT. UNCOMPLICATED CHOLELITHIASIS.; KUB X-RAY: MULTIPLE URETERIC STONES ON THE LEFT SIDE.; [redacted]20[redacted] (Rx Day 105): LEFT URETHROSCOPY, STONE LASER, RGP, JJ STENT: ALL URETERIC CALCULI REMOVED SUCCESSFULLY.

AE Stopped Rx Day	106
Duration of AE	3 DAYS
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	UNKNOWN
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Event #2: Serious Adverse Event

Event Description	HYPEREMESIS
Preferred term	嘔吐
AE Onset Date / Rx Day	[redacted]20[redacted] / 110
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 110): Alanine Aminotransferase: 18 [5 - 40] IU/L; Albumin: 35 [34 - 47] g/L; Alkaline Phosphatase: 73 [30 - 110] IU/L; Basophils: 0.10 [0.02 - 0.1] 10^9/L; Bilirubin: 5 [0 - 20] umol/L; C Reactive Protein: 17.2 [Not reported - 5] mg/L; Chloride: 105 [95 - 110] mmol/L; Creatinine: 160 [60 - 110] umol/L; Eosinophils: 0.28 [0.02 - 0.5] 10^9/L; Ery. Mean Corpuscular Hemoglobin: 29.7 [27 - 32] pg; Ery. Mean Corpuscular Volume: 86 [83 - 101] fL; Erythrocytes: 4.71 [4.5 - 5.5] 10^12/L; Erythrocytes: >1000 [Not reported - 10] Unit not reported; Hematocrit: 0.41 [0.4 - 0.5] L/L; Hemoglobin: 140 [130 - 170] g/L; Leukocytes: 8.7 [4 - 10] 10^9/L; Leukocytes: 120 [Not reported - 10] Unit not reported; Lymphocytes: 1.46 [1 - 3] 10^9/L; Monocytes: 0.79 [0.2 - 1] 10^9/L; NPTST013-ANION GAP: 14 [7 - 17] mmol/L; NPTST040-BICARBONATE: 26 [22 - 32] mmol/L; NPTST083-EGFR: 42 [90 - Not reported] Unit not reported;

NPTST115-GGT: 51 [10 - 71] IU/L; NPTST167-MCHC: 346 [315 - 360] g/L; NPTST269-UREA: 5.3 [2.8 - 8.1] mmol/L; Neutrophils: 6.05 [2 - 7] 10^9/L; Platelets: 255 [150 - 410] 10^9/L; Potassium: 4.2 [3.5 - 5.2] mmol/L; Protein: 64 [60 - 80] g/L; Sodium: 141 [135 - 145] mmol/L; pH: 5.5 [Not reported - Not reported] Unit not reported; [redacted]20[redacted] (Rx Day 111): Basophils: 0.07 [0.02 - 0.1] 10^9/L; Chloride: 109 [95 - 110] mmol/L; Creatinine: 142 [60 - 110] umol/L; Eosinophils: 0.13 [0.02 - 0.5] 10^9/L; Ery. Mean Corpuscular Hemoglobin: 29.8 [27 - 32] pg; Ery. Mean Corpuscular Volume: 85 [83 - 101] fL; Erythrocytes: 4.53 [4.5 - 5.5] 10^12/L; Hematocrit: 0.39 [0.4 - 0.5] L/L; Hemoglobin: 135 [130 - 170] g/L; Leukocytes: 7.6 [4 - 10] 10^9/L; Lymphocytes: 1.32 [1 - 3] 10^9/L; Monocytes: 0.62 [0.2 - 1] 10^9/L; NPTST013-ANION GAP: 16 [7 - 17] mmol/L; NPTST040-BICARBONATE: 24 [22 - 32] mmol/L; NPTST083-EGFR: 49 [90 - Not reported] Unit not reported; NPTST167-MCHC: 350 [315 - 360] g/L; NPTST269-UREA: 5.4 [2.8 - 8.1] mmol/L; Neutrophils: 5.49 [2 - 7] 10^9/L; Platelets: 255 [150 - 410] 10^9/L; Potassium: 4.7 [3.5 - 5.2] mmol/L; Sodium: 144 [135 - 145] mmol/L

Microbiology

[redacted]20[redacted] (Rx Day 110): URINE NPTST279-URINE MICROSCOPY/CULTURE: NEGATIVE

SAE Supplemental Procedure

Not reported

AE Stopped Rx Day	111
Duration of AE	2 DAYS
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	PERIPHERAL VERTIGO
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

オーストラリアの治験責任医師からの報告。本被験者は5[redacted]歳男性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，左側尿管結石の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，クローン病（L3），腸閉塞性膿瘍，腸管穿孔，元喫煙者（1 日 20 本を 15 年間），高血圧，腎結石及び飲酒者（1 日 2 杯未満）であった。

本治験では，Week 12 の開始時に，被験者は盲検性を維持する目的で盲検化された IV 製剤及び盲検化された皮下製剤の投与を受ける予定である。

投与 103 日後，被験者は左側尿管結石を発現した。投与 106 日後，左側尿管結石は消失した。

投与 104 日後，被験者は下痢を伴う左下腹部の腹痛及び悪心のため救急科を受診した。嘔吐は認められず，発熱及び呼吸器症状はなかった。被験者の疼痛は 8/10 であり，本質的には持続的な筋痙攣であった。自宅で単純な鎮痛療法が行われたが，効果はなかった。同日，被験者は入院した。腎臓，尿管及び膀胱の X 線及び CT スキャンが行われた。被験者は左側尿管結石（3 つ）と診断された。その後被験者は泌尿器科医のいる別の病院に転院した。投与 106 日後，被験者は退院した。投与 111 日後に泌尿器学的レビューが行われるまで結石はそのままの状態とされた。同月，JJ ステントの留置に成功し，尿管結石は除去された。

投与された薬剤は，モルヒネ，paracetamol，オキシコドン，デキサメタゾン，オンダンセトロン，ドロペリドール及び Panadeine Forte であった。

The patient’s past medications include:

PREDNISOLONE for CROHN'S DISEASE ([redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Ureteric calculus (10046390) (Ureterolithiasis (10077989)) [v.23.0] [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 RISANKIZUMAB (Blinded)

Event of LEFT SIDED URETERIC CALCULI

- Investigator: Unknown

- **AbbVie:** Risk factors include pre-existing renal stones. In addition, 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.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CREATININE:** 188 MCMOL/L (normal 60 to 110)

[redacted] **20[redacted] EGFR:** 35 ML/MIN/1.73M2 (normal >90)

[redacted] 20[redacted] HIGH-SENSITIVITY C REACTIVE PROTEIN: 8.2 MG/L (normal <5.0)

[redacted] **20[redacted] KUB CT (NON CONTRAST):** High-grade hydroureteronephrosis of the left kidney due to multiple calculi (2 5mm calculi in distal ureter and a 1mm calculi in the proximal ureter. Inflammatory changes of the left kidney with enlargement. Hepatosteatosis is present. Uncomplicated cholelithiasis.

[redacted] **20[redacted] KUB X-RAY:** Multiple ureteric stones on the left side.

[redacted] **20[redacted] LIPASE:** 152 IU/L (normal 13 to 60)

[redacted] **20[redacted] NEUTROPHILS ABS:** 7.40 X10**9/L (normal 2.00 to 7.00)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 9.5 X10**9/L (normal 4.0 to 10.0)

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

オーストラリアの治験責任医師からの報告。本被験者は 5[redacted] 歳男性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，悪阻の事象を発現した。

Event 2 の臨床経過：

関連する病歴は，腸切除，クローン病，腸閉塞，腸切除，腸管穿孔，元喫煙者（1 日 1 箱を 15 年間），臍ヘルニア，高血圧及び飲酒者（1 日 2 杯未満）であった。

本治験では，Week 12 の開始時に，被験者は盲検性を維持する目的で盲検化された IV 製剤及び盲検化された皮下製剤の投与を受ける予定である。

投与 110 日後，被験者は悪阻を発現した。投与 111 日後，悪阻は消失した。

本事象発現前の投与 104 日後から投与 106 日後まで，被験者は左側尿管結石（重篤：AER#[redacted]）を発現した。投与 105 日後，尿管ステントが留置された。

投与 110 日後，被験者は 6/10 の側腹部痛のため救急治療室を受診した。被験者は鎮痛剤による治療を受け，帰宅した。自宅で，被験者は嘔吐（発作 10 回）を伴う重度の悪心を発現した。

被験者は再度救急治療室を受診した。嘔吐量は少なく，内容物は透明／黄色であり，出血はなかった。被験者には側腹部痛がなかった。その他の身体的診察の結果は正常であった。被験者は 1 晩入院し，IV 補液及び制吐剤の投与を受けた。投与 111 日後，被験者は安定した状態で退院し，尿管ステントの予定除去のため泌尿器科医による経過観察となった。

投与された薬剤は，オンダンセトロン，インドメタシン，Ural 及びオンダンセトロンであった。

The patient's past medications include:

PREDNISOLONE for CROHN'S DISEASE ([redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Hyperemesis (10020613) (Vomiting (10047700)) [v.23.0] [10020613]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of HYPEREMESIS

- **Investigator:** Peripheral vertigo

- **AbbVie:** Risk factors include recent ureteral stone with a ureteric stent placement and peripheral vertigo as noted by PI

Relevant Laboratory & Other Diagnostic Tests

[redacted] ALKALINE PHOSPHATASE: 73 IU/L (normal 30 to 110)

[redacted] **ALT:** 18 IU/L (normal 5 to 40)

[redacted] **20[redacted] ANION GAP:** 14 MMOL/L (normal 7 to 17)

[redacted] **20[redacted] ANION GAP:** 16 MMOL/L (normal 7 to 17)

[redacted] **20[redacted] BICARBONATE:** 26 MMOL/L (normal 22 to 32)

[redacted] **20[redacted] BILIRUBIN:** 5 MCMOL/L (normal 2 to 20)

[redacted] **20[redacted] GGT:** 51 IU/L (normal 10 to 71)

[redacted] **20[redacted] HEMATOCRIT:** 0.41 L/L (normal 0.40 to 0.5)

[redacted] **20[redacted] HEMOGLOBIN:** 140 G/L (normal 130 to 170)

[redacted] 20[redacted] HIGH-SENSITIVITY C REACTIVE PROTEIN: 17.2 MG/L (normal 0 to 5)

[redacted] **20[redacted] PLT:** 255 X10**9/L (normal 150 to 410)

[redacted] **20[redacted] POTASSIUM:** 4.2 MMOL/L (normal 3.5 to 4.5)

[redacted] **20[redacted] SODIUM:** 141 MMOL/L (normal 135 to 145)

[redacted] 20[redacted] URINE MICROSCOPY/CULTURE: negative

[redacted] 20[redacted] URINE MICROSCOPY/CULTURE: negative

[redacted] **20[redacted] URINE RBC:** >1000 x10**6/L (normal 0 to 10)

[redacted] **20[redacted] URINE WBC:** 120 x10**6/L (normal 0 to 10)

[redacted] **20[redacted] WBC:** 8.7 X10**9/L (normal 4 to 10)

Subject [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
大腸穿孔	X			

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 1200 MG IV	2[redacted]	FEMALE	WHITE

Medical History	Onset Year
PANCREATITIS: PANCREATITIS SECONDARY TO PENTASA, AZATHIOPRINE AND 6-MP.	Not reported.
ANEMIA: LOW HAEMAGLOBIN INTERMITTENTLY	20[redacted]
CROHN'S DISEASE	20[redacted]
OTHER: VAGINAL THRUSH	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): BIOPSY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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	CURRENT	2 - 4

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
Risankizumab	1200 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 57	57

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
MERCAPTOPURINE	Not reported.	Not reported.	Y-M: 20[redacted]
AZATHIOPRINE	Not reported.	Not reported.	Y-M: 20[redacted]
MESALAZINE	Not reported.	Not reported.	Y-M: 20[redacted]

METRONIDAZOLE	Not reported.	Not reported.	Y-M: 20[redacted]
HYDROCORTISONE	Not reported.	Not reported.	Y-M: 20[redacted]
METHOTREXATE	Not reported.	Not reported.	Y-M: 20[redacted]
ADALIMUMAB	Not reported.	Not reported.	Y-M: 20[redacted]
ADALIMUMAB	160 mg	Not reported.	Y-M: 20[redacted]
ADALIMUMAB	40 mg	Not reported.	Y-M: 20[redacted]
PREDNISONE	Not reported.	Not reported.	Y-M: 20[redacted]
INFLIXIMAB	300 mg	Not reported.	Y-M: 20[redacted]
INFLIXIMAB	Not reported.	Not reported.	Y-M: 20[redacted]
LEVONORGESTREL	14 ug	OTHER: PER 24 HRS	Y-M: 20[redacted]
ETROLIZUMAB	105 mg	Not reported.	Y-M: 20[redacted]
ETROLIZUMAB	Not reported.	Not reported.	Y-M: 20[redacted]
ADALIMUMAB	80 mg	Not reported.	Y-M: 20[redacted] / -210
FISH OIL	2 OTHER: CAPSULES	QD	Y-M: 20[redacted] / -111
PROBIOTICS	2 OTHER: CAPSULES	QD	Y-M: 20[redacted] / -111
CLOTRIMAZOLE	1 OTHER: APPLICATION	QD	Y-M: 20[redacted] / -17
FENTANYL	100 ug	OTHER: ONCE ONLY	Y-M: 20[redacted] / -10
MIDAZOLAM	7 mg	OTHER: ONCE ONLY	Y-M: 20[redacted] / -10

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
PREDNISONE	Not reported.	Not reported.	Y-M: 20[redacted]	ONGOING
LEVONORGESTREL	14 ug	OTHER: PER 24 HRS	Y-M: 20[redacted]	ONGOING
FISH OIL	2 OTHER: CAPSULES	QD	Y-M: 20[redacted] / -111	ONGOING
PROBIOTICS	2 OTHER: CAPSULES	QD	Y-M: 20[redacted] / -111	ONGOING
PARACETAMOL	1 g	PRN	Y-M: 20[redacted] / 5	ONGOING
FENTANYL	150 ug	OTHER: ONCE ONLY	Y-M: 20[redacted] / 90	Y-M: 20[redacted] / 90
MIDAZOLAM	7 mg	OTHER: ONCE ONLY	Y-M: 20[redacted] / 90	Y-M: 20[redacted] / 90
HYDROCORTISONE	50 mg	QD	Y-M: 20[redacted] / 90	Y-M: 20[redacted] / 91
MOVICOL	13.8 g	QD	Y-M: 20[redacted] / 91	ONGOING
ENOXAPARIN	20 mg	QD	Y-M: 20[redacted] / 91	Y-M: 20[redacted] / 91
GENTAMICIN	350 mg	QD	Y-M: 20[redacted] / 91	Y-M: 20[redacted] / 91
METRONIDAZOLE	500 mg	OTHER: ONCE ONLY	Y-M: 20[redacted] / 91	Y-M: 20[redacted] / 91

PARACETAMOL	1 g	OTHER: ONCE ONLY	Y-M: 20[redacted]-[redacted] / 91	Y-M: 20[redacted]-[redacted] / 91
PIPERACILLIN W/TAZOBACTAM	4.5 g	OTHER: 8 HOURLY	Y-M: 20[redacted]-[redacted] / 91	Y-M: 20[redacted]-[redacted] / 93
HYDROCORTISONE	100 mg	QD	Y-M: 20[redacted]-[redacted] / 92	Y-M: 20[redacted]-[redacted] / 93
HYDROCORTISONE	50 mg	QD	Y-M: 20[redacted]-[redacted] / 93	Y-M: 20[redacted]-[redacted] / 93
AUGMENTIN	625 mg	TID	Y-M: 20[redacted]-[redacted] / 94	ONGOING

Event #1: Serious Adverse Event

Event Description	LOCALISED PERFORATION IN CAECAL REGION
Preferred term	大腸穿孔
AE Onset Date / Rx Day	[redacted]20[redacted] / 90 (33 DAYS AFTER LAST TREATMENT)
Age at AE Onset	2[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 90): Albumin: 30 [32 - 48] g/L; C Reactive Protein: 22 [Not reported - 5] mg/L; Hematocrit: 0.28 [0.35 - 0.46] RATIO; Hemoglobin: 92 [115 - 155] g/L; Leukocytes: 22.0 [4 - 11] 10^9/L; Lymphocytes: 0.6 [1 - 4] 10^9/L; Monocytes: 0.18 [0.2 - 1] 10^9/L; NPTST149-LACTATE: 2.1 [0.5 - 2] mmol/L; NPTST171-META/MYELOCYTES: 0.11 [0 - 0.06] 10^9/L; NPTST199-POTASSIUM - ARTERIAL: 2.6 [3.5 - 5.2] mmol/L; NPTST260-TOTAL HAEMAGLOBIN - ARTERIAL: 94 [115 - 155] g/L; Neutrophils: 21.0 [1.9 - 7.5] 10^9/L; Platelets: 559 [150 - 400] 10^9/L; Potassium: 2.5 [3.5 - 5.2] mmol/L; Sodium: 134 [135 - 145] mmol/L; [redacted]20[redacted] (Rx Day 91): Albumin: 26 [32 - 48] g/L; Blood Urea Nitrogen: 1.8 [3.2 - 7.7] mmol/L; C Reactive Protein: 108 [0 - 5] mg/L; Hematocrit: 0.27 [0.35 - 0.46] RATIO; Hemoglobin: 86 [115 - 155] g/L; Leukocytes: 19.3 [4 - 11] 10^9/L; Lymphocytes: 0.37 [1 - 4] 10^9/L; NPTST171-META/MYELOCYTES: 0.14 [0 - 0.06] 10^9/L; Neutrophils: 18.3 [1.9 - 7.5] 10^9/L; Platelets: 521 [150 - 400] 10^9/L; Potassium: 5.0 [3.5 - 5.2] mmol/L; Protein: 60 [64 - 83] g/L; [redacted]20[redacted] (Rx Day 92): Albumin: 23 [32 - 48] g/L; Blood Urea Nitrogen: 2.3 [3.2 - 7.7] mmol/L; C Reactive Protein: 60 [0 - 5] mg/L; Hematocrit: 0.25 [0.35 - 0.46] fraction of 1; Hemoglobin: 79 [115 - 155] g/L; NPTST182-NUCLEATED RED BLOOD CELLS: 0.02 [Not reported - Not reported] 10^9/L; Platelets: 469 [150 - 400] 10^9/L

Microbiology

Not reported

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 76): CHEST XRAY: NO ABNORMALITIES DETECTED; CT ABDOMEN: MURAL GAS IN CAECUM WITH SCATTERED LOCULES OF SURROUNDING PERITONEAL FREE GAS.APPEARANCES ARE CONSISTAENT WITH A LOCALISED PERFORATION IN THE CAECAL REGION

AE Stopped Rx Day	94 (37 DAYS AFTER LAST TREATMENT)
Duration of AE	5 DAYS
Severity	Severe
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	PROBABLE CAUSE IS COLONOSCOPY ON [redacted] 20[redacted]
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ニュージーランドの治験責任医師からの報告。本被験者は2[redacted]歳女性であり，AbbVie の ABBV-066（リサンキズマブ）の治験で盲検化された治験薬が投与され，盲腸領域に限局性穿孔の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，クローン病及び非喫煙者であった。

投与 90 日後，被験者は盲腸領域に限局性穿孔を発現した。投与 94 日後，盲腸領域の限局性穿孔は消失した。

投与 90 日後から投与 91 日後まで，被験者は非重篤な低カリウム血症を発現した。

投与 90 日後，被験者は治験実施計画書に規定された Week 12 の回腸結腸内視鏡検査を受けた。被験者は不快感のため大量の鎮静が必要であった。術後の退院時，被験者は体の揺れがあり，歯はガタガタと音を立てており，とても寒気を感じていた。

同日の後程，被験者は病院を受診し，3 度の失神事象，悪寒及び結腸内視鏡検査以降の複数回の嘔吐を伴う全身の不調感のため入院した。被験者には間欠性の中等度から重度の両側前頭部痛もあった。同日，被験者は入院し，CT スキャン，X 線検査を受け，IV 補液の投与を受けた。保存療法後，被験者は臨床的に改善し，投与 94 日後に退院し，帰宅した。

投与された薬剤は，paracetamol，メトロニダゾール，ピペラシリン／タゾバクタム，ゲンタマイシン，モビコール，ヒドロコルチゾン，prednisone 及びオーグメンチンであった。

The patient’s past medications include:

6-MERCAPTOPURINE for CROHN'S DISEASE (20[redacted] - 20[redacted])

AZATHIOPRINE for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

METRONIDAZOLE for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PENTASA for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

COLIFOAM ENEMA for CROHN'S DISEASE (20[redacted] - 20[redacted])

METHOTREXATE for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ADALIMUMAB for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

PREDNISONE for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

INFLIXIMAB for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

ETROLIZUMAB for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-066 (Blinded)

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1) Cecum perforation (10055432) (Large intestine perforation (10023804)) [v.21.1] [10055432]

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 ABBV-066 (Blinded)

Event of LOCALISED PERFORATION IN CAECAL REGION

- **Investigator:** PROBABLE CAUSE IS COLONOSCOPY ON [redacted] 20[redacted]

- **AbbVie:** EVENT IS MORE LIKELY A COMPLICATION OF COLONOSCOPY PROCEDURE. PRE-EXISTING CROHN'S DISEASE IS AN ADDITIONAL RISK FACTOR

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] **CHEST XRAY:** no abnormality detected

[redacted] 20[redacted] **CT ABDOMEN:** MURAL GAS IN CAECUM WITH SCATTERED LOCULES OF SURROUNDING PERITONEAL FREE GAS. APPEARANCES ARE CONSISTAENT WITH A

LOCALISED PERFORATION IN THE CAECAL REGION

[redacted] 20[redacted] **HEMATOCRIT:** 0.28 ratio (normal 0.35 to 0.46)

[redacted] 20[redacted] **HEMATOCRIT:** 0.25 fraction of 1 (normal 0.35 to 0.46)

[redacted] 20[redacted] **HEMOGLOBIN:** 92 G/DL (normal 115 to 155)

[redacted] 20[redacted] **HEMOGLOBIN:** 79 G/L (normal 115 to 155)

[redacted] 20[redacted] HIGH SENSITIVITY C REACTIVE PROTEIN: 60 mg/l (normal 0 to 5)

[redacted] 20[redacted] HIGH SENSITIVITY C REACTIVE PROTEIN: 22 mg/l (normal <5)

[redacted] 20[redacted] **LYMPHOCYTES ABS:** 0.6 X10**9/L (normal 1.0 to 4.0)

[redacted] 20[redacted] **MONOCYTES ABS:** 0.18 X10**9/L (normal 0.2 to 1.0)

[redacted] 20[redacted] **NEUTROPHIL ABS:** 21.0 X10**9/L (normal 1.9 to 7.5)

[redacted] 20[redacted] **PLATELET COUNT:** 559 X10**9/L (normal 150 to 400)

[redacted] 20[redacted] **POTASSIUM:** 2.5 MMOL/L (normal 3.5 to 5.2)

[redacted] 20[redacted] **POTASSIUM:** 5.0 MMOL/L (normal 3.5 to 5.2)

[redacted] 20[redacted] **WBC:** 22.0 X10**9/L (normal 4.0 to 11.0)

Subject [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
クローン病	X	X		

Treatment Group	Age at Study Start	Sex	Race
P1:PLACEBO	2[redacted]	FEMALE	WHITE

Medical History	Onset Year
OTHER: PSORIATIC ARTHRITIS	20[redacted]
OTHER: PSORIASIS	20[redacted]
INFLAMMATORY BOWEL DISEASE: CROHN'S	20[redacted]
CROHN'S DISEASE	20[redacted]
OTHER: DENTAL ABSESS	20[redacted]
INFLAMMATORY BOWEL DISEASE: NAUSEA	20[redacted]
OTHER: SWELLING RIGHT KNEE JOINT	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): BIOPSY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CIGARETTES	CURRENT	10 CIGARETTE	13	Not reported.
CHEWING TOBACCO	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	More than 4

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
Placebo		IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1	1

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
NORMENSAL	500 mg	QD	Y-M: 20[redacted]

ADALIMUMAB	40 mg	OTHER: EVERY 2 WEEKS	Y-M: 20[redacted]
AZATHIOPRINE	100 mg	QD	Y-M: 20[redacted]
ALLOPURINOL	100 mg	QD	Y-M: 20[redacted] / -266
MESALAZINE	4.8 g	QD	Y-M: 20[redacted] / -206
HYDROCORTISONE	100 mg	QID	Y-M: 20[redacted] / -60
PARACETAMOL	1 g	PRN	Y-M: 20[redacted] / -60
METHYLPREDNISOLONE	60 mg	QD	Y-M: 20[redacted] / -59
PREDNISONE	10 mg	QD	Y-M: 20[redacted] / -41
ONDANSETRON	4 mg	PRN	Y-M: 20[redacted] / -1

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
NORMENSAL	500 mg	QD	Y-M: 20[redacted]	ONGOING
AZATHIOPRINE	100 mg	QD	Y-M: 20[redacted]	ONGOING
ALLOPURINOL	100 mg	QD	Y-M: 20[redacted] / -266	ONGOING
MESALAZINE	4.8 g	QD	Y-M: 20[redacted] / -206	ONGOING
PARACETAMOL	1 g	PRN	Y-M: 20[redacted] / -60	ONGOING
ONDANSETRON	4 mg	PRN	Y-M: 20[redacted] / -1	ONGOING
AMIDOTRIZOIC ACID	3 OTHER: SACHETS	OTHER: ONCE ONLY	Y-M: 20[redacted] / 9	Y-M: 20[redacted] / 9
FLEBOBAG RING LACT	1 L	OTHER: CONTINUOUS	Y-M: 20[redacted] / 9	Y-M: 20[redacted] / 10
INFLIXIMAB	400 mg	OTHER: 2 WEEKLY	Y-M: 20[redacted] / 10	ONGOING
HYDROCORTISONE	100 mg	OTHER: ONCE ONLY	Y-M: 20[redacted] / 10	Y-M: 20[redacted] / 10
LORATADINE	20 mg	OTHER: ONCE ONLY	Y-M: 20[redacted] / 10	Y-M: 20[redacted] / 10
PARACETAMOL	1 g	PRN	Y-M: 20[redacted] / 10	Y-M: 20[redacted] / 10
HYOSCINE	1 mg	OTHER: 3 DAYS	Y-M: 20[redacted] / 11	ONGOING

Event #1: Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Event Description	WORSENING OF CROHN'S DISEASE
Preferred term	クローン病
AE Onset Date / Rx Day	[redacted]20[redacted] / 9 (8 DAYS AFTER LAST TREATMENT)
Age at AE Onset	2[redacted]

Laboratory Testing
[redacted]20[redacted] (Rx Day 9): C Reactive Protein: 215 [0 - 6] mg/L; Leukocytes: 12.4 [4 - 11] 10^9/L; [redacted]20[redacted] (Rx Day 15): C Reactive Protein: 14 [0 - 6] mg/L

Microbiology
Not reported

SAE Supplemental Procedure
[redacted]20[redacted] (Rx Day -15): ABDOMINAL XRAY: PROMINENT HAUSTRAL THICKENING PARTICULARLY THE RIGHT SIDE OF THE COLON; CHEST XRAY: THE HEART SIZE IS NORMAL. THE LUNGS ARE CLEAR. MEDIASTINAL AND HILAR CONTOURS APPEAR NORMAL. NO BONY OR SOFT TISSUE ABNORMALITY. NO SUBDIAPHRAGMATIC GAS; CT SCAN ABDO/PELVIS: THE APPEARANCES SUGGEST A CROHN'S COLITIS WITHOUT COMPLICATION; UPPER GI ENDOSCOPY: SCATTERED MILD INFLAMMATION CHARACTERISED BY EROSIONS WAS FOUND IN THE GASTRIC ANTRUM

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	Moderate
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	CROHNS DISEASE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ニュージーランドの治験責任医師からの報告。本被験者は2[redacted]歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，クローン病悪化の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，乾癬性関節炎，乾癬，クローン病，悪心，現喫煙者（1 日 0.5 箱を 13 年間）及び現飲酒者（1 日 4 杯以上）であった。

投与 9 日後，被験者はクローン病悪化を発現した。

投与 9 日後，被験者はクローン病悪化のため入院した。1 日 20 回の排便，腹痛，悪心及び嘔吐が続いていた。被験者は，食欲はあるが嘔吐してしまうと述べていた。被験者は IV ステロイド剤及びインフリキシマブによる治療を受けた。投与 11 日後，症状が軽快した状態で被験者は

退院した。

本事象により治験薬の投与は完全に中止された。

被験者は、投与 515 日前，投与 9 か月前，投与 7 か月前及び投与 2 か月前に，クローン病再発のため入院していた。

投与された薬剤は，ヒドロコルチゾン，インフリキシマブ及びハルトマン輸液であった。

The patient’s past medications include:

HUMIRA for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

METHYLPREDNISONE for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PREDNISONE for CROHN'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Crohn's disease aggravated (10011403) (Crohn's disease (10011401)) [v.23.0] [10011403]

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, recurrences not applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of WORSENING OF CROHN'S DISEASE

- Investigator: Crohn's Disease

- AbbVie: Event more likely related to pre-existing Crohn's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMINAL XRAY:** Prominent haustral thickening particularly the right side of the colon.

[redacted] **20[redacted] CHEST XRAY:** Prominent haustral thickening particularly the right side of the colon.

[redacted] **20[redacted] CT SCAN ABDOMEN AND PELVIS:** The appearances suggest a crohn's colitis without complication.

[redacted] **20[redacted] ENDOSCOPY:** Upper GI: Scattered mild inflammation characterized by erosions was found in the gastric antrum.

[redacted] 20[redacted] HIGH SENSITIVITY C REACTIVE PROTEIN: 215 MG/L (normal 0 to 6)

[redacted] 20[redacted] HIGH SENSITIVITY C REACTIVE PROTEIN: 14 MG/L (normal 0 to 6)

[redacted] **20[redacted] WBC:** 12.4 X10**9/L (normal 4 to 11)

Subject [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
クローン病	X			

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 1200 MG IV / P2:RZB 180 mg SC	5[redacted]	FEMALE	WHITE

Medical History	Onset Year
ANEMIA: [redacted]20[redacted] SCHEDULED BLOOD TRANSFUSION, BECAUSE SUBJECT DOES NOT TOLERATE ORAL AND INTRAVENOUS IRON REPLACEMENT THERAPY	20[redacted]
CLOTTING/BLEEDING PROBLEMS: DEEP VENOUS THROMBOSIS	20[redacted]
CROHN'S DISEASE	20[redacted]
OTHER: LEIOMYOMA OF UTERUS	20[redacted]
NEPHROLITHIASIS	20[redacted]
OTHER: OSTEOPOROSIS	20[redacted]
OTHER: MENOPAUSE	20[redacted]
LIVER DISEASE (EXCLUDING HEPATITIS): HAEMANGIOM	20[redacted]
OTHER: POLYP OF TRANSVERSE COLON, REMOVED [redacted]20[redacted] (DURING SCREENING ILEOCOLONOSCOPY)	20[redacted]
OTHER: RHINOVIRUS BRONCHITIS	20[redacted]
INFLAMMATORY BOWEL DISEASE: ABDOMINALL MASS (QUESTIONABLE)	20[redacted]

Prior Procedures	Procedure Year
SURGERY: LAPAROSCOPIC CHOLECYSTECTOMY	Not reported.
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): BIOPSY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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	FORMER	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
Risankizumab	1200 mg	IV	Every 4 Weeks	[redacted] / 1	[redacted] / 57	57
Risankizumab	180 mg	SC	Every 8 Weeks	[redacted] / 91	[redacted] / 148	58

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
MESALAZINE	2 g	BID	Y-M: [redacted]
AZATHIOPRINE	150 mg	QD	Y-M: [redacted]
RIVAROXABAN	20 mg	QD	Y-M: [redacted]
METHOTREXATE	15 mg	OTHER: ONCE A WEEK	Y-M: [redacted]
INFLIXIMAB	5 mg/kg	OTHER: INDUCTION W0,2,6 AND THEN EVERY 8WEEK, TOTAL 5 TIMES	Y-M: [redacted]
VEDOLIZUMAB	300 mg	OTHER: WEEK 0,2,6 AND THEN EVERY 8 WEEKS	Y-M: [redacted]
ZOLEDRONIC ACID	5 mg	OTHER: ONCE A YEAR	Y-M: [redacted]
VEDOLIZUMAB	300 mg	OTHER: EVERY 4 WEEKS	Y-M: [redacted]
USTEKINUMAB	190 mg	OTHER: INDUCTION	Y-M: [redacted]
USTEKINUMAB	90 mg	OTHER: EVERY 4 WEEKS	Y-M: [redacted]
PANTOPRAZOLE	40 mg	QD	Y-M: [redacted] / -174
METHYLPREDNISOLONE	20 mg	QD	Y-M: [redacted] / -154
METHYLPREDNISOLONE	12 mg	QD	Y-M: [redacted] / -82
FORTRANS	4 L	QD	Y-M: [redacted] / -50
FENTANYL	0,05 mg	QD	Y-M: [redacted] / -49
PARACETAMOL	1 g	QD	Y-M: [redacted] / -49
PROPOFOL	400 mg	PRN	Y-M: [redacted] / -49

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
MESALAZINE	2 g	BID	Y-M: [redacted]	ONGOING
RIVAROXABAN	20 mg	QD	Y-M: [redacted]	ONGOING
ZOLEDRONIC ACID	5 mg	OTHER: ONCE A YEAR	Y-M: [redacted]	ONGOING
PANTOPRAZOLE	40 mg	QD	Y-M: [redacted] / -174	ONGOING
METHYLPREDNISOLONE	12 mg	QD	Y-M: [redacted] / -82	ONGOING

ENALAPRIL	2.5 mg	QD	Y-M: 20[redacted] / 85	ONGOING
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted] / 103	ONGOING
POTASSIUM	600 mg	TID	Y-M: 20[redacted] / 103	Y-M: 20[redacted] / 127
RINGER	500 mL	QD	Y-M: 20[redacted] / 103	Y-M: 20[redacted] / 127
CALCIGRAN	500/200 mg	BID	Y-M: 20[redacted] / 116	ONGOING
RINGER	1000 mL	QD	Y-M: 20[redacted] / 116	Y-M: 20[redacted] / 116
CIPROFLOXACIN	500 mg	BID	Y-M: 20[redacted] / 116	Y-M: 20[redacted] / 127
ENOXAPARIN	0,6 mL	QD	Y-M: 20[redacted] / 116	Y-M: 20[redacted] / 127
FOLIC ACID	5 mg	QD	Y-M: 20[redacted] / 116	Y-M: 20[redacted] / 127
GRANISETRON	1 mg	TID	Y-M: 20[redacted] / 116	Y-M: 20[redacted] / 127
METRONIDAZOLE	500 mg	TID	Y-M: 20[redacted] / 116	Y-M: 20[redacted] / 127
PHOSPHORIC ACID	500 mg	QD	Y-M: 20[redacted] / 116	Y-M: 20[redacted] / 127
POTASSIUM	1200 mg	TID	Y-M: 20[redacted] / 116	Y-M: 20[redacted] / 127
THIAMINE	300 mg	QD	Y-M: 20[redacted] / 116	Y-M: 20[redacted] / 127
ESOMEPRAZOLE	40 mg	QD	Y-M: 20[redacted] / 116	Y-M: 20[redacted] / 131
DEXAMETHASONE	12 mg	OTHER: SINGLE DOSE	Y-M: 20[redacted] / 148	Y-M: 20[redacted] / 148
FORTRANS	1 L	QID	Y-M: 20[redacted] / 174	Y-M: 20[redacted] / 174
AUGMENTIN	1.2 g	BID	Y-M: 20[redacted] / 175	Y-M: 20[redacted] / 175
DEXAMETHASONE	12 mg	QD	Y-M: 20[redacted] / 175	Y-M: 20[redacted] / 175

Event #1: Serious Adverse Event

Event Description	CROHN'S DISEASE EXACERBATION
Preferred term	クローン病
AE Onset Date / Rx Day	[redacted]20[redacted] / 116
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 116): Albumin: 40 [35 - 52] g/L; Alkaline Phosphatase: 59 [35 - 104] U/L; Aspartate Aminotransferase: 11 [Not reported - 33] U/L; Bilirubin: 7.9 [21 - 21] umol/L; C Reactive Protein: 12 [5 - 5]

mg/L; Calcium: 2.21 [2.2 - 2.5] mmol/L; Creatinine: 61 [59 - 104] umol/L; Ery. Mean Corpuscular Volume: 83.5 [80 - 98] fL; Glucose: 4.9 [4.1 - 5.9] mmol/L; Hematocrit: 32.9 [36 - 47] %; Hemoglobin: 101 [120 - 160] g/L; Lipase: 41 [13 - 60] U/L; Lymphocytes: 4.35 [1 - 3.6] 10^9/L; NPTST064-CMV IGM: NEG [Not reported - Not reported] Unit not reported; NPTST149-LACTATE: 3.3 [0.5 - 2.2] mmol/L; NPTST248-SOLUBLE TRANSFERRIN RECEPTOR: 7.6 [1.8 - 4.6] mg/L; Neutrophils: 6.3 [2.2 - 7.6] 10^9/L; Potassium: 3.3 [3.4 - 4.8] mmol/L; Prothrombin Intl. Normalized Ratio: 0.97 [0.8 - 1.2] RATIO; Prothrombin Intl. Normalized Ratio: 0,97 [0.8 - 1.2] RATIO; Sodium: 142 [136 - 145] mmol/L; Thyrotropin: 1.86 [0.27 - 4.2] mU/L; [redacted] (Rx Day 118): NPTST072-CULTURE: NEG [Not reported - Not reported] Unit not reported; [redacted] (Rx Day 127): Alanine Aminotransferase: 9 [Not reported - 32] U/L; Ery. Mean Corpuscular Hemoglobin: 25.6 [28 - 34] pg; Erythrocytes: 3.94 [4.5 - 6] 10^12/L; Leukocytes: 11.97 [4 - 10] 10^9/L; Platelets: 517 [150 - 400] 10^9/L; [redacted] (Rx Day 131): Occult Blood: 35 [15 - 15] Unit not reported

Microbiology

[redacted] (Rx Day 118): STOOL NPTST254-STOOL CULTURE: NEGATIVE-NO FOUND: YERSINIA, SALMONELLA, SHIGELLA, E.COLI (ENTEROPATOG), CAMPYLOBACTER JE)

SAE Supplemental Procedure

[redacted] (Rx Day 103): MRI ENTEROGRAPHY: INFLAMMATORY CHANGES IN THE RIGHT COLON AND TERMINAL ILEUM. NO EVIDENCE OF A STENOTIC SEGMENT, ABSCESS OR FISTULA IN THE INTESTINE. THERE ARE TWO HAEMANGIOMAS IN THE LIVER. THE UTERINE MYOMA.; THYROID ULTRASOUND: TI-RADS 2 NODULES IN THE THYROID GLAND DO NOT REQUIRE PUNCTURING OR MONITORING.; WHOLE BODY COMPUTED TOMOGRAPHY: THYROID HYPODENSE FOCI. TWO SMALL LESIONS SUITABLE FOR HEMANGIOMA IN THE LIVER. MILD ENLARGEMENT OF THE CENTRAL BILIARY TRACT. IN THE SMALL INTESTINE WALL, THICKENING OF THE WALL WAS OBSERVED AT TIMES. ALMOST ALL THE LARGE INTESTINE WALL IS THICKENED (FAT HALO SIGN). CHANGES RELATED TO CROHN'S DISEASE ARE LIKELY. TWO SMALL LESIONS SUITABLE FOR HEMANGIOMA IN THE LIVER. MILD ENLARGEMENT OF THE INTESTINAL BILIARY TRACT AT THE CENTRAL LEVEL. HYPODENSIC FOCI OF THE THYROID GLAND. THE UTERINE MYOMA? NO OTHER SIGNIFICANT CHANGES ARE NOTED.

AE Stopped Rx Day	175 (27 DAYS AFTER LAST TREATMENT)
Duration of AE	60 DAYS
Severity	Moderate
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	PROGRESION OF CROHN DISEASE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

エストニアの治験責任医師からの報告。本被験者は 5[redacted] 歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，クローン病増悪の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，貧血，クローン病，閉経，横行結腸ポリープ，炎症性腸疾患，［腹部腫瘤（可能性あり）］，非喫煙者及び元飲酒者（1 日 2 杯未満）であった。

本治験では，Week 12 の開始時に，被験者は盲検性を維持する目的で盲検化された IV 製剤及び盲検化された皮下製剤の投与を受ける予定である。

投与 116 日後，被験者はクローン病増悪を発現した。投与 175 日後，クローン病増悪は消失した。

投与 116 日後，被験者は嘔吐及び血性下痢のため入院した。臨床検査及び画像検査が行われ，クローン病増悪と診断された。葉酸欠乏（非重篤）も診断された。被験者は治療により速やかに改善した。投与 127 日後，被験者は退院した。

投与された薬剤は，Calcigran，APO-K，リンゲル，Folverlan，チアミン，Fosfat，パントプラゾール，カイトリル，Ciprinol，メトロニダゾール及びクレキサンであった。

The patient’s past medications include:

IMURAN for CROHN'S DISEASE ([redacted])

TREXAN for CROHN'S DISEASE ([redacted])

REMSIMA for CROHN'S DISEASE ([redacted])

ENTYVIO for CROHN'S DISEASE ([redacted])

STELARA for CROHN'S DISEASE ([redacted])

Causality for RISANKIZUMAB (Blinded)

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1) Crohn's disease aggravated (10011403) (Crohn's disease (10011401)) v.23.0] [10011403]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of CROHN'S DISEASE EXACERBATION

- Investigator: Progression of Crohn's disease

- AbbVie: Event is more likely related to pre-existing history of Crohn's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] ALANINE AMINO TRANSFERASE: 9 U/L (normal <32)

[redacted] **20[redacted] ALBUMIN:** 40 G/L (normal 35 to 52)

[redacted] 20[redacted] ALKALINE PHOSPHATASE: 59 U/L (normal 35 to 104)

[redacted] 20[redacted] ASPARTATE AMINO TRANSFERASE: 11 U/L (normal <33)

[redacted] **20[redacted] BILIRUBIN:** 7.9 MCMOL/L (normal <21)

[redacted] **20[redacted] CALCIUM:** 2.21 MMOL/L (normal 2.2 to 2.5)

[redacted] 20[redacted] CMV IGM: negative

[redacted] 20[redacted] CREATININE: 61 No units

[redacted] **20[redacted] CT SCAN:** Thyroid hypodense foci. Two small lesions suitable for hemangioma in the liver. Mild enlargement of the central biliary tract. In the small intestine wall, thickening of the wall was observed at times. Almost all the large intestine wall is thickened (fat halo sign). Changes related to crohn's disease are likely. Two small lesions suitable for hemangioma in the liver. Mild enlargement of the intestinal biliary tract at the central level. Hypodensic foci of the thyroid gland. The uterine myoma? No other significant changes are noted.

[redacted] 20[redacted] INTERNATIONAL NORMALISED RATIO: 0.97 Ratio (normal 0.8 to 1.2)

[redacted] **20[redacted] LACTATE:** 3.3 MMOL/L (normal 0.5 to 2.2)

[redacted] **20[redacted] MRI ABDOMEN:** Inflammatory changes in the right colon and terminal ileum. No evidence of a stenotic segment, abscess or fistula in the intestine. There are two haemangiomas in the liver. The uterine myoma.

[redacted] **20[redacted] STOOL CULTURE:** Negative-No found: yersinia, salmonella, shigella, e.coli (enteropatog), campylobacter je

[redacted] **20[redacted] THYROID ULTRASOUND:** TI-RADS 2 nodules in the thyroid gland do not require puncturing or monitoring.

[redacted] **20[redacted] TSH:** 1.86 mU/L (normal 0.270 to 4.20)

[redacted] **20[redacted] WHITE BLOOD CELL:** 11.97 X10**9/L (normal 4 to 10)

Subject [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
虫垂炎	X			X

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 600 MG IV	5[redacted]	FEMALE	WHITE

Medical History	Onset Year
OSTEOARTHRITIS	20[redacted]
CROHN'S DISEASE	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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	UNKNOWN	Not reported.

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
Risankizumab	600 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 57	57

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
THIOPENTAL	500 mg	QD	Y-M: 20[redacted]
LEFLUNOMIDE	20 mg	QD	Y-M: 20[redacted]
MESALAZINE	1000 mg	QID	Y-M: 20[redacted]
METHYLPREDNISOLONE	8 mg	QD	Y-M: 20[redacted]
MESALAZINE	1000 mg	TID	Y-M: 20[redacted] / -37
METHYLPREDNISOLONE	16 mg	QD	Y-M: 20[redacted] / -37
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted] / -37

SUPREP BOWEL PREP	176 mL	QD	Y-M: 20[redacted] / -4

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
THIOPENTAL	500 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 74
MESALAZINE	1000 mg	TID	Y-M: 20[redacted] / -37	ONGOING
METHYLPREDNISOLONE	16 mg	QD	Y-M: 20[redacted] / -37	ONGOING
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted] / -37	ONGOING
METFORMIN	1000 mg	BID	Y-M: 20[redacted] / 63	ONGOING
MORPHINE	1 mL	TID	Y-M: 20[redacted] / 74	Y-M: 20[redacted] / 75
CEFTRIAXONE	1000 mg	QD	Y-M: 20[redacted] / 74	Y-M: 20[redacted] / 81
BEMIPARIN	0,4 mL	BID	Y-M: 20[redacted] / 74	Y-M: 20[redacted] / 82

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

Event Description	ACUTE APPENDICITIS
Preferred term	虫垂炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 74 (17 DAYS AFTER LAST TREATMENT)
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (Rx Day 74): Glucose: 9.42 [3.33 - 6.1] mmol/L; Hemoglobin: 102 [120 - 160] g/L; Lymphocytes/Leukocytes: 11.4 [19 - 37] %; NPTST091-ESR: 20 [3 - 12] g/L

Microbiology

Not reported

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 47): APPENDECTOMY: WITHOUT CONSEGUENCES; ECG: NORM

AE Stopped Rx Day	82 (25 DAYS AFTER LAST TREATMENT)
Duration of AE	9 DAYS
Severity	Moderate
Relation to Study Drug by Investigator	No Reasonable Possibility
Investigator Alternative Etiology	COMPLEX OF REASONS: -OBSTRUCTION OF THE APPENDIX. -EXPOSURE TO AN INFECTIOUS AGENT - VIOLATION OF INTESTINAL INNERVATION
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT, LIFE THREATENING

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ウクライナの治験責任医師からの報告。本被験者は 5[redacted] 歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，急性虫垂炎の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，クローン病及び非喫煙者であった。

投与 74 日後，被験者は急性虫垂炎を発現した。投与 82 日後，急性虫垂炎は消失した。

投与 74 日後，被験者は腹部右側の急性疼痛のため入院し，虫垂切除を受けた。クローン病に関連する合併症は考えられず，入院中に合併症は認められなかった。投与 82 日後，被験者は退院した。

投与された薬剤は，Loraxon であった。

Causality for RISANKIZUMAB (Blinded)

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1) Acute appendicitis (10000677) (Appendicitis (10003011)) [v.23.0] [10000677]

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

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

Dechallenge: Not Applicable

Alternative Etiology for RISANKIZUMAB (Blinded)

Event of ACUTE APPENDICITIS

- Investigator: Complex of reasons: Obstruction of the appendix, exposure to an infectious agent, and violation of intestinal innervation

- AbbVie: Event is common in the general population; lifetime incidence is 8.6 percent in males and 6.7 percent in females. (Martin, RF. Acute appendicitis in adults: diagnostic evaluation. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on [redacted], 20[redacted].))

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] ECG: Normal

[redacted] **20[redacted] ESR:** 20 G/L (normal 3 to 12)

[redacted] **20[redacted] GLUCOSE:** 9.42 G/L (normal 3.33 to 6.1)

[redacted] **20[redacted] HGB:** 4.9 G/L (normal 3.8 to 5.5)

[redacted] **20[redacted] LYMPHOCYTES %:** 11.4 % (normal 19.0 to 37.0)

Subject [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
クローン病	X	X		

Treatment Group	Age at Study Start	Sex	Race
P1:RZB 1200 MG IV	3[redacted]	FEMALE	WHITE

Medical History	Onset Year
CROHN'S DISEASE	20[redacted]
OTHER: ARTHRALGIA RIGHT HIP JOIN	20[redacted]

Prior Procedures	Procedure Year
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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)
Risankizumab	1200 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 29	29

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / Rx Day
MESALAZINE	1.0 g	TID	Y-M: 20[redacted] / -175
FORTRANS	192 g	PRN	Y-M: 20[redacted] / -14

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
MESALAZINE	1.0 g	TID	Y-M: 20[redacted]- / - 175	ONGOING

Event #1: Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Event Description WORSENING CROHN`S DISEASE SYMPTOMS

Preferred term クローン病

AE Onset Date / Rx Day [redacted]20[redacted] / 38 (9 DAYS AFTER LAST TREATMENT)

Age at AE Onset 3[redacted]

Laboratory Testing

Not reported

Microbiology

Not reported

SAE Supplemental Procedure

[redacted]20[redacted] (Rx Day 39): ABDOMINAL CT WITH IV TOMOHEXOL (100 ML): TIPHLITIS WITH MESENTERIAL FISTULA FORMATION; COLONIC BIOPSIE: OTHER, SPECIFY (HISTOPATOLOGY RESULTS: THE MORPHOLOGICAL PICTURE IS CHARACTERISTIC OF PERFORATION OF THE INTESTINAL WALL IN CROHNS DISEASE); RIGHT SIDE COLECTOMY WITH ILEOSTOMY: PENDING DATA

AE Stopped Rx Day 85 (56 DAYS AFTER LAST TREATMENT)

Duration of AE 48 DAYS

Severity Severe

Relation to Study Drug by Investigator No Reasonable Possibility

Investigator Alternative Etiology WORSENING CROHN`S DISEASE SYMPTOMS

Discontinued Study Drug Due to the Event YES

SAE Criteria REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]20[redacted]:20:26
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-006

ウクライナの治験責任医師からの報告。本被験者は3[redacted]歳女性であり，AbbVie のリサンキズマブの治験で盲検化された治験薬が投与され，クローン病の症状悪化の事象を発現した。

Event 1 の臨床経過：

関連する病歴は，クローン病，非喫煙者及び非飲酒者であった。

投与 38 日後，被験者はクローン病の症状悪化を発現した。投与 85 日後，クローン病の症状悪化は消失した。

投与 38 日後，被験者はクローン病の症状悪化のため入院した。投与の約 2 か月後，被験者は右側結腸切除，並びに回腸瘻造設及びハルトマン手術を受けた。

Causality for RISANKIZUMAB (Blinded)

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1) Crohns disease aggravated (10011408) (Crohn's disease (10011401)) [v.23.0] [10011408]

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 RISANKIZUMAB (Blinded)

Event of WORSENING CROHN`S DISEASE SYMPTOMS

- Investigator: Worsening Crohn's disease symptoms

- AbbVie: Event more likely related to pre-existing Crohn's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMINAL CT:** Tiphlitis with mesenteral fistula formation

[redacted] **20[redacted] COLONIC BIOPSY:** Histopathology results: The morphological picture is characteristic of perforation of the intestinal wall in Crohn's disease.

Subject [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:RZB 600 MG IV / P2:RZB 360 mg SC	2[redacted]	FEMALE	WHITE

Medical History	Onset Year
CROHN'S DISEASE	20[redacted]
OTHER: ABSCESS OF ABDOMINAL CAVITY	20[redacted]
OTHER: PERITONITIS	20[redacted]
ANEMIA: MODERATE LEVEL	20[redacted]
OTHER: ABSCESS OF ABDOMINAL CAVITY	20[redacted]
OTHER: INTESTINAL OBSTRUCTION	20[redacted]
OTHER: PERITONEAL ABDOMINAL ADHESIONS	20[redacted]
OTHER: VITAMIN D DEFICIENCY	20[redacted]

Prior Procedures	Procedure Year
SURGERY: APPENDECTOMY	20[redacted]
CROHN'S DISEASE SURGICAL HISTORY: BOWEL RESECTION	20[redacted]
SURGERY: DUE TO PENENTRATION	20[redacted]
CROHN'S DISEASE SURGICAL HISTORY: BOWEL RESECTION	20[redacted]
CROHN'S DISEASE HISTORY: COLONOSCOPY	20[redacted]
ENDOSCOPY (SCREENING): BIOPSY	20[redacted]
ENDOSCOPY (SCREENING): ILEOCOLONOSCOPY	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)
Risankizumab	600 mg	IV	Every 4 Weeks	[redacted]20[redacted] / 1	[redacted]20[redacted] / 57	57