Dossier zur Nutzenbewertung gemäß § 35a SGB V

Upadacitinib (RINVOQ®)

AbbVie Deutschland GmbH & Co. KG

Anhang 4-G: Ergänzende Unterlagen

Behandlung der mittelschweren bis schweren aktiven Colitis ulcerosa bei erwachsenen Patienten, die auf eine konventionelle Therapie oder ein Biologikum unzureichend angesprochen haben, nicht mehr darauf ansprechen oder diese nicht vertragen haben.

Stand: 13.09.2022

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Disclaimer

Im Folgenden werden die UE, SUE und UE differenziert nach Schweregrad nach Organsystemen und Einzelereignissen (als System Organ Class [SOCs] und Preferred Terms [PT] nach MedDRA) für die Upadacitinib Einzelstudien U-ACHIEVE und U-ACCOMPLISH dargestellt. Zusätzlich werden die UE von speziellem Interesse für die Induktionsphase aufgeführt.

Eine weitere Auswertung im Rahmen eines indirekten Vergleiches ist aus methodischen Gründen nicht gerechtfertigt.

Anhang 4-G1: Alle UE nach SOC/PT

Anhang 4-G1.1: Induktionsphase

Anhang 4-G1.1.1: U-ACHIEVE Substudie 1

09JUL2021 10:50 <! m14234ae-ss1.sas >
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TABLE 14.3_1.3.1_A

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Substudy 1 - SA1A Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=46) n (%)	ABT-494 7.5 mg QD (N=47) n (%)	ABT-494 15 mg QD (N=49) n (%)	ABT-494 30 mg QD (N=52) n (%)	ABT-494 45 mg QD (N=56) n (%)	ABT-494 Total (N=204) n (%)
Any adverse event	33 (71.7)	31 (66.0)	31 (63.3)	37 (71.2)	36 (64.3)	135 (66.2)
Blood and lymphatic system disorders	4 (8.7)	0	3 (6.1)	5 (9.6)	2 (3.6)	10 (4.9)
Anaemia	3 (6.5)	0	3 (6.1)	1 (1.9)	0	4 (2.0)
Eosinophilia	1 (2.2)	0	0	0	0	0
Iron deficiency anaemia	0	0	0	1 (1.9)	0	1 (0.5)
Leukocytosis	0	0	0	1 (1.9)	0	1 (0.5)
Leukopenia	0	0	0	1 (1.9)	0	1 (0.5)
Lymphopenia	0	0	0	1 (1.9)	1 (1.8)	2 (1.0)
Neutropenia	0	0	0	0	1 (1.8)	1 (0.5)
Cardiac disorders	3 (6.5)	0	1 (2.0)	0	0	1 (0.5)
Bradycardia	0	0	1 (2.0)	0	0	1 (0.5)
Palpitations	2 (4.3)	0	0	0	0	0
Supraventricular extrasystoles	1 (2.2)	0	0	0	0	0
Ear and labyrinth disorders	0	1 (2.1)	0	0	2 (3.6)	3 (1.5)
Meniere's disease	0	0	0	0	1 (1.8)	1 (0.5)
Tinnitus	0	1 (2.1)	0	0	0	1 (0.5)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
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TABLE 14.3_1.3.1 A

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Ear and labyrinth disorders (Cont.)						
Vertigo	0	0	0	0	1 (1.8)	1 (0.5)
Endocrine disorders	0	2 (4.3)	0	0	0	2 (1.0)
Cushingoid	0	2 (4.3)	0	0	0	2 (1.0)
Eye disorders	0	2 (4.3)	2 (4.1)	1 (1.9)	1 (1.8)	6 (2.9)
Conjunctival haemorrhage	0	1 (2.1)	0	0	0	1 (0.5)
Corneal erosion	0	0	1 (2.0)	0	0	1 (0.5)
Dry eye	0	0	1 (2.0)	0	0	1 (0.5)
Eye haemorrhage	0	0	0	0	1 (1.8)	1 (0.5)
Photopsia	0	1 (2.1)	0	0	0	1 (0.5)
Vitreous floaters	0	0	0	1 (1.9)	0	1 (0.5)
Gastrointestinal disorders	14 (30.4)	9 (19.1)	9 (18.4)	16 (30.8)	14 (25.0)	48 (23.5)
Abdominal discomfort	1 (2.2)	0	1 (2.0)	0	0	1 (0.5)
Abdominal distension	0	3 (6.4)	1 (2.0)	0	1 (1.8)	5 (2.5)
Abdominal pain	1 (2.2)	0	1 (2.0)	1 (1.9)	2 (3.6)	4 (2.0)
Abdominal pain lower	0	0	0	0	1 (1.8)	1 (0.5)
Abdominal pain upper	0	0	1 (2.0)	1 (1.9)	0	2 (1.0)

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TABLE 14.3_1.3.1_A

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Gastrointestinal disorders (Cont.)						
Abdominal tenderness	1 (2.2)	0	0	1 (1.9)	2 (3.6)	3 (1.5)
Anal ulcer	0	0	0	0	1 (1.8)	1 (0.5)
Anorectal discomfort	0	0	0	0	1 (1.8)	1 (0.5)
Colitis	1 (2.2)	0	0	0	0	0
Colitis ulcerative	6 (13.0)	1 (2.1)	3 (6.1)	6 (11.5)	4 (7.1)	14 (6.9)
Constipation	1 (2.2)	0	0	1 (1.9)	0	1 (0.5)
Defaecation urgency	1 (2.2)	0	0	0	0	0
Diarrhoea	0	0	0	0	1 (1.8)	1 (0.5)
Dry mouth	0	0	1 (2.0)	0	0	1 (0.5)
Dyschezia	1 (2.2)	0	0	0	0	0
Dyspepsia	0	0	0	1 (1.9)	0	1 (0.5)
Dysphagia	0	0	0	0	1 (1.8)	1 (0.5)
Epigastric discomfort	0	0	1 (2.0)	0	0	1 (0.5)
Flatulence	2 (4.3)	2 (4.3)	0	2 (3.8)	0	4 (2.0)
Frequent bowel movements	0	0	1 (2.0)	0	0	1 (0.5)
Gastrointestinal pain	0	0	1 (2.0)	0	0	1 (0.5)

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TABLE 14.3_1.3.1 A

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Gastrointestinal disorders (Cont.)						
Large intestine polyp	0	0	1 (2.0)	0	0	1 (0.5)
Mouth ulceration	0	0	0	0	1 (1.8)	1 (0.5)
Nausea	2 (4.3)	1 (2.1)	1 (2.0)	6 (11.5)	0	8 (3.9)
Oesophageal ulcer	0	0	0	0	1 (1.8)	1 (0.5)
Proctalgia	0	1 (2.1)	0	0	2 (3.6)	3 (1.5)
Rectal discharge	1 (2.2)	0	0	0	0	0
Rectal tenesmus	0	0	0	0	1 (1.8)	1 (0.5)
Stomatitis	0	0	0	0	1 (1.8)	1 (0.5)
Vomiting	1 (2.2)	1 (2.1)	1 (2.0)	1 (1.9)	0	3 (1.5)
General disorders and administration site conditions	7 (15.2)	5 (10.6)	1 (2.0)	11 (21.2)	4 (7.1)	21 (10.3)
Asthenia	0	1 (2.1)	0	0	0	1 (0.5)
Chest discomfort	1 (2.2)	0	0	0	0	0
Chest pain	0	0	0	1 (1.9)	0	1 (0.5)
Chills	1 (2.2)	0	0	2 (3.8)	0	2 (1.0)
Fatigue	1 (2.2)	2 (4.3)	1 (2.0)	2 (3.8)	1 (1.8)	6 (2.9)
Feeling abnormal	0	0	0	0	1 (1.8)	1 (0.5)

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General disorders and administration site conditions (Cont.)						
Generalised oedema	0	0	0	1 (1.9)	0	1 (0.5)
Hangover	1 (2.2)	0	0	0	0	0
Influenza like illness	1 (2.2)	1 (2.1)	0	1 (1.9)	0	2 (1.0)
Malaise	0	1 (2.1)	0	0	0	1 (0.5)
Mass	0	0	0	0	1 (1.8)	1 (0.5)
Pain	1 (2.2)	1 (2.1)	0	3 (5.8)	0	4 (2.0)
Peripheral swelling	1 (2.2)	0	0	0	0	0
Pyrexia	1 (2.2)	1 (2.1)	0	5 (9.6)	1 (1.8)	7 (3.4)
Swelling face	0	1 (2.1)	0	0	0	1 (0.5)
Hepatobiliary disorders	1 (2.2)	0	0	0	1 (1.8)	1 (0.5)
Drug-induced liver injury	0	0	0	0	1 (1.8)	1 (0.5)
Portal vein thrombosis	1 (2.2)	0	0	0	0	0
Immune system disorders	0	0	0	1 (1.9)	0	1 (0.5)
Seasonal allergy	0	0	0	1 (1.9)	0	1 (0.5)
Infections and infestations	16 (34.8)	9 (19.1)	10 (20.4)	9 (17.3)	13 (23.2)	41 (20.1)
Abscess	1 (2.2)	0	0	0	0	0

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Infections and infestations (Cont.)						
Bacterial vaginosis	0	0	0	0	1 (1.8)	1 (0.5)
Bronchitis	2 (4.3)	0	0	1 (1.9)	0	1 (0.5)
Cellulitis	1 (2.2)	0	0	0	0	0
Clostridium difficile infection	1 (2.2)	0	1 (2.0)	0	0	1 (0.5)
Cystitis	0	1 (2.1)	0	0	0	1 (0.5)
Cytomegalovirus infection	1 (2.2)	0	0	0	0	0
Dermatophytosis	0	1 (2.1)	0	0	0	1 (0.5)
Ear infection	0	0	0	1 (1.9)	0	1 (0.5)
Folliculitis	1 (2.2)	1 (2.1)	0	1 (1.9)	1 (1.8)	3 (1.5)
Gastroenteritis	0	1 (2.1)	1 (2.0)	0	0	2 (1.0)
Gastroenteritis viral	0	0	0	1 (1.9)	0	1 (0.5)
Genital herpes	0	0	0	1 (1.9)	0	1 (0.5)
Gingivitis	0	0	0	0	1 (1.8)	1 (0.5)
Herpes zoster disseminated	0	0	0	0	1 (1.8)	1 (0.5)
Hordeolum	0	0	0	0	1 (1.8)	1 (0.5)
Impetigo	0	0	0	1 (1.9)	0	1 (0.5)

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Infections and infestations (Cont.)						
Influenza	0	0	0	1 (1.9)	0	1 (0.5)
Localised infection	1 (2.2)	0	0	0	0	0
Lower respiratory tract infection	1 (2.2)	0	0	0	0	0
Lyme disease	0	0	0	0	1 (1.8)	1 (0.5)
Nasopharyngitis	3 (6.5)	1 (2.1)	3 (6.1)	3 (5.8)	3 (5.4)	10 (4.9)
Onychomycosis	0	1 (2.1)	0	0	0	1 (0.5)
Oral herpes	1 (2.2)	0	0	0	1 (1.8)	1 (0.5)
Otitis media	0	0	0	0	1 (1.8)	1 (0.5)
Pharyngitis	1 (2.2)	0	0	0	0	0
Pustule	0	1 (2.1)	0	0	0	1 (0.5)
Respiratory syncytial virus infection	0	0	0	0	1 (1.8)	1 (0.5)
Rhinitis	1 (2.2)	0	0	0	0	0
Sepsis	0	0	0	0	1 (1.8)	1 (0.5)
Sinusitis	1 (2.2)	1 (2.1)	0	0	0	1 (0.5)
Tinea cruris	0	0	0	1 (1.9)	0	1 (0.5)
Upper respiratory tract infection	0	1 (2.1)	4 (8.2)	0	1 (1.8)	6 (2.9)

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Infections and infestations (Cont.)						
Urinary tract infection	0	1 (2.1)	0	0	0	1 (0.5)
Urosepsis	0	0	1 (2.0)	0	0	1 (0.5)
Viral infection	1 (2.2)	0	0	0	0	0
Viral pharyngitis	0	0	0	0	1 (1.8)	1 (0.5)
Vulvovaginal candidiasis	0	1 (2.1)	0	0	0	1 (0.5)
Wound infection	1 (2.2)	0	0	0	0	0
Injury, poisoning and procedural complications	5 (10.9)	2 (4.3)	2 (4.1)	3 (5.8)	4 (7.1)	11 (5.4)
Accidental overdose	3 (6.5)	0	2 (4.1)	1 (1.9)	1 (1.8)	4 (2.0)
Anastomotic leak	1 (2.2)	0	0	0	0	0
Contusion	0	0	0	0	1 (1.8)	1 (0.5)
Ligament sprain	1 (2.2)	0	0	1 (1.9)	0	1 (0.5)
Muscle strain	0	0	0	0	1 (1.8)	1 (0.5)
Overdose	0	1 (2.1)	0	0	0	1 (0.5)
Road traffic accident	0	0	0	1 (1.9)	0	1 (0.5)
Skin abrasion	0	0	0	0	1 (1.8)	1 (0.5)
Spinal compression fracture	0	1 (2.1)	0	0	0	1 (0.5)

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TABLE 14.3_1.3.1 A

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Substudy 1 - SA1A Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=46) n (%)	ABT-494 7.5 mg QD (N=47) n (%)	ABT-494 15 mg QD (N=49) n (%)	ABT-494 30 mg QD (N=52) n (%)	ABT-494 45 mg QD (N=56) n (%)	ABT-494 Total (N=204) n (%)
Investigations	3 (6.5)	3 (6.4)	6 (12.2)	2 (3.8)	8 (14.3)	19 (9.3)
Alanine aminotransferase increased	1 (2.2)	2 (4.3)	0	0	0	2 (1.0)
Aspartate aminotransferase increased	1 (2.2)	2 (4.3)	0	0	3 (5.4)	5 (2.5)
Blood alkaline phosphatase decreased	0	0	0	0	1 (1.8)	1 (0.5)
Blood alkaline phosphatase increased	1 (2.2)	0	0	0	0	0
Blood bilirubin increased	0	0	0	0	1 (1.8)	1 (0.5)
Blood creatine phosphokinase increased	0	0	3 (6.1)	2 (3.8)	5 (8.9)	10 (4.9)
Blood creatinine increased	0	0	0	0	1 (1.8)	1 (0.5)
Electrocardiogram repolarisation abnormality	0	0	1 (2.0)	0	0	1 (0.5)
Gamma-glutamyltransferase increased	1 (2.2)	0	0	0	0	0
Haematocrit decreased	0	0	1 (2.0)	0	0	1 (0.5)
Haemoglobin decreased	0	1 (2.1)	1 (2.0)	0	0	2 (1.0)
Hepatic enzyme increased	0	0	0	0	1 (1.8)	1 (0.5)
Lymphocyte count decreased	0	0	1 (2.0)	0	0	1 (0.5)
Lymphocyte percentage decreased	0	0	0	0	1 (1.8)	1 (0.5)
Neutrophil count decreased	0	0	0	0	1 (1.8)	1 (0.5)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Treatment-emergent AEs during Substudy 1 are defined as events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and within 30 days after the last dose of the study medication in Substudy 1 for subjects who discontinued Substudy 1 and are not enrolled into Substudy 3 or study M14-533, or events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and up to the first dose of the study medication in Substudy 3 or study M14-533.

program source code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234ae-ss1.sas

1621

09JUL2021 10:50 <! m14234ae-ss1.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 1
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 10 OF 15

TABLE 14.3_1.3.1_A

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Substudy 1 - SA1A Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=46) n (%)	ABT-494 7.5 mg QD (N=47) n (%)	ABT-494 15 mg QD (N=49) n (%)	ABT-494 30 mg QD (N=52) n (%)	ABT-494 45 mg QD (N=56) n (%)	ABT-494 Total (N=204) n (%)
Investigations (Cont.)						
Neutrophil count increased	0	0	1 (2.0)	0	1 (1.8)	2 (1.0)
Protein urine present	1 (2.2)	0	0	0	0	0
Red blood cell count decreased	0	0	1 (2.0)	0	0	1 (0.5)
Weight decreased	1 (2.2)	0	0	0	0	0
White blood cell count decreased	0	0	1 (2.0)	0	0	1 (0.5)
White blood cell count increased	0	0	1 (2.0)	0	1 (1.8)	2 (1.0)
Metabolism and nutrition disorders	6 (13.0)	3 (6.4)	3 (6.1)	3 (5.8)	1 (1.8)	10 (4.9)
Decreased appetite	2 (4.3)	0	1 (2.0)	0	0	1 (0.5)
Diabetic metabolic decompensation	0	0	1 (2.0)	0	0	1 (0.5)
Fluid retention	0	1 (2.1)	0	0	0	1 (0.5)
Hyperglycaemia	1 (2.2)	1 (2.1)	1 (2.0)	0	1 (1.8)	3 (1.5)
Hyperlipidaemia	1 (2.2)	0	0	0	0	0
Hypokalaemia	0	1 (2.1)	0	1 (1.9)	0	2 (1.0)
Hypomagnesaemia	0	0	0	1 (1.9)	0	1 (0.5)
Hypophosphataemia	2 (4.3)	0	0	2 (3.8)	0	2 (1.0)
Iron deficiency	1 (2.2)	0	0	0	0	0

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Treatment-emergent AEs during Substudy 1 are defined as events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and within 30 days after the last dose of the study medication in Substudy 1 for subjects who discontinued Substudy 1 and are not enrolled into Substudy 3 or study M14-533, or events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and up to the first dose of the study medication in Substudy 3 or study M14-533.

program source code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234ae-ss1.sas

1622

09JUL2021 10:50 <! m14234ae-ss1.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 1
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 11 OF 15

TABLE 14.3_1.3.1 A

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Substudy 1 - SA1A Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=46) n (%)	ABT-494 7.5 mg QD (N=47) n (%)	ABT-494 15 mg QD (N=49) n (%)	ABT-494 30 mg QD (N=52) n (%)	ABT-494 45 mg QD (N=56) n (%)	ABT-494 Total (N=204) n (%)
Musculoskeletal and connective tissue disorders	8 (17.4)	4 (8.5)	5 (10.2)	4 (7.7)	4 (7.1)	17 (8.3)
Arthralgia	1 (2.2)	2 (4.3)	0	1 (1.9)	0	3 (1.5)
Arthropathy	0	1 (2.1)	0	1 (1.9)	1 (1.8)	3 (1.5)
Back pain	1 (2.2)	0	0	1 (1.9)	0	1 (0.5)
Bursitis	0	0	1 (2.0)	0	0	1 (0.5)
Flank pain	1 (2.2)	0	0	0	0	0
Intervertebral disc protrusion	0	0	1 (2.0)	0	0	1 (0.5)
Joint swelling	1 (2.2)	0	0	0	0	0
Muscle discomfort	1 (2.2)	0	0	0	0	0
Muscle spasms	1 (2.2)	0	1 (2.0)	1 (1.9)	0	2 (1.0)
Musculoskeletal chest pain	0	0	1 (2.0)	0	0	1 (0.5)
Musculoskeletal pain	1 (2.2)	0	0	0	0	0
Musculoskeletal stiffness	0	0	0	0	1 (1.8)	1 (0.5)
Osteoporosis	0	1 (2.1)	0	0	1 (1.8)	2 (1.0)
Pain in extremity	3 (6.5)	0	0	0	1 (1.8)	1 (0.5)
Polyarthritis	1 (2.2)	0	0	0	0	0

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Treatment-emergent AEs during Substudy 1 are defined as events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and within 30 days after the last dose of the study medication in Substudy 1 for subjects who discontinued Substudy 1 and are not enrolled into Substudy 3 or study M14-533, or events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and up to the first dose of the study medication in Substudy 3 or study M14-533.

program source code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234ae-ss1.sas

1623

09JUL2021 10:50 <! m14234ae-ss1.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 1
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TABLE 14.3_1.3.1 A

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Substudy 1 - SA1A Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=46) n (%)	ABT-494 7.5 mg QD (N=47) n (%)	ABT-494 15 mg QD (N=49) n (%)	ABT-494 30 mg QD (N=52) n (%)	ABT-494 45 mg QD (N=56) n (%)	Total (N=204) n (%)
Musculoskeletal and connective tissue disorders (Cont.)						
Spondyloarthropathy	0	0	1 (2.0)	0	0	1 (0.5)
Temporomandibular joint syndrome	0	0	0	0	1 (1.8)	1 (0.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (2.1)	0	0	0	1 (0.5)
Melanocytic naevus	0	1 (2.1)	0	0	0	1 (0.5)
Nervous system disorders	6 (13.0)	7 (14.9)	5 (10.2)	6 (11.5)	6 (10.7)	24 (11.8)
Disturbance in attention	0	1 (2.1)	0	0	0	1 (0.5)
Dizziness	1 (2.2)	1 (2.1)	0	1 (1.9)	0	2 (1.0)
Headache	5 (10.9)	4 (8.5)	4 (8.2)	5 (9.6)	5 (8.9)	18 (8.8)
Neuralgia	0	0	0	0	1 (1.8)	1 (0.5)
Radial nerve palsy	0	0	0	1 (1.9)	0	1 (0.5)
Tension headache	1 (2.2)	0	0	0	0	0
Tremor	0	1 (2.1)	1 (2.0)	0	0	2 (1.0)
Psychiatric disorders	2 (4.3)	3 (6.4)	1 (2.0)	3 (5.8)	2 (3.6)	9 (4.4)
Affective disorder	0	0	0	0	1 (1.8)	1 (0.5)
Agitation	0	1 (2.1)	0	0	0	1 (0.5)
Anxiety	1 (2.2)	0	1 (2.0)	1 (1.9)	0	2 (1.0)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Treatment-emergent AEs during Substudy 1 are defined as events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and within 30 days after the last dose of the study medication in Substudy 1 for subjects who discontinued Substudy 1 and are not enrolled into Substudy 3 or study M14-533, or events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and up to the first dose of the study medication in Substudy 3 or study M14-533.

program source code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234ae-ss1.sas

1624

09JUL2021 10:50 <! m14234ae-ss1.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 1
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TABLE PAGE 13 OF 15

TABLE 14.3_1.3.1 A

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Substudy 1 - SA1A Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=46) n (%)	ABT-494 7.5 mg QD (N=47) n (%)	ABT-494 15 mg QD (N=49) n (%)	ABT-494 30 mg QD (N=52) n (%)	ABT-494 45 mg QD (N=56) n (%)	ABT-494 Total (N=204) n (%)
Psychiatric disorders (Cont.)						
Depression	0	1 (2.1)	0	0	0	1 (0.5)
Initial insomnia	0	0	0	1 (1.9)	0	1 (0.5)
Insomnia	1 (2.2)	1 (2.1)	1 (2.0)	1 (1.9)	1 (1.8)	4 (2.0)
Renal and urinary disorders	1 (2.2)	2 (4.3)	0	0	2 (3.6)	4 (2.0)
Bladder pain	1 (2.2)	0	0	0	0	0
Nephrolithiasis	0	0	0	0	1 (1.8)	1 (0.5)
Pollakiuria	1 (2.2)	1 (2.1)	0	0	1 (1.8)	2 (1.0)
Renal pain	0	1 (2.1)	0	0	0	1 (0.5)
Reproductive system and breast disorders	0	1 (2.1)	0	0	0	1 (0.5)
Vulvovaginal pain	0	1 (2.1)	0	0	0	1 (0.5)
Respiratory, thoracic and mediastinal disorders	2 (4.3)	3 (6.4)	2 (4.1)	5 (9.6)	2 (3.6)	12 (5.9)
Cough	1 (2.2)	1 (2.1)	1 (2.0)	2 (3.8)	1 (1.8)	5 (2.5)
Dyspnoea	0	0	0	2 (3.8)	0	2 (1.0)
Oropharyngeal pain	0	1 (2.1)	2 (4.1)	2 (3.8)	0	5 (2.5)
Paranasal sinus hypersecretion	0	1 (2.1)	0	0	0	1 (0.5)
Pneumothorax	1 (2.2)	0	0	0	0	0

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Treatment-emergent AEs during Substudy 1 are defined as events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and within 30 days after the last dose of the study medication in Substudy 1 for subjects who discontinued Substudy 1 and are not enrolled into Substudy 3 or study M14-533, or events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and up to the first dose of the study medication in Substudy 3 or study M14-533.

program source code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234ae-ss1.sas

1625

09JUL2021 10:50 <! m14234ae-ss1.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 1
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 14 OF 15

TABLE 14.3_1.3.1_A

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Substudy 1 - SA1A Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=46) n (%)	ABT-494 7.5 mg QD (N=47) n (%)	ABT-494 15 mg QD (N=49) n (%)	ABT-494 30 mg QD (N=52) n (%)	ABT-494 45 mg QD (N=56) n (%)	ABT-494 Total (N=204) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)						
Pulmonary embolism	0	0	0	0	1 (1.8)	1 (0.5)
Rhinorrhoea	0	0	0	1 (1.9)	0	1 (0.5)
Rhonchi	0	0	0	0	1 (1.8)	1 (0.5)
Skin and subcutaneous tissue disorders	2 (4.3)	3 (6.4)	2 (4.1)	12 (23.1)	6 (10.7)	23 (11.3)
Acne	0	1 (2.1)	1 (2.0)	4 (7.7)	1 (1.8)	7 (3.4)
Alopecia	0	0	1 (2.0)	1 (1.9)	1 (1.8)	3 (1.5)
Dermatitis acneiform	0	0	0	1 (1.9)	0	1 (0.5)
Dermatitis contact	1 (2.2)	0	0	0	0	0
Ecchymosis	0	0	0	0	1 (1.8)	1 (0.5)
Erythema	0	0	0	1 (1.9)	0	1 (0.5)
Night sweats	0	1 (2.1)	0	0	0	1 (0.5)
Pain of skin	0	0	0	0	1 (1.8)	1 (0.5)
Pruritus	1 (2.2)	0	0	0	0	0
Rash	0	1 (2.1)	0	3 (5.8)	1 (1.8)	5 (2.5)
Rash follicular	0	0	0	0	1 (1.8)	1 (0.5)
Rash pruritic	0	0	0	1 (1.9)	0	1 (0.5)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Treatment-emergent AEs during Substudy 1 are defined as events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and within 30 days after the last dose of the study medication in Substudy 1 for subjects who discontinued Substudy 1 and are not enrolled into Substudy 3 or study M14-533, or events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and up to the first dose of the study medication in Substudy 3 or study M14-533.

program source code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234ae-ss1.sas

1626

09JUL2021 10:50 <! m14234ae-ss1.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 1
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 15 OF 15

TABLE 14.3_1.3.1 A

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Substudy 1 - SA1A Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=46) n (%)	ABT-494 7.5 mg QD (N=47) n (%)	ABT-494 15 mg QD (N=49) n (%)	ABT-494 30 mg QD (N=52) n (%)	ABT-494 45 mg QD (N=56) n (%)	ABT-494 Total (N=204) n (%)
Skin and subcutaneous tissue disorders (Cont.)						
Rosacea	0	0	0	1 (1.9)	0	1 (0.5)
Skin fissures	0	0	0	0	1 (1.8)	1 (0.5)
Vascular disorders	1 (2.2)	2 (4.3)	2 (4.1)	0	1 (1.8)	5 (2.5)
Deep vein thrombosis	0	0	0	0	1 (1.8)	1 (0.5)
Flushing	0	1 (2.1)	1 (2.0)	0	0	2 (1.0)
Haematoma	0	1 (2.1)	0	0	0	1 (0.5)
Hypertension	0	0	1 (2.0)	0	0	1 (0.5)
Hypotension	1 (2.2)	0	0	0	0	0

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Treatment-emergent AEs during Substudy 1 are defined as events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and within 30 days after the last dose of the study medication in Substudy 1 for subjects who discontinued Substudy 1 and are not enrolled into Substudy 3 or study M14-533, or events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and up to the first dose of the study medication in Substudy 3 or study M14-533.

program source code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234ae-ss1.sas

1627

Anhang 4-G1.1.2: U-ACHIEVE Substudie 2

09JUL2021 10:50 <! m14234aesum-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 30

TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Any adverse event	96 (61.9)	180 (56.4)	51 (60.0)	31 (52.5)
Blood and lymphatic system disorders	13 (8.4)	24 (7.5)	10 (11.8)	1 (1.7)
Anaemia	9 (5.8)	8 (2.5)	7 (8.2)	1 (1.7)
Blood loss anaemia	0	1 (0.3)	1 (1.2)	0
Iron deficiency anaemia	1 (0.6)	2 (0.6)	1 (1.2)	0
Leukocytosis	0	1 (0.3)	0	0
Leukopenia	0	4 (1.3)	0	0
Lymphopenia	1 (0.6)	6 (1.9)	0	0
Neutropenia	1 (0.6)	6 (1.9)	3 (3.5)	0
Normocytic anaemia	1 (0.6)	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

1887

09JUL2021 10:50 <! m14234aesum-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 30

TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Cardiac disorders	3 (1.9)	2 (0.6)	0	0
Palpitations	2 (1.3)	1 (0.3)	0	0
Pericarditis	0	1 (0.3)	0	0
Tachycardia	1 (0.6)	0	0	0
Ear and labyrinth disorders	2 (1.3)	1 (0.3)	1 (1.2)	1 (1.7)
Deafness neurosensory	0	0	1 (1.2)	0
Ear discomfort	0	1 (0.3)	0	0
Sudden hearing loss	1 (0.6)	0	0	0
Tinnitus	0	0	0	1 (1.7)
Vertigo	1 (0.6)	0	0	0
Endocrine disorders	0	1 (0.3)	0	0
Cushingoid	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Eye disorders	0	7 (2.2)	3 (3.5)	1 (1.7)
Asthenopia	0	1 (0.3)	0	0
Cataract	0	1 (0.3)	1 (1.2)	0
Chalazion	0	0	1 (1.2)	0
Conjunctival haemorrhage	0	1 (0.3)	0	0
Conjunctival hyperaemia	0	0	0	1 (1.7)
Dry eye	0	1 (0.3)	1 (1.2)	0
Eyelid irritation	0	1 (0.3)	0	0
Eyelid thickening	0	1 (0.3)	0	0
Ocular hypertension	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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09JUL2021 10:50 <! m14234aesum-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Gastrointestinal disorders	29 (18.7)	40 (12.5)	11 (12.9)	6 (10.2)
Abdominal distension	0	3 (0.9)	1 (1.2)	0
Abdominal pain	1 (0.6)	4 (1.3)	1 (1.2)	2 (3.4)
Abdominal pain lower	1 (0.6)	0	0	0
Abdominal pain upper	1 (0.6)	4 (1.3)	0	0
Achlorhydria	0	0	0	1 (1.7)
Anal fissure	0	2 (0.6)	0	0
Anal inflammation	1 (0.6)	0	0	0
Aphthous ulcer	0	2 (0.6)	0	0
Colitis	1 (0.6)	0	0	0
Colitis ulcerative	21 (13.5)	3 (0.9)	3 (3.5)	2 (3.4)
Constipation	0	6 (1.9)	2 (2.4)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
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Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Gastrointestinal disorders (Cont.)				
Defaecation urgency	1 (0.6)	0	0	0
Diaphragmatic hernia	1 (0.6)	0	0	0
Diarrhoea	0	1 (0.3)	0	0
Dyspepsia	1 (0.6)	3 (0.9)	0	0
Eructation	0	1 (0.3)	0	0
Faecaloma	1 (0.6)	0	0	0
Flatulence	2 (1.3)	2 (0.6)	0	0
Food poisoning	0	1 (0.3)	0	0
Frequent bowel movements	0	1 (0.3)	0	0
Gastrooesophageal reflux disease	1 (0.6)	3 (0.9)	0	0
Gingival pain	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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09JUL2021 10:50 <! m14234aesum-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Gastrointestinal disorders (Cont.)				
Haemorrhoids	0	4 (1.3)	2 (2.4)	1 (1.7)
Large intestine polyp	0	1 (0.3)	0	0
Lip blister	0	0	1 (1.2)	0
Lip dry	0	1 (0.3)	0	0
Mouth ulceration	0	0	1 (1.2)	0
Nausea	3 (1.9)	4 (1.3)	1 (1.2)	0
Odynophagia	0	1 (0.3)	0	0
Oral pain	0	1 (0.3)	0	0
Pancreatitis	0	1 (0.3)	0	0
Rectal dysplasia	0	1 (0.3)	0	0
Rectal polyp	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
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Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Gastrointestinal disorders (Cont.)				
Stomatitis	1 (0.6)	0	0	0
Tongue ulceration	0	1 (0.3)	0	1 (1.7)
Tooth disorder	0	1 (0.3)	0	0
Vomiting	0	2 (0.6)	1 (1.2)	0
General disorders and administration site conditions	4 (2.6)	22 (6.9)	9 (10.6)	2 (3.4)
Adverse drug reaction	0	1 (0.3)	0	0
Asthenia	0	3 (0.9)	1 (1.2)	0
Chest discomfort	0	2 (0.6)	1 (1.2)	0
Chest pain	1 (0.6)	0	0	1 (1.7)
Chills	0	2 (0.6)	0	1 (1.7)
Face oedema	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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09JUL2021 10:50 <! m14234aesum-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

MedDRA 23.0 System Organ Class Preferred Term	Part 1 Placebo (N=155) n (%)	Part 1 UPA 45 mg QD (N=319) n (%)	Part 2 Placebo/ UPA 45 mg QD (N=85) n (%)	Part 2 UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
General disorders and administration site conditions (Cont.)				
Fatigue	1 (0.6)	2 (0.6)	0	1 (1.7)
Hyperplasia	0	1 (0.3)	0	0
Malaise	0	3 (0.9)	0	0
Nodule	0	1 (0.3)	0	0
Non-cardiac chest pain	0	0	1 (1.2)	0
Oedema peripheral	0	1 (0.3)	0	0
Pyrexia	2 (1.3)	9 (2.8)	6 (7.1)	0
Tenderness	0	1 (0.3)	0	0
Hepatobiliary disorders	1 (0.6)	2 (0.6)	1 (1.2)	1 (1.7)
Cholelithiasis	0	1 (0.3)	0	1 (1.7)
Cholestasis	1 (0.6)	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
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09JUL2021 10:50 <! m14234aesum-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Hepatobiliary disorders (Cont.)				
Hepatic function abnormal	0	1 (0.3)	0	0
Hypertransaminasaemia	0	0	1 (1.2)	0
Immune system disorders	1 (0.6)	0	1 (1.2)	0
Hypersensitivity	0	0	1 (1.2)	0
Seasonal allergy	1 (0.6)	0	0	0
Infections and infestations	32 (20.6)	71 (22.3)	21 (24.7)	7 (11.9)
Abscess	0	1 (0.3)	0	0
Appendicitis	0	2 (0.6)	0	0
Asymptomatic bacteriuria	0	1 (0.3)	0	0
Bronchitis	0	0	2 (2.4)	0
Candida infection	0	0	1 (1.2)	0

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Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Infections and infestations (Cont.)				
Cellulitis	2 (1.3)	0	0	0
Cestode infection	0	1 (0.3)	0	0
Conjunctivitis	1 (0.6)	0	0	0
Cystitis	0	1 (0.3)	1 (1.2)	0
Dermatophytosis of nail	0	1 (0.3)	0	0
Ear infection	2 (1.3)	0	0	1 (1.7)
Escherichia infection	1 (0.6)	0	0	0
Folliculitis	1 (0.6)	8 (2.5)	0	0
Fungal infection	1 (0.6)	0	0	0
Fungal skin infection	1 (0.6)	0	1 (1.2)	0
Gastroenteritis	3 (1.9)	3 (0.9)	0	0

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Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

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UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Infections and infestations (Cont.)				
Gastroenteritis norovirus	1 (0.6)	1 (0.3)	0	0
Gastroenteritis viral	0	1 (0.3)	0	0
Genital herpes	0	2 (0.6)	0	0
Genital herpes simplex	0	0	1 (1.2)	0
Gingivitis	1 (0.6)	1 (0.3)	0	0
Herpes simplex	0	1 (0.3)	0	0
Herpes zoster	0	1 (0.3)	5 (5.9)	3 (5.1)
Influenza	1 (0.6)	3 (0.9)	1 (1.2)	0
Lower respiratory tract infection	0	0	1 (1.2)	0
Muscle abscess	1 (0.6)	0	0	0
Nasopharyngitis	6 (3.9)	15 (4.7)	4 (4.7)	1 (1.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
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Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Infections and infestations (Cont.)				
Oral fungal infection	0	1 (0.3)	0	0
Oral herpes	0	4 (1.3)	2 (2.4)	0
Otitis externa fungal	0	1 (0.3)	0	0
Otitis media	0	1 (0.3)	0	0
Paronychia	0	1 (0.3)	0	0
Pharyngitis	1 (0.6)	2 (0.6)	3 (3.5)	1 (1.7)
Pneumonia	1 (0.6)	2 (0.6)	0	0
Pustule	0	2 (0.6)	0	0
Rash pustular	0	1 (0.3)	0	0
Respiratory tract infection	0	1 (0.3)	0	0
Respiratory tract infection viral	1 (0.6)	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
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Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Infections and infestations (Cont.)				
Sinusitis	0	2 (0.6)	1 (1.2)	1 (1.7)
Tinea pedis	0	1 (0.3)	0	0
Tinea versicolour	0	1 (0.3)	0	0
Tooth infection	0	1 (0.3)	0	0
Upper respiratory tract infection	6 (3.9)	8 (2.5)	0	0
Urinary tract infection	3 (1.9)	3 (0.9)	2 (2.4)	0
Vaginal abscess	1 (0.6)	0	0	0
Viral infection	0	1 (0.3)	0	0
Viral upper respiratory tract infection	0	2 (0.6)	0	0
Vulvovaginal candidiasis	1 (0.6)	1 (0.3)	0	0
Vulvovaginal mycotic infection	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
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Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Injury, poisoning and procedural complications	1 (0.6)	7 (2.2)	1 (1.2)	1 (1.7)
Contusion	0	3 (0.9)	0	0
Heat exhaustion	0	0	1 (1.2)	0
Injury	0	1 (0.3)	0	0
Ligament sprain	0	1 (0.3)	0	0
Meniscus injury	0	0	0	1 (1.7)
Post-traumatic neck syndrome	0	1 (0.3)	0	0
Skin abrasion	1 (0.6)	0	0	0
Skin laceration	0	1 (0.3)	0	0
Wound complication	0	1 (0.3)	0	0

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Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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09JUL2021 10:50 <! m14234aesum-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Investigations	19 (12.3)	35 (11.0)	9 (10.6)	7 (11.9)
Alanine aminotransferase increased	3 (1.9)	4 (1.3)	0	1 (1.7)
Alpha hydroxybutyrate dehydrogenase increased	0	1 (0.3)	0	0
Amylase increased	0	1 (0.3)	0	0
Aspartate aminotransferase increased	4 (2.6)	5 (1.6)	1 (1.2)	1 (1.7)
Blood bilirubin increased	0	2 (0.6)	0	0
Blood bilirubin unconjugated increased	0	1 (0.3)	0	0
Blood cholesterol decreased	0	0	1 (1.2)	0
Blood cholesterol increased	0	1 (0.3)	0	1 (1.7)
Blood creatine phosphokinase increased	3 (1.9)	16 (5.0)	5 (5.9)	4 (6.8)
Blood glucose increased	2 (1.3)	0	0	0
Blood iron decreased	0	1 (0.3)	0	0

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Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

MedDRA 23.0 System Organ Class Preferred Term	Part 1 Placebo (N=155) n (%)	Part 1 UPA 45 mg QD (N=319) n (%)	Part 2 Placebo/ UPA 45 mg QD (N=85) n (%)	Part 2 UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Investigations (Cont.)				
Blood lactate dehydrogenase increased	0	1 (0.3)	0	0
Blood magnesium decreased	0	1 (0.3)	0	0
Blood triglycerides increased	0	0	0	1 (1.7)
Blood urine present	0	1 (0.3)	0	0
Cardiac murmur	1 (0.6)	0	0	0
Crystal urine present	1 (0.6)	0	0	0
Gamma-glutamyltransferase increased	3 (1.9)	0	0	0
Glucose urine present	1 (0.6)	0	0	0
Haemoglobin decreased	3 (1.9)	0	0	1 (1.7)
High density lipoprotein increased	0	1 (0.3)	0	0
Intraocular pressure increased	0	1 (0.3)	0	0

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Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

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UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Investigations (Cont.)				
Lipase increased	0	1 (0.3)	0	0
Liver function test increased	1 (0.6)	0	0	0
Low density lipoprotein decreased	0	0	1 (1.2)	0
Low density lipoprotein increased	0	1 (0.3)	0	0
Lymphocyte count decreased	0	3 (0.9)	0	1 (1.7)
Lymphocyte count increased	0	3 (0.9)	0	0
Lymphocyte percentage decreased	0	2 (0.6)	0	0
Lymphocyte percentage increased	0	1 (0.3)	0	0
Neutrophil count decreased	0	10 (3.1)	2 (2.4)	1 (1.7)
Neutrophil count increased	0	1 (0.3)	0	0
Neutrophil percentage increased	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

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UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Investigations (Cont.)				
Platelet count increased	0	0	1 (1.2)	0
Prostatic specific antigen increased	0	1 (0.3)	0	0
Protein urine present	3 (1.9)	0	0	0
Urine analysis abnormal	1 (0.6)	0	0	0
Urine ketone body present	1 (0.6)	0	0	0
Vitamin D decreased	1 (0.6)	0	0	0
Weight decreased	1 (0.6)	0	1 (1.2)	0
Weight increased	1 (0.6)	0	0	0
White blood cell count decreased	1 (0.6)	5 (1.6)	3 (3.5)	0
White blood cell count increased	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
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UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Metabolism and nutrition disorders	6 (3.9)	6 (1.9)	1 (1.2)	3 (5.1)
Decreased appetite	1 (0.6)	0	0	0
Dehydration	1 (0.6)	0	0	0
Folate deficiency	0	1 (0.3)	0	0
Hypercholesterolaemia	0	0	0	1 (1.7)
Hyperglycaemia	0	0	1 (1.2)	1 (1.7)
Hyperlipidaemia	0	1 (0.3)	0	1 (1.7)
Hypernatraemia	0	0	0	1 (1.7)
Hypertriglyceridaemia	1 (0.6)	0	0	0
Hypoalbuminaemia	1 (0.6)	1 (0.3)	0	0
Hypokalaemia	0	1 (0.3)	0	0
Hyponatraemia	1 (0.6)	0	0	0

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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Metabolism and nutrition disorders (Cont.)				
Hypophosphataemia	0	1 (0.3)	0	0
Increased appetite	0	1 (0.3)	0	0
Iron deficiency	2 (1.3)	0	0	0
Vitamin B12 deficiency	0	1 (0.3)	0	0
Musculoskeletal and connective tissue disorders	15 (9.7)	20 (6.3)	5 (5.9)	2 (3.4)
Arthralgia	7 (4.5)	5 (1.6)	0	0
Arthritis	1 (0.6)	1 (0.3)	0	0
Arthritis enteropathic	0	0	0	1 (1.7)
Arthropathy	0	1 (0.3)	0	0
Back pain	1 (0.6)	3 (0.9)	1 (1.2)	0
Costochondritis	0	1 (0.3)	0	0

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UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

MedDRA 23.0 System Organ Class Preferred Term	Part 1 Placebo (N=155) n (%)	Part 1 UPA 45 mg QD (N=319) n (%)	Part 2 Placebo/ UPA 45 mg QD (N=85) n (%)	Part 2 UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Flank pain	0	0	0	1 (1.7)
Muscle spasms	1 (0.6)	1 (0.3)	2 (2.4)	0
Muscle tightness	0	1 (0.3)	0	0
Musculoskeletal pain	0	1 (0.3)	0	0
Musculoskeletal stiffness	0	1 (0.3)	0	0
Myalgia	1 (0.6)	1 (0.3)	1 (1.2)	0
Myositis	1 (0.6)	0	0	0
Osteopenia	1 (0.6)	0	0	0
Osteoporosis	0	1 (0.3)	0	0
Pain in extremity	1 (0.6)	1 (0.3)	2 (2.4)	0
Spinal pain	1 (0.6)	1 (0.3)	0	0

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UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Spondyloarthropathy	1 (0.6)	1 (0.3)	0	0
Tendonitis	0	1 (0.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	4 (1.3)	0	0
Ganglioneuroma	0	1 (0.3)	0	0
Skin papilloma	0	2 (0.6)	0	0
Uterine leiomyoma	0	1 (0.3)	0	0
Nervous system disorders	6 (3.9)	20 (6.3)	7 (8.2)	3 (5.1)
Dizziness	0	4 (1.3)	1 (1.2)	0
Headache	4 (2.6)	13 (4.1)	4 (4.7)	2 (3.4)
Migraine	1 (0.6)	0	1 (1.2)	0
Neuralgia	0	0	0	1 (1.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
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TABLE PAGE 23 OF 30

TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Nervous system disorders (Cont.)				
Paraesthesia	0	1 (0.3)	0	0
Post herpetic neuralgia	0	1 (0.3)	0	0
Presyncope	0	1 (0.3)	0	0
Sciatica	0	0	1 (1.2)	0
Syncope	1 (0.6)	0	0	0
Tremor	0	1 (0.3)	0	0
Psychiatric disorders	5 (3.2)	4 (1.3)	0	2 (3.4)
Anxiety	2 (1.3)	2 (0.6)	0	0
Depression	1 (0.6)	0	0	0
Insomnia	2 (1.3)	1 (0.3)	0	2 (3.4)
Sleep disorder	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
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Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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09JUL2021 10:50 <! m14234aesum-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 24 OF 30

TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Renal and urinary disorders	3 (1.9)	8 (2.5)	3 (3.5)	0
Chronic kidney disease	0	2 (0.6)	0	0
Dysuria	0	1 (0.3)	1 (1.2)	0
Haematuria	1 (0.6)	0	0	0
Leukocyturia	0	0	1 (1.2)	0
Micturition disorder	0	1 (0.3)	0	0
Nephrolithiasis	0	1 (0.3)	0	0
Pollakiuria	0	1 (0.3)	0	0
Proteinuria	2 (1.3)	1 (0.3)	0	0
Renal colic	0	2 (0.6)	0	0
Renal pain	0	0	1 (1.2)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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09JUL2021 10:50 <! m14234aesum-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
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TABLE PAGE 25 OF 30

TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Reproductive system and breast disorders	0	5 (1.6)	0	0
Dysmenorrhoea	0	1 (0.3)	0	0
Menstruation irregular	0	1 (0.3)	0	0
Semen discolouration	0	1 (0.3)	0	0
Seminal vesiculitis	0	1 (0.3)	0	0
Vulvovaginal discomfort	0	1 (0.3)	0	0
Respiratory, thoracic and mediastinal disorders	7 (4.5)	18 (5.6)	4 (4.7)	2 (3.4)
Alveolitis	0	0	1 (1.2)	0
Catarrh	1 (0.6)	0	0	0
Cough	2 (1.3)	5 (1.6)	2 (2.4)	1 (1.7)
Cystic lung disease	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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09JUL2021 10:50 <! m14234aesum-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

MedDRA 23.0 System Organ Class Preferred Term	Part 1 Placebo (N=155) n (%)	Part 1 UPA 45 mg QD (N=319) n (%)	Part 2 Placebo/ UPA 45 mg QD (N=85) n (%)	Part 2 UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Dry throat	0	1 (0.3)	0	0
Dyspnoea	0	2 (0.6)	0	0
Nasal congestion	0	0	1 (1.2)	0
Oropharyngeal pain	1 (0.6)	6 (1.9)	1 (1.2)	0
Pharyngeal erythema	0	1 (0.3)	0	0
Pleural disorder	1 (0.6)	0	0	0
Pneumonitis	1 (0.6)	0	0	0
Productive cough	0	1 (0.3)	0	0
Pulmonary mass	2 (1.3)	1 (0.3)	0	0
Respiratory tract congestion	0	1 (0.3)	0	0
Rhinitis allergic	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Sinus congestion	0	0	0	1 (1.7)
Sinus disorder	0	1 (0.3)	0	0
Upper respiratory tract inflammation	1 (0.6)	0	0	0
Skin and subcutaneous tissue disorders	9 (5.8)	37 (11.6)	8 (9.4)	6 (10.2)
Acne	1 (0.6)	15 (4.7)	2 (2.4)	1 (1.7)
Alopecia	0	1 (0.3)	3 (3.5)	2 (3.4)
Dermatitis	0	0	0	1 (1.7)
Dermatitis acneiform	1 (0.6)	4 (1.3)	0	0
Dry skin	1 (0.6)	0	0	0
Dyshidrotic eczema	1 (0.6)	0	0	0
Ecchymosis	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Eczema	1 (0.6)	1 (0.3)	1 (1.2)	0
Erythema multiforme	0	1 (0.3)	0	0
Hyperkeratosis	0	1 (0.3)	0	0
Ingrowing nail	0	0	0	1 (1.7)
Pain of skin	0	1 (0.3)	0	0
Papule	0	3 (0.9)	1 (1.2)	0
Photosensitivity reaction	0	0	0	1 (1.7)
Pruritus	4 (2.6)	1 (0.3)	0	0
Rash	1 (0.6)	8 (2.5)	0	1 (1.7)
Rash macular	0	1 (0.3)	0	0
Rash papular	0	2 (0.6)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Seborrhoeic dermatitis	0	1 (0.3)	0	0
Skin discolouration	0	1 (0.3)	0	0
Skin exfoliation	0	1 (0.3)	0	0
Skin lesion	0	0	1 (1.2)	0
Skin striae	0	1 (0.3)	0	0
Vascular disorders	4 (2.6)	7 (2.2)	1 (1.2)	2 (3.4)
Arteriosclerosis	0	1 (0.3)	0	0
Hypertension	2 (1.3)	5 (1.6)	1 (1.2)	1 (1.7)
Hypotension	0	0	0	1 (1.7)
Peripheral coldness	1 (0.6)	0	0	0
Raynaud's phenomenon	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
R&D/20/1294 - CLINICAL/STATISTICAL
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TABLE 14.3_1.2.1.1_B

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Vascular disorders (Cont.)				
Thrombophlebitis superficial	1 (0.6)	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
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Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

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Anhang 4-G1.1.3: U-ACCOMPLISH

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UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-675
R&D/21/0078 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 28

TABLE 14.3_1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Any adverse event	70 (39.5)	182 (52.9)	52 (44.8)	28 (41.2)
Blood and lymphatic system disorders	5 (2.8)	27 (7.8)	7 (6.0)	6 (8.8)
Anaemia	4 (2.3)	14 (4.1)	3 (2.6)	4 (5.9)
Increased tendency to bruise	0	1 (0.3)	0	0
Iron deficiency anaemia	0	0	1 (0.9)	0
Leukopenia	1 (0.6)	1 (0.3)	2 (1.7)	0
Lymph node pain	0	1 (0.3)	0	0
Lymphopenia	1 (0.6)	4 (1.2)	1 (0.9)	1 (1.5)
Neutropenia	0	6 (1.7)	1 (0.9)	0
Thrombocytopenia	0	1 (0.3)	0	1 (1.5)
Thrombocytosis	1 (0.6)	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /homx/SDA/ABT-494/UC/CSR/M14-675/O/14.3/PCMS_RUN/m14675aesum.sas

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UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-675
R&D/21/0078 - CLINICAL/STATISTICAL
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TABLE 14.3_1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Cardiac disorders	2 (1.1)	2 (0.6)	1 (0.9)	0
Palpitations	1 (0.6)	2 (0.6)	0	0
Sinus arrhythmia	1 (0.6)	0	0	0
Sinus tachycardia	0	0	1 (0.9)	0
Tachycardia	1 (0.6)	0	0	0
Ear and labyrinth disorders	1 (0.6)	2 (0.6)	0	0
Ear pain	1 (0.6)	0	0	0
Hypoacusis	0	1 (0.3)	0	0
Sudden hearing loss	0	1 (0.3)	0	0
Tinnitus	0	2 (0.6)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
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TABLE 14.3_1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Eye disorders	4 (2.3)	7 (2.0)	1 (0.9)	0
Blepharitis	0	1 (0.3)	0	0
Conjunctival haemorrhage	0	1 (0.3)	0	0
Dry eye	0	1 (0.3)	1 (0.9)	0
Eye allergy	1 (0.6)	0	0	0
Keratitis	0	1 (0.3)	0	0
Lacrimation increased	1 (0.6)	0	0	0
Ocular discomfort	1 (0.6)	0	0	0
Ocular hyperaemia	0	1 (0.3)	0	0
Pterygium	1 (0.6)	0	0	0
Vision blurred	1 (0.6)	2 (0.6)	0	0

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TABLE 14.3_1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Gastrointestinal disorders	26 (14.7)	46 (13.4)	11 (9.5)	5 (7.4)
Abdominal discomfort	0	0	1 (0.9)	0
Abdominal distension	1 (0.6)	2 (0.6)	1 (0.9)	0
Abdominal pain	1 (0.6)	5 (1.5)	1 (0.9)	1 (1.5)
Abdominal pain lower	0	1 (0.3)	1 (0.9)	0
Abdominal pain upper	2 (1.1)	1 (0.3)	0	0
Anal fissure	1 (0.6)	2 (0.6)	1 (0.9)	0
Aphthous ulcer	2 (1.1)	2 (0.6)	0	0
Colitis	1 (0.6)	0	0	0
Colitis ulcerative	8 (4.5)	6 (1.7)	2 (1.7)	3 (4.4)
Constipation	2 (1.1)	5 (1.5)	1 (0.9)	0
Dental caries	1 (0.6)	1 (0.3)	0	0

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TABLE 14.3_1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Gastrointestinal disorders (Cont.)				
Diarrhoea	0	3 (0.9)	1 (0.9)	0
Diarrhoea haemorrhagic	0	1 (0.3)	0	0
Dry mouth	0	2 (0.6)	0	0
Dyspepsia	1 (0.6)	1 (0.3)	0	0
Flatulence	1 (0.6)	1 (0.3)	1 (0.9)	0
Food poisoning	0	1 (0.3)	0	0
Gastritis erosive	0	1 (0.3)	0	0
Gastrooesophageal reflux disease	1 (0.6)	3 (0.9)	0	1 (1.5)
Gingival pain	0	0	0	1 (1.5)
Gingival swelling	0	1 (0.3)	0	0
Haemorrhoidal haemorrhage	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
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TABLE 14.3_1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Gastrointestinal disorders (Cont.)				
Haemorrhoids	2 (1.1)	5 (1.5)	0	0
Hyperchlorhydria	0	1 (0.3)	0	0
Large intestine perforation	1 (0.6)	0	0	0
Large intestine polyp	0	0	0	1 (1.5)
Mouth ulceration	0	0	1 (0.9)	0
Nausea	4 (2.3)	3 (0.9)	1 (0.9)	0
Oral pain	0	1 (0.3)	0	1 (1.5)
Periodontal disease	0	1 (0.3)	0	0
Proctalgia	0	1 (0.3)	0	0
Pseudopolyposis	0	1 (0.3)	0	0
Stomatitis	1 (0.6)	4 (1.2)	3 (2.6)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
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TABLE 14.3__1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Gastrointestinal disorders (Cont.)				
Toothache	0	1 (0.3)	0	0
Vomiting	1 (0.6)	0	2 (1.7)	0
General disorders and administration site conditions	8 (4.5)	19 (5.5)	4 (3.4)	4 (5.9)
Asthenia	1 (0.6)	2 (0.6)	0	0
Chest discomfort	0	0	0	1 (1.5)
Chest pain	0	1 (0.3)	0	0
Chills	1 (0.6)	0	0	0
Fatigue	3 (1.7)	6 (1.7)	0	0
Influenza like illness	0	1 (0.3)	0	0
Infusion site reaction	0	1 (0.3)	0	0
Oedema peripheral	1 (0.6)	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
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TABLE 14.3__1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
General disorders and administration site conditions (Cont.)				
Pain	1 (0.6)	0	0	0
Peripheral swelling	0	1 (0.3)	0	0
Pseudopolyp	0	1 (0.3)	0	0
Pyrexia	3 (1.7)	8 (2.3)	4 (3.4)	4 (5.9)
Swelling face	1 (0.6)	1 (0.3)	0	0
Vaccination site erythema	1 (0.6)	0	0	0
Vaccination site pain	1 (0.6)	0	0	0
Hepatobiliary disorders	1 (0.6)	1 (0.3)	0	0
Hepatic function abnormal	0	1 (0.3)	0	0
Hyperbilirubinaemia	1 (0.6)	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

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TABLE 14.3_1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Immune system disorders	0	1 (0.3)	0	0
Seasonal allergy	0	1 (0.3)	0	0
Infections and infestations	16 (9.0)	58 (16.9)	22 (19.0)	11 (16.2)
Bacterial vaginosis	1 (0.6)	0	0	0
Body tinea	0	1 (0.3)	0	0
Borrelia infection	0	1 (0.3)	0	0
Bronchitis	0	1 (0.3)	0	0
Clostridium difficile infection	0	0	0	1 (1.5)
Conjunctivitis viral	1 (0.6)	0	0	0
COVID-19	0	0	0	1 (1.5)
COVID-19 pneumonia	0	1 (0.3)	1 (0.9)	0
Cytomegalovirus colitis	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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TABLE 14.3__1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Infections and infestations (Cont.)				
Cytomegalovirus infection	0	1 (0.3)	0	0
Demodicidosis	0	0	1 (0.9)	0
Dengue fever	0	1 (0.3)	0	0
Ear infection	0	1 (0.3)	0	0
Enterococcal infection	1 (0.6)	0	0	0
Escherichia infection	1 (0.6)	0	0	0
Folliculitis	0	7 (2.0)	2 (1.7)	0
Furuncle	0	1 (0.3)	0	0
Gastroenteritis	0	0	0	2 (2.9)
Gastroenteritis viral	0	0	1 (0.9)	1 (1.5)
Genital herpes	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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TABLE 14.3_1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Infections and infestations (Cont.)				
Herpes simplex	0	2 (0.6)	1 (0.9)	0
Herpes zoster	0	2 (0.6)	0	1 (1.5)
Hordeolum	1 (0.6)	0	1 (0.9)	0
Impetigo	0	0	0	1 (1.5)
Influenza	0	3 (0.9)	3 (2.6)	1 (1.5)
Nasopharyngitis	4 (2.3)	13 (3.8)	2 (1.7)	1 (1.5)
Oral candidiasis	0	0	1 (0.9)	0
Oral herpes	0	4 (1.2)	2 (1.7)	1 (1.5)
Otitis media acute	0	0	1 (0.9)	0
Periodontitis	0	0	1 (0.9)	0
Pharyngitis	0	0	0	1 (1.5)

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TABLE 14.3__1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Infections and infestations (Cont.)				
Pharyngitis streptococcal	0	0	1 (0.9)	0
Pilonidal cyst	0	0	1 (0.9)	0
Pneumonia	0	1 (0.3)	0	0
Post procedural infection	1 (0.6)	0	0	0
Pulpitis dental	1 (0.6)	0	0	0
Pustule	0	1 (0.3)	0	0
Pyelonephritis	0	1 (0.3)	0	0
Pyuria	1 (0.6)	0	0	0
Rash pustular	0	0	1 (0.9)	0
Respiratory tract infection	0	1 (0.3)	0	0
Respiratory tract infection viral	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
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TABLE 14.3_1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Infections and infestations (Cont.)				
Sinusitis	1 (0.6)	1 (0.3)	0	0
Tinea cruris	0	0	1 (0.9)	0
Tinea infection	0	0	0	1 (1.5)
Tonsillitis	0	0	1 (0.9)	0
Tooth abscess	0	1 (0.3)	0	0
Tooth infection	0	1 (0.3)	0	0
Upper respiratory tract infection	1 (0.6)	7 (2.0)	2 (1.7)	2 (2.9)
Urinary tract infection	4 (2.3)	4 (1.2)	0	0
Viral infection	0	0	1 (0.9)	0
Vulvovaginal candidiasis	0	1 (0.3)	0	1 (1.5)

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TABLE 14.3__1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Injury, poisoning and procedural complications	3 (1.7)	6 (1.7)	1 (0.9)	2 (2.9)
Contusion	1 (0.6)	1 (0.3)	0	1 (1.5)
Fall	0	0	1 (0.9)	0
Gastrointestinal stoma necrosis	1 (0.6)	0	0	0
Hand fracture	0	1 (0.3)	0	0
Injury	0	0	0	1 (1.5)
Ligament sprain	1 (0.6)	2 (0.6)	0	1 (1.5)
Rib fracture	0	0	0	1 (1.5)
Skin abrasion	0	1 (0.3)	0	0
Skin laceration	0	0	1 (0.9)	0
Spinal column injury	0	0	1 (0.9)	0
Wound	0	2 (0.6)	0	0

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TABLE 14.3_1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Investigations	4 (2.3)	41 (11.9)	10 (8.6)	9 (13.2)
Alanine aminotransferase increased	0	3 (0.9)	2 (1.7)	0
Amylase increased	0	1 (0.3)	0	0
Aspartate aminotransferase increased	0	5 (1.5)	1 (0.9)	0
Blood alkaline phosphatase increased	0	1 (0.3)	0	0
Blood bilirubin increased	0	1 (0.3)	0	0
Blood chloride decreased	0	1 (0.3)	0	0
Blood cholesterol increased	0	1 (0.3)	0	0
Blood creatine phosphokinase increased	2 (1.1)	16 (4.7)	5 (4.3)	4 (5.9)
Blood creatinine increased	1 (0.6)	2 (0.6)	0	0
Blood glucose increased	1 (0.6)	0	0	0

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TABLE 14.3__1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

MedDRA 23.0 System Organ Class Preferred Term	Part 1 Placebo (N=177) n (%)	Part 1 UPA 45 mg QD (N=344) n (%)	Part 2 Placebo/ UPA 45 mg QD (N=116) n (%)	Part 2 UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Investigations (Cont.)				
Blood phosphorus decreased	0	3 (0.9)	0	0
Blood uric acid increased	0	0	1 (0.9)	0
Body temperature increased	0	1 (0.3)	0	0
Clostridium test positive	0	1 (0.3)	1 (0.9)	1 (1.5)
Gamma-glutamyltransferase increased	1 (0.6)	2 (0.6)	0	0
Glomerular filtration rate decreased	0	1 (0.3)	0	1 (1.5)
Haemoglobin decreased	0	1 (0.3)	0	0
Hepatic enzyme increased	0	1 (0.3)	0	2 (2.9)
Intraocular pressure increased	0	1 (0.3)	0	0
Lymphocyte count decreased	0	2 (0.6)	0	0
Lymphocyte count increased	0	0	1 (0.9)	0

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Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

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TABLE 14.3__1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Investigations (Cont.)				
Lymphocyte percentage decreased	0	1 (0.3)	0	0
Neutrophil count decreased	0	9 (2.6)	0	1 (1.5)
Platelet count decreased	0	1 (0.3)	0	0
Transaminases increased	0	1 (0.3)	0	0
Vitamin D decreased	0	0	1 (0.9)	0
Weight increased	0	1 (0.3)	0	1 (1.5)
White blood cell count decreased	0	7 (2.0)	0	1 (1.5)
White blood cell count increased	0	1 (0.3)	0	0
Metabolism and nutrition disorders	4 (2.3)	6 (1.7)	1 (0.9)	1 (1.5)
Decreased appetite	0	1 (0.3)	0	0
Diabetes mellitus	1 (0.6)	0	0	0

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TABLE 14.3_1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Metabolism and nutrition disorders (Cont.)				
Gout	0	1 (0.3)	0	0
Hypercholesterolaemia	1 (0.6)	0	0	0
Hyperglycaemia	1 (0.6)	0	0	0
Hyperkalaemia	0	1 (0.3)	0	0
Hyperuricaemia	1 (0.6)	1 (0.3)	0	0
Hyponatraemia	0	1 (0.3)	0	0
Hypophosphataemia	0	0	1 (0.9)	0
Hypoproteinaemia	0	0	0	1 (1.5)
Malnutrition	0	1 (0.3)	0	0
Musculoskeletal and connective tissue disorders	18 (10.2)	18 (5.2)	3 (2.6)	3 (4.4)
Arthralgia	3 (1.7)	5 (1.5)	3 (2.6)	2 (2.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
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TABLE 14.3__1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Arthritis	0	2 (0.6)	0	0
Arthropathy	5 (2.8)	1 (0.3)	0	0
Back pain	1 (0.6)	2 (0.6)	0	1 (1.5)
Bursitis	1 (0.6)	0	0	0
Coccydynia	0	1 (0.3)	0	0
Flank pain	0	1 (0.3)	0	0
Joint laxity	0	0	1 (0.9)	0
Joint lock	0	0	1 (0.9)	0
Joint swelling	1 (0.6)	0	0	0
Muscle contracture	0	1 (0.3)	0	0
Muscle disorder	0	1 (0.3)	0	0

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TABLE 14.3__1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Muscle spasms	3 (1.7)	1 (0.3)	0	0
Musculoskeletal chest pain	0	1 (0.3)	0	0
Musculoskeletal discomfort	0	1 (0.3)	0	0
Myalgia	1 (0.6)	1 (0.3)	1 (0.9)	0
Neck pain	1 (0.6)	0	0	0
Osteoarthritis	1 (0.6)	0	0	0
Pain in extremity	2 (1.1)	0	0	0
Pathological fracture	0	1 (0.3)	0	0
Spondyloarthropathy	1 (0.6)	0	0	0
Trigger finger	0	1 (0.3)	0	0
Trismus	1 (0.6)	0	0	0

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TABLE 14.3_1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	1 (0.9)	0
Lipoma	0	0	1 (0.9)	0
Nervous system disorders	11 (6.2)	16 (4.7)	5 (4.3)	2 (2.9)
Burning sensation	0	1 (0.3)	0	0
Cerebral ischaemia	0	1 (0.3)	0	0
Dizziness	0	2 (0.6)	0	1 (1.5)
Headache	9 (5.1)	8 (2.3)	2 (1.7)	2 (2.9)
Hypoaesthesia	0	2 (0.6)	0	0
Migraine	1 (0.6)	1 (0.3)	1 (0.9)	0
Neuropathy peripheral	0	1 (0.3)	0	0
Paraesthesia	0	1 (0.3)	0	0

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TABLE 14.3_1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Nervous system disorders (Cont.)				
Presyncope	1 (0.6)	0	0	0
Somnolence	0	1 (0.3)	0	0
Syncope	0	0	1 (0.9)	0
Taste disorder	0	1 (0.3)	0	0
Tremor	0	0	1 (0.9)	0
Psychiatric disorders	7 (4.0)	7 (2.0)	1 (0.9)	1 (1.5)
Acute psychosis	0	1 (0.3)	0	0
Anxiety	4 (2.3)	1 (0.3)	1 (0.9)	0
Anxiety disorder	0	0	0	1 (1.5)
Depression	1 (0.6)	1 (0.3)	1 (0.9)	0
Insomnia	2 (1.1)	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

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TABLE 14.3_1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

MedDRA 23.0 System Organ Class Preferred Term	Part 1 Placebo (N=177) n (%)	Part 1 UPA 45 mg QD (N=344) n (%)	Part 2 Placebo/ UPA 45 mg QD (N=116) n (%)	Part 2 UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Psychiatric disorders (Cont.)				
Libido decreased	0	1 (0.3)	0	0
Nightmare	0	1 (0.3)	0	0
Panic attack	1 (0.6)	0	0	0
Sleep disorder	1 (0.6)	1 (0.3)	0	0
Renal and urinary disorders	0	2 (0.6)	0	0
Dysuria	0	1 (0.3)	0	0
Ureterolithiasis	0	1 (0.3)	0	0
Reproductive system and breast disorders	0	5 (1.5)	1 (0.9)	0
Amenorrhoea	0	1 (0.3)	0	0
Benign prostatic hyperplasia	0	1 (0.3)	0	0
Menstruation irregular	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

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TABLE 14.3_1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Reproductive system and breast disorders (Cont.)				
Premenstrual headache	0	0	1 (0.9)	0
Semen discolouration	0	1 (0.3)	0	0
Varicocele	0	1 (0.3)	0	0
Respiratory, thoracic and mediastinal disorders	9 (5.1)	5 (1.5)	2 (1.7)	3 (4.4)
Chronic obstructive pulmonary disease	1 (0.6)	0	1 (0.9)	0
Cough	2 (1.1)	2 (0.6)	1 (0.9)	1 (1.5)
Diaphragmalgia	1 (0.6)	0	0	0
Dyspnoea	0	1 (0.3)	0	0
Nasal congestion	1 (0.6)	0	0	0
Oropharyngeal pain	1 (0.6)	1 (0.3)	0	0
Paranasal sinus discomfort	1 (0.6)	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

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TABLE 14.3__1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Productive cough	0	0	0	1 (1.5)
Pulmonary embolism	1 (0.6)	0	0	0
Rhinalgia	0	0	0	1 (1.5)
Rhinitis allergic	0	1 (0.3)	0	0
Sinus congestion	3 (1.7)	0	0	0
Upper-airway cough syndrome	1 (0.6)	0	0	0
Skin and subcutaneous tissue disorders	11 (6.2)	46 (13.4)	11 (9.5)	5 (7.4)
Acne	3 (1.7)	24 (7.0)	6 (5.2)	0
Alopecia	0	2 (0.6)	0	1 (1.5)
Androgenetic alopecia	0	1 (0.3)	0	0
Dermatitis	1 (0.6)	0	0	1 (1.5)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

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TABLE 14.3__1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Dermatitis acneiform	0	1 (0.3)	0	0
Dry skin	1 (0.6)	0	0	0
Eczema	2 (1.1)	1 (0.3)	0	0
Fixed eruption	0	0	0	1 (1.5)
Hyperhidrosis	1 (0.6)	0	0	0
Miliaria	0	1 (0.3)	0	0
Night sweats	1 (0.6)	0	0	0
Papule	0	0	0	1 (1.5)
Photosensitivity reaction	0	1 (0.3)	0	0
Pruritus	1 (0.6)	2 (0.6)	0	0
Pyoderma gangrenosum	1 (0.6)	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

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TABLE 14.3_1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Rash	1 (0.6)	8 (2.3)	4 (3.4)	0
Rash erythematous	1 (0.6)	0	0	0
Rash maculo-papular	0	1 (0.3)	0	0
Rash papular	0	2 (0.6)	0	0
Rosacea	0	0	0	1 (1.5)
Seborrhoeic dermatitis	0	3 (0.9)	1 (0.9)	0
Skin lesion	0	1 (0.3)	0	0
Skin ulcer	0	0	1 (0.9)	0
Telangiectasia	0	0	0	1 (1.5)
Vitiligo	1 (0.6)	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

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UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3_1.2.1.1

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Vascular disorders	4 (2.3)	2 (0.6)	1 (0.9)	2 (2.9)
Essential hypertension	0	0	0	1 (1.5)
Flushing	1 (0.6)	0	0	1 (1.5)
Haematoma	1 (0.6)	0	0	0
Hot flush	0	1 (0.3)	0	0
Hypertension	1 (0.6)	2 (0.6)	0	0
Pelvic venous thrombosis	1 (0.6)	0	0	0
Thrombophlebitis	0	0	1 (0.9)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

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Anhang 4-G1.2: Erhaltungsphase

Anhang 4-G1.2.1: U-ACHIEVE Substudie 3

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UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Any adverse event	186 (75.9)	193 (77.2)	198 (78.9)
Blood and lymphatic system disorders	23 (9.4)	16 (6.4)	16 (6.4)
Anaemia	10 (4.1)	9 (3.6)	7 (2.8)
Eosinophilia	1 (0.4)	0	0
Increased tendency to bruise	0	0	1 (0.4)
Iron deficiency anaemia	5 (2.0)	0	0
Leukocytosis	1 (0.4)	0	0
Leukopenia	3 (1.2)	5 (2.0)	1 (0.4)
Lymphadenopathy	0	0	1 (0.4)
Lymphocytosis	1 (0.4)	0	0
Lymphopenia	2 (0.8)	2 (0.8)	1 (0.4)
Microcytic anaemia	0	0	1 (0.4)
Neutropenia	3 (1.2)	3 (1.2)	6 (2.4)
Splenomegaly	0	1 (0.4)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Blood and lymphatic system disorders (Cont.)			
Thrombocytopenia	1 (0.4)	0	0
Thrombocytosis	0	0	1 (0.4)
Cardiac disorders	5 (2.0)	4 (1.6)	8 (3.2)
Acute myocardial infarction	1 (0.4)	0	0
Arrhythmia	0	1 (0.4)	0
Atrial fibrillation	1 (0.4)	0	0
Bifascicular block	0	0	1 (0.4)
Cardiac failure	0	0	1 (0.4)
Cardiac failure congestive	1 (0.4)	1 (0.4)	0
Chronic left ventricular failure	0	0	1 (0.4)
Palpitations	2 (0.8)	1 (0.4)	0
Pericarditis	0	0	1 (0.4)
Sinus bradycardia	0	1 (0.4)	1 (0.4)
Supraventricular tachycardia	0	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Cardiac disorders (Cont.)			
Tachycardia	1 (0.4)	0	0
Ventricular extrasystoles	0	0	1 (0.4)
Wolff-Parkinson-White syndrome	0	0	1 (0.4)
Congenital, familial and genetic disorders	0	1 (0.4)	2 (0.8)
Dermoid cyst	0	0	1 (0.4)
Gastrointestinal arteriovenous malformation	0	0	1 (0.4)
Gilbert's syndrome	0	1 (0.4)	0
Ear and labyrinth disorders	3 (1.2)	4 (1.6)	1 (0.4)
Deafness neurosensory	0	1 (0.4)	0
Deafness unilateral	0	0	1 (0.4)
Ear pain	0	1 (0.4)	0
Ear swelling	1 (0.4)	0	0
Exostosis of external ear canal	1 (0.4)	0	0
Middle ear effusion	1 (0.4)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

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TABLE 14.3_1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Ear and labyrinth disorders (Cont.)			
Vertigo	0	2 (0.8)	0
Endocrine disorders	1 (0.4)	1 (0.4)	0
Cushing's syndrome	1 (0.4)	0	0
Goitre	0	1 (0.4)	0
Eye disorders	12 (4.9)	7 (2.8)	9 (3.6)
Blepharitis	1 (0.4)	0	2 (0.8)
Cataract	1 (0.4)	2 (0.8)	2 (0.8)
Chalazion	0	0	3 (1.2)
Conjunctival hyperaemia	1 (0.4)	0	0
Conjunctivitis allergic	1 (0.4)	1 (0.4)	1 (0.4)
Corneal opacity	1 (0.4)	0	0
Dry eye	0	1 (0.4)	1 (0.4)
Episcleritis	1 (0.4)	0	0
Eye irritation	0	1 (0.4)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

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TABLE 14.3_1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Eye disorders (Cont.)			
Eye pruritus	0	1 (0.4)	0
Eye swelling	0	1 (0.4)	0
Eyelid disorder	1 (0.4)	0	0
Eyelid rash	1 (0.4)	0	0
Keratitis	1 (0.4)	0	1 (0.4)
Lacrimation increased	0	1 (0.4)	0
Ocular hyperaemia	0	1 (0.4)	1 (0.4)
Periorbital swelling	1 (0.4)	0	0
Ulcerative keratitis	1 (0.4)	0	0
Uveitis	1 (0.4)	0	0
Gastrointestinal disorders	110 (44.9)	62 (24.8)	58 (23.1)
Abdominal distension	1 (0.4)	2 (0.8)	5 (2.0)
Abdominal mass	1 (0.4)	0	0
Abdominal pain	6 (2.4)	6 (2.4)	4 (1.6)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3_1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Gastrointestinal disorders (Cont.)			
Abdominal pain lower	3 (1.2)	0	0
Abdominal pain upper	2 (0.8)	3 (1.2)	2 (0.8)
Abdominal tenderness	0	0	2 (0.8)
Abnormal faeces	1 (0.4)	0	0
Anal fissure	1 (0.4)	1 (0.4)	0
Anal fistula	0	0	1 (0.4)
Anal inflammation	0	0	1 (0.4)
Anal pruritus	2 (0.8)	0	0
Aphthous ulcer	2 (0.8)	1 (0.4)	3 (1.2)
Colitis	3 (1.2)	2 (0.8)	0
Colitis ischaemic	0	1 (0.4)	0
Colitis ulcerative	74 (30.2)	29 (11.6)	19 (7.6)
Colon dysplasia	0	1 (0.4)	0
Constipation	2 (0.8)	3 (1.2)	6 (2.4)

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Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Gastrointestinal disorders (Cont.)			
Defaecation urgency	0	0	1 (0.4)
Dental caries	1 (0.4)	1 (0.4)	0
Dental cyst	0	0	1 (0.4)
Diarrhoea	2 (0.8)	2 (0.8)	2 (0.8)
Dry mouth	0	0	1 (0.4)
Dyspepsia	3 (1.2)	1 (0.4)	1 (0.4)
Dysphagia	1 (0.4)	1 (0.4)	1 (0.4)
Enteritis	0	1 (0.4)	2 (0.8)
Faeces discoloured	0	0	1 (0.4)
Femoral hernia	1 (0.4)	0	0
Flatulence	3 (1.2)	0	2 (0.8)
Gastric ulcer	0	1 (0.4)	0
Gastritis	0	3 (1.2)	1 (0.4)
Gastrooesophageal reflux disease	3 (1.2)	1 (0.4)	3 (1.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3_1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Gastrointestinal disorders (Cont.)			
Gingival swelling	1 (0.4)	0	0
Glossodynia	1 (0.4)	0	0
Haematochezia	1 (0.4)	0	0
Haemorrhoidal haemorrhage	2 (0.8)	1 (0.4)	0
Haemorrhoids	1 (0.4)	2 (0.8)	2 (0.8)
Haemorrhoids thrombosed	1 (0.4)	0	0
Inguinal hernia	0	1 (0.4)	0
Intestinal obstruction	0	1 (0.4)	0
Irritable bowel syndrome	0	0	1 (0.4)
Large intestine perforation	1 (0.4)	0	0
Large intestine polyp	2 (0.8)	0	1 (0.4)
Lip swelling	0	0	1 (0.4)
Mouth cyst	1 (0.4)	0	0
Mouth ulceration	2 (0.8)	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Gastrointestinal disorders (Cont.)			
Mucous stools	1 (0.4)	0	0
Nausea	5 (2.0)	4 (1.6)	5 (2.0)
Noninfective gingivitis	0	0	1 (0.4)
Odynophagia	1 (0.4)	0	0
Oesophagitis	0	1 (0.4)	0
Oral disorder	0	0	1 (0.4)
Pancreatitis	1 (0.4)	0	0
Periodontal disease	1 (0.4)	0	1 (0.4)
Proctalgia	0	1 (0.4)	0
Proctitis	1 (0.4)	0	0
Rectal discharge	0	0	1 (0.4)
Rectal haemorrhage	1 (0.4)	0	1 (0.4)
Rectal spasm	1 (0.4)	0	0
Rectal tenesmus	1 (0.4)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Gastrointestinal disorders (Cont.)			
Stomatitis	3 (1.2)	1 (0.4)	2 (0.8)
Tooth impacted	0	1 (0.4)	0
Tooth loss	0	0	1 (0.4)
Toothache	0	4 (1.6)	3 (1.2)
Umbilical hernia	1 (0.4)	0	0
Vomiting	1 (0.4)	1 (0.4)	1 (0.4)
General disorders and administration site conditions	22 (9.0)	16 (6.4)	28 (11.2)
Chest discomfort	0	1 (0.4)	0
Chest pain	1 (0.4)	2 (0.8)	2 (0.8)
Chills	2 (0.8)	1 (0.4)	0
Device intolerance	1 (0.4)	0	0
Drug ineffective	1 (0.4)	0	0
Fatigue	5 (2.0)	2 (0.8)	4 (1.6)
Generalised oedema	0	1 (0.4)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
General disorders and administration site conditions (Cont.)			
Hyperthermia	1 (0.4)	0	0
Inflammation	0	0	1 (0.4)
Influenza like illness	1 (0.4)	0	2 (0.8)
Injection site pain	0	1 (0.4)	2 (0.8)
Malaise	1 (0.4)	0	2 (0.8)
Mass	0	0	1 (0.4)
Mucosal dryness	1 (0.4)	0	0
Nodule	0	0	1 (0.4)
Non-cardiac chest pain	1 (0.4)	0	0
Oedema	0	1 (0.4)	0
Oedema peripheral	3 (1.2)	1 (0.4)	1 (0.4)
Pain	1 (0.4)	1 (0.4)	0
Peripheral swelling	1 (0.4)	1 (0.4)	1 (0.4)
Pyrexia	7 (2.9)	8 (3.2)	15 (6.0)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
General disorders and administration site conditions (Cont.)			
Sensation of foreign body	1 (0.4)	0	0
Swelling	0	0	1 (0.4)
Swelling face	0	0	1 (0.4)
Hepatobiliary disorders	3 (1.2)	6 (2.4)	2 (0.8)
Drug-induced liver injury	0	1 (0.4)	1 (0.4)
Hepatic function abnormal	2 (0.8)	1 (0.4)	0
Hepatic steatosis	0	2 (0.8)	0
Hypertransaminasaemia	0	1 (0.4)	0
Liver disorder	0	0	1 (0.4)
Liver injury	1 (0.4)	1 (0.4)	0
Immune system disorders	1 (0.4)	2 (0.8)	1 (0.4)
Drug hypersensitivity	1 (0.4)	0	0
Seasonal allergy	0	2 (0.8)	1 (0.4)
Infections and infestations	92 (37.6)	98 (39.2)	105 (41.8)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Infections and infestations (Cont.)			
Abdominal abscess	1 (0.4)	0	0
Acarodermatitis	0	2 (0.8)	0
Acute endocarditis	1 (0.4)	0	0
Anal abscess	0	1 (0.4)	0
Anorectal infection	1 (0.4)	0	0
Arthritis bacterial	0	1 (0.4)	0
Bacterial infection	0	0	1 (0.4)
Bacterial vaginosis	1 (0.4)	0	0
Breast abscess	0	1 (0.4)	0
Bronchitis	3 (1.2)	5 (2.0)	1 (0.4)
Bursitis infective	0	0	1 (0.4)
Campylobacter infection	0	1 (0.4)	0
Candida infection	1 (0.4)	0	0
Cellulitis	0	1 (0.4)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Infections and infestations (Cont.)			
Clostridium difficile infection	2 (0.8)	1 (0.4)	2 (0.8)
Conjunctivitis	0	2 (0.8)	1 (0.4)
COVID-19	8 (3.3)	5 (2.0)	10 (4.0)
COVID-19 pneumonia	1 (0.4)	1 (0.4)	2 (0.8)
Cystitis	0	3 (1.2)	2 (0.8)
Cytomegalovirus infection	1 (0.4)	1 (0.4)	0
Demodicidosis	0	3 (1.2)	2 (0.8)
Dermatophytosis	1 (0.4)	0	0
Diverticulitis	0	0	1 (0.4)
Ear infection	0	1 (0.4)	2 (0.8)
Enteritis infectious	0	0	1 (0.4)
Enterovirus infection	0	0	1 (0.4)
Escherichia urinary tract infection	0	1 (0.4)	0
Folliculitis	4 (1.6)	4 (1.6)	9 (3.6)

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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Infections and infestations (Cont.)			
Fungal infection	0	0	1 (0.4)
Fungal skin infection	0	0	2 (0.8)
Furuncle	0	1 (0.4)	0
Gastroenteritis	4 (1.6)	5 (2.0)	3 (1.2)
Gastroenteritis viral	0	0	2 (0.8)
Gingival abscess	0	0	1 (0.4)
Gingivitis	0	1 (0.4)	0
Haemophilus infection	1 (0.4)	0	0
Herpes dermatitis	0	1 (0.4)	0
Herpes simplex	0	2 (0.8)	1 (0.4)
Herpes zoster	0	11 (4.4)	14 (5.6)
Herpes zoster meningitis	0	0	1 (0.4)
Hordeolum	3 (1.2)	0	2 (0.8)
Impetigo	1 (0.4)	1 (0.4)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Infections and infestations (Cont.)			
Infected dermal cyst	0	1 (0.4)	0
Influenza	3 (1.2)	7 (2.8)	8 (3.2)
Large intestine infection	0	1 (0.4)	0
Laryngitis	1 (0.4)	0	1 (0.4)
Latent tuberculosis	0	0	2 (0.8)
Lower respiratory tract infection	1 (0.4)	1 (0.4)	0
Mastitis	0	1 (0.4)	0
Molluscum contagiosum	1 (0.4)	0	0
Nasopharyngitis	20 (8.2)	23 (9.2)	26 (10.4)
Oesophageal candidiasis	0	1 (0.4)	0
Onychomycosis	2 (0.8)	1 (0.4)	1 (0.4)
Oral candidiasis	2 (0.8)	1 (0.4)	1 (0.4)
Oral herpes	3 (1.2)	5 (2.0)	7 (2.8)
Otitis externa	1 (0.4)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
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TABLE 14.3_1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Infections and infestations (Cont.)			
Papilloma viral infection	0	0	1 (0.4)
Paronychia	0	1 (0.4)	0
Periodontitis	1 (0.4)	0	2 (0.8)
Pharyngitis	4 (1.6)	2 (0.8)	1 (0.4)
Pharyngitis streptococcal	1 (0.4)	2 (0.8)	1 (0.4)
Pilonidal cyst	0	1 (0.4)	0
Pleural infection	0	0	1 (0.4)
Pneumocystis jirovecii pneumonia	1 (0.4)	0	0
Pneumonia	4 (1.6)	1 (0.4)	2 (0.8)
Pneumonia cryptococcal	0	0	2 (0.8)
Pneumonia viral	0	0	1 (0.4)
Pulpitis dental	0	1 (0.4)	1 (0.4)
Pustule	1 (0.4)	0	1 (0.4)
Pyelonephritis	1 (0.4)	1 (0.4)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Infections and infestations (Cont.)			
Pyoderma	0	0	1 (0.4)
Respiratory tract infection viral	1 (0.4)	4 (1.6)	0
Rhinitis	3 (1.2)	1 (0.4)	2 (0.8)
Serratia infection	1 (0.4)	0	0
Sinusitis	4 (1.6)	2 (0.8)	3 (1.2)
Staphylococcal infection	1 (0.4)	0	0
Tinea infection	2 (0.8)	0	0
Tinea pedis	2 (0.8)	3 (1.2)	1 (0.4)
Tinea versicolour	0	1 (0.4)	1 (0.4)
Tonsillitis	1 (0.4)	2 (0.8)	3 (1.2)
Tooth abscess	0	1 (0.4)	1 (0.4)
Tooth infection	2 (0.8)	0	3 (1.2)
Trichomoniasis	1 (0.4)	0	0
Upper respiratory tract infection	8 (3.3)	12 (4.8)	11 (4.4)

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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Infections and infestations (Cont.)			
Urinary tract infection	6 (2.4)	7 (2.8)	3 (1.2)
Varicella zoster virus infection	0	1 (0.4)	0
Viraemia	1 (0.4)	0	0
Viral infection	0	1 (0.4)	2 (0.8)
Viral upper respiratory tract infection	3 (1.2)	1 (0.4)	3 (1.2)
Vulvovaginal candidiasis	1 (0.4)	1 (0.4)	1 (0.4)
Vulvovaginal mycotic infection	1 (0.4)	1 (0.4)	1 (0.4)
Injury, poisoning and procedural complications	11 (4.5)	12 (4.8)	12 (4.8)
Animal scratch	1 (0.4)	0	0
Bone contusion	1 (0.4)	0	1 (0.4)
Contusion	0	0	3 (1.2)
Exposure to toxic agent	0	1 (0.4)	0
Eye injury	0	0	1 (0.4)
Heat illness	1 (0.4)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
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TABLE 14.3_1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Injury, poisoning and procedural complications (Cont.)			
Injury	1 (0.4)	0	0
Joint injury	0	2 (0.8)	0
Ligament sprain	1 (0.4)	1 (0.4)	1 (0.4)
Limb injury	1 (0.4)	1 (0.4)	0
Limb traumatic amputation	0	0	1 (0.4)
Lumbar vertebral fracture	0	0	1 (0.4)
Muscle rupture	0	0	1 (0.4)
Muscle strain	1 (0.4)	1 (0.4)	0
Post-traumatic pain	0	2 (0.8)	0
Pulmonary contusion	0	1 (0.4)	0
Rib fracture	1 (0.4)	0	0
Road traffic accident	1 (0.4)	0	0
Skin laceration	1 (0.4)	3 (1.2)	0
Spinal compression fracture	1 (0.4)	0	0

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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
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TABLE 14.3_1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Injury, poisoning and procedural complications (Cont.)			
Subcutaneous haematoma	1 (0.4)	0	0
Thoracic vertebral fracture	0	1 (0.4)	0
Tooth fracture	1 (0.4)	0	2 (0.8)
Wound	0	1 (0.4)	0
Wrist fracture	0	0	1 (0.4)
Investigations	16 (6.5)	42 (16.8)	53 (21.1)
Alanine aminotransferase increased	1 (0.4)	7 (2.8)	7 (2.8)
Amylase increased	1 (0.4)	1 (0.4)	0
Antinuclear antibody increased	1 (0.4)	0	0
Aspartate aminotransferase increased	2 (0.8)	9 (3.6)	5 (2.0)
Blood albumin decreased	0	1 (0.4)	0
Blood albumin increased	0	1 (0.4)	1 (0.4)
Blood bilirubin increased	0	2 (0.8)	3 (1.2)
Blood calcium increased	0	1 (0.4)	0

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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3_1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Investigations (Cont.)			
Blood cholesterol decreased	0	1 (0.4)	0
Blood cholesterol increased	0	2 (0.8)	6 (2.4)
Blood creatine phosphokinase increased	5 (2.0)	15 (6.0)	19 (7.6)
Blood creatinine increased	2 (0.8)	0	4 (1.6)
Blood folate decreased	0	1 (0.4)	0
Blood glucose increased	0	1 (0.4)	1 (0.4)
Blood potassium decreased	0	2 (0.8)	0
Blood potassium increased	0	1 (0.4)	0
Blood sodium increased	0	1 (0.4)	0
Blood triglycerides abnormal	0	1 (0.4)	0
Blood urine present	0	0	2 (0.8)
Body temperature increased	0	1 (0.4)	1 (0.4)
Gamma-glutamyltransferase increased	1 (0.4)	5 (2.0)	1 (0.4)
Glomerular filtration rate decreased	1 (0.4)	1 (0.4)	0

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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
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TABLE 14.3_1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Investigations (Cont.)			
Granulocyte count decreased	0	0	1 (0.4)
Grip strength decreased	0	1 (0.4)	0
Haemoglobin decreased	1 (0.4)	2 (0.8)	1 (0.4)
Haemoglobin urine present	0	0	1 (0.4)
Hepatic enzyme increased	0	1 (0.4)	1 (0.4)
Hepatitis B DNA assay positive	0	0	1 (0.4)
High density lipoprotein increased	0	3 (1.2)	1 (0.4)
Lipase increased	0	1 (0.4)	0
Liver function test increased	0	0	1 (0.4)
Low density lipoprotein decreased	0	1 (0.4)	0
Low density lipoprotein increased	0	1 (0.4)	5 (2.0)
Lymphocyte count decreased	2 (0.8)	5 (2.0)	4 (1.6)
Lymphocyte count increased	1 (0.4)	1 (0.4)	2 (0.8)
Lymphocyte percentage decreased	0	1 (0.4)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Investigations (Cont.)			
Lymphocyte percentage increased	0	1 (0.4)	0
Monocyte count increased	0	1 (0.4)	0
Neutrophil count decreased	2 (0.8)	5 (2.0)	8 (3.2)
Neutrophil count increased	2 (0.8)	2 (0.8)	2 (0.8)
Neutrophil percentage increased	0	0	1 (0.4)
Platelet count decreased	1 (0.4)	0	0
Platelet count increased	0	0	2 (0.8)
Prealbumin decreased	0	1 (0.4)	0
Protein total decreased	0	1 (0.4)	0
Protein total increased	0	0	1 (0.4)
Protein urine present	1 (0.4)	1 (0.4)	1 (0.4)
Red blood cell count decreased	0	1 (0.4)	2 (0.8)
Red blood cell sedimentation rate increased	0	1 (0.4)	0
Staphylococcus test positive	0	1 (0.4)	0

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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Investigations (Cont.)			
Urine analysis abnormal	0	1 (0.4)	0
Vitamin D decreased	0	1 (0.4)	0
Weight increased	0	1 (0.4)	2 (0.8)
White blood cell count decreased	2 (0.8)	4 (1.6)	6 (2.4)
White blood cell count increased	0	1 (0.4)	1 (0.4)
White blood cells urine positive	0	1 (0.4)	0
Metabolism and nutrition disorders	16 (6.5)	16 (6.4)	15 (6.0)
Decreased appetite	1 (0.4)	0	0
Dyslipidaemia	0	4 (1.6)	1 (0.4)
Folate deficiency	0	0	1 (0.4)
Glucose tolerance impaired	1 (0.4)	0	0
Gout	0	1 (0.4)	0
Hypercalcaemia	0	0	1 (0.4)
Hypercholesterolaemia	2 (0.8)	4 (1.6)	4 (1.6)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Metabolism and nutrition disorders (Cont.)			
Hyperglycaemia	1 (0.4)	2 (0.8)	0
Hyperlipasaemia	1 (0.4)	0	0
Hyperlipidaemia	0	1 (0.4)	2 (0.8)
Hyperuricaemia	0	0	1 (0.4)
Hypokalaemia	3 (1.2)	1 (0.4)	0
Hyponatraemia	2 (0.8)	0	1 (0.4)
Hypophosphataemia	1 (0.4)	0	0
Iron deficiency	1 (0.4)	0	1 (0.4)
Metabolic syndrome	0	0	1 (0.4)
Type 2 diabetes mellitus	1 (0.4)	0	0
Vitamin D deficiency	2 (0.8)	3 (1.2)	2 (0.8)
Musculoskeletal and connective tissue disorders	51 (20.8)	36 (14.4)	27 (10.8)
Ankylosing spondylitis	1 (0.4)	0	0
Arthralgia	25 (10.2)	14 (5.6)	7 (2.8)

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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Arthritis	0	1 (0.4)	0
Arthritis enteropathic	1 (0.4)	0	0
Arthropathy	7 (2.9)	1 (0.4)	3 (1.2)
Back pain	10 (4.1)	7 (2.8)	1 (0.4)
Bone pain	0	0	1 (0.4)
Bursitis	0	0	1 (0.4)
Cervical spinal stenosis	0	0	1 (0.4)
Chondromalacia	0	0	1 (0.4)
Coccydynia	1 (0.4)	0	0
Costochondritis	1 (0.4)	0	1 (0.4)
Fibromyalgia	0	1 (0.4)	0
Flank pain	1 (0.4)	0	1 (0.4)
Haemarthrosis	1 (0.4)	0	0
Intervertebral disc degeneration	1 (0.4)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Joint stiffness	0	1 (0.4)	0
Joint swelling	0	2 (0.8)	1 (0.4)
Lumbar spinal stenosis	0	0	1 (0.4)
Muscular weakness	1 (0.4)	0	0
Musculoskeletal chest pain	2 (0.8)	1 (0.4)	0
Musculoskeletal pain	3 (1.2)	2 (0.8)	1 (0.4)
Musculoskeletal stiffness	1 (0.4)	0	0
Myalgia	2 (0.8)	2 (0.8)	1 (0.4)
Myositis	1 (0.4)	1 (0.4)	0
Neck pain	1 (0.4)	2 (0.8)	2 (0.8)
Osteitis	0	0	1 (0.4)
Osteoarthritis	2 (0.8)	0	0
Osteonecrosis	0	1 (0.4)	0
Osteopenia	0	1 (0.4)	2 (0.8)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

800

22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
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TABLE 14.3_1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Osteoporosis	1 (0.4)	1 (0.4)	1 (0.4)
Pain in extremity	4 (1.6)	1 (0.4)	3 (1.2)
Periarthritis	0	0	2 (0.8)
Plantar fasciitis	0	0	1 (0.4)
Rotator cuff syndrome	2 (0.8)	2 (0.8)	0
Spinal osteoarthritis	1 (0.4)	0	0
Spondyloarthropathy	1 (0.4)	1 (0.4)	0
Tendon pain	1 (0.4)	0	0
Tendonitis	1 (0.4)	0	0
Tenosynovitis	1 (0.4)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (1.2)	5 (2.0)	8 (3.2)
Adenocarcinoma of colon	0	0	1 (0.4)
Basal cell carcinoma	0	0	3 (1.2)
Benign spleen tumour	0	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
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TABLE 14.3_1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Colon adenoma	1 (0.4)	0	0
Fibrous histiocytoma	0	0	1 (0.4)
Haemangioma of skin	0	1 (0.4)	0
Invasive breast carcinoma	1 (0.4)	1 (0.4)	0
Melanocytic naevus	0	1 (0.4)	0
Ovarian germ cell teratoma benign	0	1 (0.4)	0
Seborrhoeic keratosis	1 (0.4)	1 (0.4)	0
Skin papilloma	0	0	1 (0.4)
Small cell carcinoma	0	0	1 (0.4)
Nervous system disorders	22 (9.0)	18 (7.2)	20 (8.0)
Carpal tunnel syndrome	1 (0.4)	1 (0.4)	2 (0.8)
Cervical radiculopathy	1 (0.4)	0	0
Dizziness	3 (1.2)	2 (0.8)	2 (0.8)
Dysgeusia	1 (0.4)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Nervous system disorders (Cont.)			
Epilepsy	1 (0.4)	0	0
Essential tremor	1 (0.4)	0	0
Headache	11 (4.5)	8 (3.2)	9 (3.6)
Hyperaesthesia	1 (0.4)	0	0
Hypoaesthesia	1 (0.4)	4 (1.6)	1 (0.4)
Lumbosacral radiculopathy	0	1 (0.4)	0
Migraine	3 (1.2)	1 (0.4)	3 (1.2)
Nerve compression	0	0	1 (0.4)
Neuropathy peripheral	1 (0.4)	0	0
Paraesthesia	2 (0.8)	1 (0.4)	1 (0.4)
Sciatica	0	1 (0.4)	0
Spondylitic myelopathy	0	0	1 (0.4)
Subarachnoid haemorrhage	0	0	1 (0.4)
Subdural effusion	0	1 (0.4)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3_1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Nervous system disorders (Cont.)			
Syncope	1 (0.4)	0	0
Psychiatric disorders	14 (5.7)	7 (2.8)	13 (5.2)
Anxiety	6 (2.4)	1 (0.4)	2 (0.8)
Anxiety disorder	0	1 (0.4)	0
Depressed mood	0	0	1 (0.4)
Depression	2 (0.8)	1 (0.4)	4 (1.6)
Insomnia	7 (2.9)	2 (0.8)	8 (3.2)
Irritability	1 (0.4)	0	0
Mental disorder	1 (0.4)	0	0
Panic attack	0	1 (0.4)	0
Sleep disorder	0	1 (0.4)	0
Suicidal ideation	1 (0.4)	0	0
Renal and urinary disorders	7 (2.9)	6 (2.4)	12 (4.8)
Acute kidney injury	1 (0.4)	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Renal and urinary disorders (Cont.)			
Dysuria	1 (0.4)	0	1 (0.4)
Glycosuria	1 (0.4)	0	0
Haematuria	1 (0.4)	1 (0.4)	2 (0.8)
Hydronephrosis	1 (0.4)	0	0
Hypertonic bladder	0	0	1 (0.4)
Leukocyturia	1 (0.4)	0	0
Micturition disorder	0	0	1 (0.4)
Nephrocalcinosis	1 (0.4)	0	0
Nephrolithiasis	2 (0.8)	3 (1.2)	2 (0.8)
Pollakiuria	0	0	1 (0.4)
Proteinuria	1 (0.4)	0	0
Renal colic	0	0	4 (1.6)
Renal impairment	0	1 (0.4)	0
Ureterolithiasis	0	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3_1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Renal and urinary disorders (Cont.)			
Urinary retention	0	1 (0.4)	0
Reproductive system and breast disorders	8 (3.3)	10 (4.0)	7 (2.8)
Amenorrhoea	0	1 (0.4)	1 (0.4)
Bartholin's cyst	1 (0.4)	0	0
Benign prostatic hyperplasia	0	1 (0.4)	2 (0.8)
Breast cyst	1 (0.4)	1 (0.4)	0
Breast pain	0	1 (0.4)	0
Cervical dysplasia	0	0	2 (0.8)
Dysfunctional uterine bleeding	1 (0.4)	0	0
Dysmenorrhoea	0	1 (0.4)	0
Menopausal symptoms	1 (0.4)	0	0
Menorrhagia	0	1 (0.4)	0
Menstruation irregular	1 (0.4)	0	0
Metrorrhagia	0	1 (0.4)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3_1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Reproductive system and breast disorders (Cont.)			
Ovarian vein thrombosis	1 (0.4)	0	0
Polycystic ovaries	0	1 (0.4)	0
Prostatic mass	0	0	1 (0.4)
Prostatitis	1 (0.4)	1 (0.4)	1 (0.4)
Semen discolouration	0	0	1 (0.4)
Vaginal discharge	0	1 (0.4)	0
Vaginal haemorrhage	1 (0.4)	1 (0.4)	0
Vulvovaginal pruritus	1 (0.4)	0	0
Respiratory, thoracic and mediastinal disorders	18 (7.3)	15 (6.0)	20 (8.0)
Acute respiratory failure	1 (0.4)	0	1 (0.4)
Asthma	0	1 (0.4)	1 (0.4)
Bronchiectasis	1 (0.4)	0	0
Chronic obstructive pulmonary disease	0	1 (0.4)	0
Cough	3 (1.2)	3 (1.2)	4 (1.6)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Dyspnoea	0	1 (0.4)	0
Dyspnoea exertional	0	0	1 (0.4)
Emphysema	0	0	1 (0.4)
Epistaxis	0	0	1 (0.4)
Haemoptysis	1 (0.4)	0	0
Hiccups	1 (0.4)	0	1 (0.4)
Interstitial lung disease	1 (0.4)	0	0
Lung hyperinflation	0	0	1 (0.4)
Lung infiltration	0	0	1 (0.4)
Nasal congestion	3 (1.2)	0	2 (0.8)
Noninfective bronchitis	0	0	1 (0.4)
Oropharyngeal pain	5 (2.0)	3 (1.2)	6 (2.4)
Productive cough	1 (0.4)	2 (0.8)	0
Pulmonary embolism	0	2 (0.8)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pulmonary haemorrhage	1 (0.4)	0	0
Rhinitis allergic	2 (0.8)	1 (0.4)	1 (0.4)
Rhinorrhoea	0	0	1 (0.4)
Sinus congestion	2 (0.8)	0	1 (0.4)
Throat irritation	0	0	1 (0.4)
Upper respiratory tract inflammation	2 (0.8)	1 (0.4)	0
Upper-airway cough syndrome	0	0	1 (0.4)
Skin and subcutaneous tissue disorders	49 (20.0)	38 (15.2)	50 (19.9)
Acne	8 (3.3)	6 (2.4)	9 (3.6)
Alopecia	0	2 (0.8)	3 (1.2)
Asteatosis	0	0	1 (0.4)
Dermal cyst	0	1 (0.4)	1 (0.4)
Dermatitis	3 (1.2)	2 (0.8)	3 (1.2)
Dermatitis atopic	2 (0.8)	3 (1.2)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Dermatitis contact	2 (0.8)	1 (0.4)	1 (0.4)
Diffuse alopecia	0	1 (0.4)	0
Dry skin	5 (2.0)	0	1 (0.4)
Dyshidrotic eczema	2 (0.8)	0	0
Ecchymosis	1 (0.4)	0	1 (0.4)
Eczema	5 (2.0)	2 (0.8)	5 (2.0)
Eczema asteatotic	1 (0.4)	0	1 (0.4)
Erythema	2 (0.8)	3 (1.2)	1 (0.4)
Erythema nodosum	1 (0.4)	0	1 (0.4)
Mechanical urticaria	0	0	1 (0.4)
Neurodermatitis	1 (0.4)	0	0
Night sweats	1 (0.4)	1 (0.4)	1 (0.4)
Onychoclasis	1 (0.4)	0	1 (0.4)
Onycholysis	0	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Palmoplantar pustulosis	0	1 (0.4)	0
Panniculitis	0	1 (0.4)	0
Papule	0	0	1 (0.4)
Photodermatosis	1 (0.4)	0	0
Photosensitivity reaction	1 (0.4)	0	1 (0.4)
Pruritus	6 (2.4)	2 (0.8)	1 (0.4)
Pyoderma gangrenosum	1 (0.4)	0	0
Rash	9 (3.7)	8 (3.2)	11 (4.4)
Rash erythematous	1 (0.4)	1 (0.4)	0
Rash follicular	0	1 (0.4)	0
Rash macular	0	1 (0.4)	1 (0.4)
Rash maculo-papular	1 (0.4)	1 (0.4)	1 (0.4)
Rash papular	0	1 (0.4)	0
Rash pruritic	0	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Rosacea	1 (0.4)	2 (0.8)	1 (0.4)
Seborrhoeic dermatitis	7 (2.9)	2 (0.8)	2 (0.8)
Skin burning sensation	1 (0.4)	0	0
Skin erosion	1 (0.4)	0	0
Skin exfoliation	1 (0.4)	0	0
Skin fissures	1 (0.4)	0	0
Skin hyperpigmentation	1 (0.4)	0	0
Skin lesion	0	0	2 (0.8)
Skin mass	0	1 (0.4)	0
Skin ulcer	0	0	1 (0.4)
Urticaria	2 (0.8)	0	4 (1.6)
Surgical and medical procedures	0	2 (0.8)	0
Abortion induced	0	2 (0.8)	0
Vascular disorders	4 (1.6)	8 (3.2)	9 (3.6)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
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Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
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TABLE 14.3 1.2.1.1.3

Subjects with Treatment-Emergent Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Vascular disorders (Cont.)			
Aortic aneurysm	0	1 (0.4)	0
Aortic arteriosclerosis	0	0	1 (0.4)
Bleeding varicose vein	0	1 (0.4)	0
Deep vein thrombosis	0	0	2 (0.8)
Haematoma	0	0	1 (0.4)
Hypertension	2 (0.8)	6 (2.4)	5 (2.0)
Hypotension	1 (0.4)	0	0
Peripheral arterial occlusive disease	0	0	1 (0.4)
Venous thrombosis	1 (0.4)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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Anhang 4-G2: Schwere UE nach SOC/PT

Anhang 4-G2.1: Induktionsphase

Anhang 4-G2.1.1: U-ACHIEVE Substudie 1

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UPADACITINIB (ULCERATIVE COLITIS)
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R&D/20/1294 - CLINICAL/STATISTICAL
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TABLE 14.3__1.9 A

Number and Percentage of Subjects with Treatment-Emergent Severe Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Substudy 1 - SA1A Population)

		ABT-494				
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=46) n (%)	7.5 mg QD (N=47) n (%)	15 mg QD (N=49) n (%)	30 mg QD (N=52) n (%)	45 mg QD (N=56) n (%)	Total (N=204) n (%)
Any adverse event	7 (15.2)	2 (4.3)	3 (6.1)	3 (5.8)	4 (7.1)	12 (5.9)
Blood and lymphatic system disorders	0	0	1 (2.0)	0	0	1 (0.5)
Anaemia	0	0	1 (2.0)	0	0	1 (0.5)
Gastrointestinal disorders	4 (8.7)	0	1 (2.0)	2 (3.8)	2 (3.6)	5 (2.5)
Anal ulcer	0	0	0	0	1 (1.8)	1 (0.5)
Colitis	1 (2.2)	0	0	0	0	0
Colitis ulcerative	2 (4.3)	0	1 (2.0)	2 (3.8)	1 (1.8)	4 (2.0)
Dyschezia	1 (2.2)	0	0	0	0	0
General disorders and administration site conditions	0	1 (2.1)	0	1 (1.9)	0	2 (1.0)
Chills	0	0	0	1 (1.9)	0	1 (0.5)
Pyrexia	0	1 (2.1)	0	1 (1.9)	0	2 (1.0)
Infections and infestations	2 (4.3)	0	1 (2.0)	0	1 (1.8)	2 (1.0)
Cellulitis	1 (2.2)	0	0	0	0	0

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Treatment-emergent AEs during Substudy 1 are defined as events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and within 30 days after the last dose of the study medication in Substudy 1 for subjects who discontinued Substudy 1 and are not enrolled into Substudy 3 or study M14-533, or events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and up to the first dose of the study medication in Substudy 3 or study M14-533.

program source code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234ae-ss1.sas

1826

09JUL2021 10:50 <! m14234ae-ss1.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 1
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 2

TABLE 14.3 1.9 A

Number and Percentage of Subjects with Treatment-Emergent Severe Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Substudy 1 - SA1A Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=46) n (%)	ABT-494 7.5 mg QD (N=47) n (%)	ABT-494 15 mg QD (N=49) n (%)	ABT-494 30 mg QD (N=52) n (%)	ABT-494 45 mg QD (N=56) n (%)	ABT-494 Total (N=204) n (%)
Infections and infestations (Cont.)						
Respiratory syncytial virus infection	0	0	0	0	1 (1.8)	1 (0.5)
Sepsis	0	0	0	0	1 (1.8)	1 (0.5)
Sinusitis	1 (2.2)	0	0	0	0	0
Urosepsis	0	0	1 (2.0)	0	0	1 (0.5)
Investigations	0	1 (2.1)	1 (2.0)	0	0	2 (1.0)
Blood creatine phosphokinase increased	0	0	1 (2.0)	0	0	1 (0.5)
Haemoglobin decreased	0	1 (2.1)	0	0	0	1 (0.5)
Metabolism and nutrition disorders	1 (2.2)	0	0	0	0	0
Hypophosphataemia	1 (2.2)	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	0	0	0	0	1 (1.8)	1 (0.5)
Pulmonary embolism	0	0	0	0	1 (1.8)	1 (0.5)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Treatment-emergent AEs during Substudy 1 are defined as events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and within 30 days after the last dose of the study medication in Substudy 1 for subjects who discontinued Substudy 1 and are not enrolled into Substudy 3 or study M14-533, or events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and up to the first dose of the study medication in Substudy 3 or study M14-533.

program source code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234ae-ss1.sas

1827

Anhang 4-G2.1.2: U-ACHIEVE Substudie 2

09JUL2021 10:50 <! m14234aesum-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 3

TABLE 14.3_1.3.3 B

Subjects with Treatment-Emergent Severe Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Any adverse event	14 (9.0)	9 (2.8)	5 (5.9)	1 (1.7)
Blood and lymphatic system disorders	1 (0.6)	2 (0.6)	1 (1.2)	0
Anaemia	1 (0.6)	0	1 (1.2)	0
Lymphopenia	0	2 (0.6)	0	0
Gastrointestinal disorders	11 (7.1)	3 (0.9)	1 (1.2)	1 (1.7)
Abdominal pain	0	1 (0.3)	0	0
Colitis	1 (0.6)	0	0	0
Colitis ulcerative	9 (5.8)	2 (0.6)	1 (1.2)	1 (1.7)
Flatulence	1 (0.6)	0	0	0
Infections and infestations	1 (0.6)	2 (0.6)	1 (1.2)	0
Appendicitis	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

2244

09JUL2021 10:50 <! m14234aesum-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 3

TABLE 14.3_1.3.3 B

Subjects with Treatment-Emergent Severe Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Infections and infestations (Cont.)				
Cellulitis	1 (0.6)	0	0	0
Gastroenteritis norovirus	0	1 (0.3)	0	0
Herpes zoster	0	0	1 (1.2)	0
Investigations	2 (1.3)	3 (0.9)	1 (1.2)	0
Amylase increased	0	1 (0.3)	0	0
Blood creatine phosphokinase increased	1 (0.6)	1 (0.3)	0	0
Haemoglobin decreased	1 (0.6)	0	0	0
Neutrophil count decreased	0	1 (0.3)	1 (1.2)	0
White blood cell count increased	0	1 (0.3)	0	0
Metabolism and nutrition disorders	1 (0.6)	1 (0.3)	0	0
Hypoalbuminaemia	1 (0.6)	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

2245

09JUL2021 10:50 <! m14234aesum-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 3 OF 3

TABLE 14.3_1.3.3 B

Subjects with Treatment-Emergent Severe Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Metabolism and nutrition disorders (Cont.)				
Hypophosphataemia	0	1 (0.3)	0	0
Skin and subcutaneous tissue disorders	0	1 (0.3)	1 (1.2)	0
Eczema	0	0	1 (1.2)	0
Erythema multiforme	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

2246

Anhang 4-G2.1.3: U-ACCOMPLISH

10JUN2021 16:30 <! m14675aesum.sas DBV O >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-675
R&D/21/0078 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 2

TABLE 14.3 1.3.3

Subjects with Treatment-Emergent Severe Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Any adverse event	7 (4.0)	9 (2.6)	2 (1.7)	0
Blood and lymphatic system disorders	0	1 (0.3)	0	0
Lymphopenia	0	1 (0.3)	0	0
Gastrointestinal disorders	6 (3.4)	3 (0.9)	0	0
Colitis	1 (0.6)	0	0	0
Colitis ulcerative	4 (2.3)	3 (0.9)	0	0
Diarrhoea	0	1 (0.3)	0	0
Diarrhoea haemorrhagic	0	1 (0.3)	0	0
Large intestine perforation	1 (0.6)	0	0	0
Infections and infestations	0	1 (0.3)	1 (0.9)	0
COVID-19 pneumonia	0	1 (0.3)	1 (0.9)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /homx/SDA/ABT-494/UC/CSR/M14-675/O/14.3/PCMS_RUN/m14675aesum.sas

1131

10JUN2021 16:30 <! m14675aesum.sas DBV O >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-675
R&D/21/0078 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 2

TABLE 14.3 1.3.3

Subjects with Treatment-Emergent Severe Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Investigations	0	4 (1.2)	0	0
Blood creatine phosphokinase increased	0	1 (0.3)	0	0
Blood phosphorus decreased	0	1 (0.3)	0	0
Haemoglobin decreased	0	1 (0.3)	0	0
Neutrophil count decreased	0	1 (0.3)	0	0
Nervous system disorders	1 (0.6)	0	0	0
Headache	1 (0.6)	0	0	0
Respiratory, thoracic and mediastinal disorders	0	0	1 (0.9)	0
Chronic obstructive pulmonary disease	0	0	1 (0.9)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /homx/SDA/ABT-494/UC/CSR/M14-675/O/14.3/PCMS_RUN/m14675aesum.sas

1132

Anhang 4-G2.2: Erhaltungsphase

Anhang 4-G2.2.1: U-ACHIEVE Substudie 3

22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
R&D/21/1542 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 6

TABLE 14.3__1.3.3.3

Subjects with Treatment-Emergent Severe Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Any adverse event	23 (9.4)	14 (5.6)	20 (8.0)
Blood and lymphatic system disorders	2 (0.8)	0	2 (0.8)
Anaemia	0	0	1 (0.4)
Iron deficiency anaemia	1 (0.4)	0	0
Neutropenia	1 (0.4)	0	1 (0.4)
Cardiac disorders	1 (0.4)	0	2 (0.8)
Acute myocardial infarction	1 (0.4)	0	0
Chronic left ventricular failure	0	0	1 (0.4)
Supraventricular tachycardia	0	0	1 (0.4)
Eye disorders	0	1 (0.4)	0
Cataract	0	1 (0.4)	0
Gastrointestinal disorders	11 (4.5)	1 (0.4)	2 (0.8)
Abdominal mass	1 (0.4)	0	0
Anal fistula	0	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

1770

22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
R&D/21/1542 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 6

TABLE 14.3_1.3.3.3

Subjects with Treatment-Emergent Severe Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Gastrointestinal disorders (Cont.)			
Colitis ulcerative	9 (3.7)	1 (0.4)	1 (0.4)
Large intestine perforation	1 (0.4)	0	0
Pancreatitis	1 (0.4)	0	0
General disorders and administration site conditions	1 (0.4)	0	0
Pyrexia	1 (0.4)	0	0
Hepatobiliary disorders	0	0	1 (0.4)
Liver disorder	0	0	1 (0.4)
Infections and infestations	4 (1.6)	7 (2.8)	7 (2.8)
Abdominal abscess	1 (0.4)	0	0
Acute endocarditis	1 (0.4)	0	0
Anal abscess	0	1 (0.4)	0
Breast abscess	0	1 (0.4)	0
Bursitis infective	0	0	1 (0.4)
Clostridium difficile infection	0	1 (0.4)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

1771

22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
R&D/21/1542 - CLINICAL/STATISTICAL
TABLE PAGE 3 OF 6

TABLE 14.3_1.3.3.3

Subjects with Treatment-Emergent Severe Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Infections and infestations (Cont.)			
COVID-19 pneumonia	0	0	2 (0.8)
Herpes simplex	0	1 (0.4)	0
Herpes zoster	0	1 (0.4)	0
Herpes zoster meningitis	0	0	1 (0.4)
Influenza	0	1 (0.4)	0
Large intestine infection	0	1 (0.4)	0
Pharyngitis streptococcal	0	0	1 (0.4)
Pneumocystis jirovecii pneumonia	1 (0.4)	0	0
Pneumonia	1 (0.4)	0	0
Pneumonia cryptococcal	0	0	2 (0.8)
Injury, poisoning and procedural complications	0	1 (0.4)	0
Pulmonary contusion	0	1 (0.4)	0
Thoracic vertebral fracture	0	1 (0.4)	0
Investigations	1 (0.4)	1 (0.4)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

1772

22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
R&D/21/1542 - CLINICAL/STATISTICAL
TABLE PAGE 4 OF 6

TABLE 14.3_1.3.3.3

Subjects with Treatment-Emergent Severe Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Investigations (Cont.)			
Aspartate aminotransferase increased	0	0	1 (0.4)
Blood creatine phosphokinase increased	0	0	1 (0.4)
Lymphocyte count decreased	0	1 (0.4)	0
Lymphocyte percentage decreased	0	1 (0.4)	0
Neutrophil count decreased	1 (0.4)	0	0
Musculoskeletal and connective tissue disorders	0	1 (0.4)	0
Arthritis	0	1 (0.4)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.4)	1 (0.4)	2 (0.8)
Adenocarcinoma of colon	0	0	1 (0.4)
Invasive breast carcinoma	1 (0.4)	1 (0.4)	0
Small cell carcinoma	0	0	1 (0.4)
Nervous system disorders	1 (0.4)	0	1 (0.4)
Headache	1 (0.4)	0	0
Migraine	1 (0.4)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

1773

22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
R&D/21/1542 - CLINICAL/STATISTICAL
TABLE PAGE 5 OF 6

TABLE 14.3_1.3.3.3

Subjects with Treatment-Emergent Severe Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Nervous system disorders (Cont.)			
Subarachnoid haemorrhage	0	0	1 (0.4)
Psychiatric disorders	1 (0.4)	0	1 (0.4)
Anxiety	1 (0.4)	0	1 (0.4)
Depression	1 (0.4)	0	1 (0.4)
Mental disorder	1 (0.4)	0	0
Suicidal ideation	1 (0.4)	0	0
Reproductive system and breast disorders	0	0	1 (0.4)
Cervical dysplasia	0	0	1 (0.4)
Respiratory, thoracic and mediastinal disorders	0	1 (0.4)	1 (0.4)
Acute respiratory failure	0	0	1 (0.4)
Pulmonary embolism	0	1 (0.4)	0
Skin and subcutaneous tissue disorders	1 (0.4)	0	0
Erythema nodosum	1 (0.4)	0	0
Surgical and medical procedures	0	1 (0.4)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

1774

22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
R&D/21/1542 - CLINICAL/STATISTICAL
TABLE PAGE 6 OF 6

TABLE 14.3_1.3.3.3

Subjects with Treatment-Emergent Severe Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Surgical and medical procedures (Cont.)			
Abortion induced	0	1 (0.4)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

1775

Anhang 4-G3: Schwerwiegende UE (SUE) nach SOC/PT

Anhang 4-G3.1: Induktionsphase

Anhang 4-G3.1.1: U-ACHIEVE Substudie 1

09JUL2021 10:50 <! m14234ae-ss1.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 1
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 2

TABLE 14.3_2.1.1 A

Number and Percentage of Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Substudy 1 - SA1A Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=46) n (%)	ABT-494 7.5 mg QD (N=47) n (%)	ABT-494 15 mg QD (N=49) n (%)	ABT-494 30 mg QD (N=52) n (%)	ABT-494 45 mg QD (N=56) n (%)	ABT-494 Total (N=204) n (%)
Any adverse event	5 (10.9)	0	2 (4.1)	3 (5.8)	3 (5.4)	8 (3.9)
Gastrointestinal disorders	2 (4.3)	0	1 (2.0)	3 (5.8)	2 (3.6)	6 (2.9)
Colitis ulcerative	2 (4.3)	0	1 (2.0)	3 (5.8)	2 (3.6)	6 (2.9)
Infections and infestations	2 (4.3)	0	1 (2.0)	0	2 (3.6)	3 (1.5)
Cellulitis	1 (2.2)	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	1 (1.8)	1 (0.5)
Sepsis	0	0	0	0	1 (1.8)	1 (0.5)
Sinusitis	1 (2.2)	0	0	0	0	0
Urosepsis	0	0	1 (2.0)	0	0	1 (0.5)
Viral pharyngitis	0	0	0	0	1 (1.8)	1 (0.5)
Investigations	0	0	0	0	1 (1.8)	1 (0.5)
Aspartate aminotransferase increased	0	0	0	0	1 (1.8)	1 (0.5)
Metabolism and nutrition disorders	1 (2.2)	0	0	0	0	0

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Treatment-emergent AEs during Substudy 1 are defined as events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and within 30 days after the last dose of the study medication in Substudy 1 for subjects who discontinued Substudy 1 and are not enrolled into Substudy 3 or study M14-533, or events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and up to the first dose of the study medication in Substudy 3 or study M14-533.

program source code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234ae-ss1.sas

2294

09JUL2021 10:50 <! m14234ae-ss1.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 1
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 2

TABLE 14.3 2.1.1 A

Number and Percentage of Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(Substudy 1 - SA1A Population)

		ABT-494				
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=46) n (%)	7.5 mg QD (N=47) n (%)	15 mg QD (N=49) n (%)	30 mg QD (N=52) n (%)	45 mg QD (N=56) n (%)	Total (N=204) n (%)
Metabolism and nutrition disorders (Cont.)						
Hypophosphataemia	1 (2.2)	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	0	0	0	0	1 (1.8)	1 (0.5)
Pulmonary embolism	0	0	0	0	1 (1.8)	1 (0.5)
Vascular disorders	0	0	0	0	1 (1.8)	1 (0.5)
Deep vein thrombosis	0	0	0	0	1 (1.8)	1 (0.5)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Treatment-emergent AEs during Substudy 1 are defined as events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and within 30 days after the last dose of the study medication in Substudy 1 for subjects who discontinued Substudy 1 and are not enrolled into Substudy 3 or study M14-533, or events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and up to the first dose of the study medication in Substudy 3 or study M14-533.

program source code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234ae-ss1.sas

2295

Anhang 4-G3.1.2: U-ACHIEVE Substudie 2

09JUL2021 10:50 <! m14234aesum-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 2

TABLE 14.3 2.1.1 B

Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Any adverse event	9 (5.8)	8 (2.5)	2 (2.4)	2 (3.4)
Blood and lymphatic system disorders	0	0	2 (2.4)	0
Anaemia	0	0	2 (2.4)	0
Gastrointestinal disorders	6 (3.9)	2 (0.6)	1 (1.2)	1 (1.7)
Colitis	1 (0.6)	0	0	0
Colitis ulcerative	5 (3.2)	2 (0.6)	1 (1.2)	1 (1.7)
Diaphragmatic hernia	1 (0.6)	0	0	0
General disorders and administration site conditions	0	1 (0.3)	0	0
Pyrexia	0	1 (0.3)	0	0
Infections and infestations	2 (1.3)	5 (1.6)	0	0
Appendicitis	0	2 (0.6)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

2718

09JUL2021 10:50 <! m14234aesum-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 2

TABLE 14.3 2.1.1 B

Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Infections and infestations (Cont.)				
Cellulitis	1 (0.6)	0	0	0
Gastroenteritis norovirus	0	1 (0.3)	0	0
Muscle abscess	1 (0.6)	0	0	0
Pneumonia	0	1 (0.3)	0	0
Viral infection	0	1 (0.3)	0	0
Metabolism and nutrition disorders	1 (0.6)	0	0	0
Hypoalbuminaemia	1 (0.6)	0	0	0
Vascular disorders	0	0	0	1 (1.7)
Hypotension	0	0	0	1 (1.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

2719

Anhang 4-G3.1.3: U-ACCOMPLISH

10JUN2021 16:30 <! m14675aesum.sas DBV O >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-675
R&D/21/0078 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 3

TABLE 14.3 2.1.1

Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Any adverse event	8 (4.5)	11 (3.2)	4 (3.4)	1 (1.5)
Blood and lymphatic system disorders	1 (0.6)	1 (0.3)	0	0
Anaemia	1 (0.6)	1 (0.3)	0	0
Gastrointestinal disorders	5 (2.8)	4 (1.2)	2 (1.7)	1 (1.5)
Abdominal discomfort	0	0	1 (0.9)	0
Abdominal pain lower	0	0	1 (0.9)	0
Colitis	1 (0.6)	0	0	0
Colitis ulcerative	3 (1.7)	4 (1.2)	1 (0.9)	1 (1.5)
Large intestine perforation	1 (0.6)	0	0	0
General disorders and administration site conditions	0	1 (0.3)	0	0
Chest pain	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /homx/SDA/ABT-494/UC/CSR/M14-675/O/14.3/PCMS_RUN/m14675aesum.sas

1185

10JUN2021 16:30 <! m14675aesum.sas DBV O >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-675
R&D/21/0078 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 3

TABLE 14.3 2.1.1

Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Infections and infestations	1 (0.6)	2 (0.6)	1 (0.9)	0
COVID-19 pneumonia	0	1 (0.3)	1 (0.9)	0
Dengue fever	0	1 (0.3)	0	0
Enterococcal infection	1 (0.6)	0	0	0
Escherichia infection	1 (0.6)	0	0	0
Injury, poisoning and procedural complications	1 (0.6)	1 (0.3)	0	0
Gastrointestinal stoma necrosis	1 (0.6)	0	0	0
Hand fracture	0	1 (0.3)	0	0
Metabolism and nutrition disorders	0	1 (0.3)	0	0
Malnutrition	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /homx/SDA/ABT-494/UC/CSR/M14-675/O/14.3/PCMS_RUN/m14675aesum.sas

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10JUN2021 16:30 <! m14675aesum.sas DBV O >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-675
R&D/21/0078 - CLINICAL/STATISTICAL
TABLE PAGE 3 OF 3

TABLE 14.3 2.1.1

Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Psychiatric disorders	0	1 (0.3)	0	0
Acute psychosis	0	1 (0.3)	0	0
Respiratory, thoracic and mediastinal disorders	1 (0.6)	0	1 (0.9)	0
Chronic obstructive pulmonary disease	0	0	1 (0.9)	0
Pulmonary embolism	1 (0.6)	0	0	0
Skin and subcutaneous tissue disorders	1 (0.6)	0	0	0
Pyoderma gangrenosum	1 (0.6)	0	0	0
Vascular disorders	1 (0.6)	0	0	0
Pelvic venous thrombosis	1 (0.6)	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /homx/SDA/ABT-494/UC/CSR/M14-675/O/14.3/PCMS_RUN/m14675aesum.sas

1187

Anhang 4-G3.2: Erhaltungsphase

Anhang 4-G3.2.1: U-ACHIEVE Substudie 3

22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
R&D/21/1542 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 6

TABLE 14.3 2.1.1.3

Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Any adverse event	23 (9.4)	21 (8.4)	21 (8.4)
Blood and lymphatic system disorders	1 (0.4)	0	1 (0.4)
Anaemia	0	0	1 (0.4)
Iron deficiency anaemia	1 (0.4)	0	0
Cardiac disorders	2 (0.8)	0	0
Acute myocardial infarction	1 (0.4)	0	0
Atrial fibrillation	1 (0.4)	0	0
Eye disorders	0	1 (0.4)	0
Cataract	0	1 (0.4)	0
Gastrointestinal disorders	7 (2.9)	1 (0.4)	3 (1.2)
Anal fistula	0	0	1 (0.4)
Colitis	1 (0.4)	0	0
Colitis ulcerative	5 (2.0)	1 (0.4)	2 (0.8)
Pancreatitis	1 (0.4)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
R&D/21/1542 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 6

TABLE 14.3 2.1.1.3

Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
General disorders and administration site conditions	2 (0.8)	0	0
Device intolerance	1 (0.4)	0	0
Pyrexia	1 (0.4)	0	0
Hepatobiliary disorders	0	0	1 (0.4)
Liver disorder	0	0	1 (0.4)
Infections and infestations	8 (3.3)	9 (3.6)	7 (2.8)
Abdominal abscess	1 (0.4)	0	0
Acute endocarditis	1 (0.4)	0	0
Anal abscess	0	1 (0.4)	0
Arthritis bacterial	0	1 (0.4)	0
Breast abscess	0	1 (0.4)	0
Bronchitis	0	1 (0.4)	0
Bursitis infective	0	0	1 (0.4)
Clostridium difficile infection	0	1 (0.4)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

1973

22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
R&D/21/1542 - CLINICAL/STATISTICAL
TABLE PAGE 3 OF 6

TABLE 14.3 2.1.1.3

Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Infections and infestations (Cont.)			
COVID-19	0	0	1 (0.4)
COVID-19 pneumonia	1 (0.4)	1 (0.4)	2 (0.8)
Herpes zoster	0	1 (0.4)	0
Herpes zoster meningitis	0	0	1 (0.4)
Influenza	0	1 (0.4)	0
Large intestine infection	0	1 (0.4)	0
Mastitis	0	1 (0.4)	0
Pneumocystis jirovecii pneumonia	1 (0.4)	0	0
Pneumonia	3 (1.2)	0	0
Pneumonia cryptococcal	0	0	2 (0.8)
Tonsillitis	1 (0.4)	0	0
Injury, poisoning and procedural complications	0	2 (0.8)	0
Pulmonary contusion	0	1 (0.4)	0
Skin laceration	0	1 (0.4)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

1974

22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
R&D/21/1542 - CLINICAL/STATISTICAL
TABLE PAGE 4 OF 6

TABLE 14.3 2.1.1.3

Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Injury, poisoning and procedural complications (Cont.)			
Thoracic vertebral fracture	0	1 (0.4)	0
Musculoskeletal and connective tissue disorders	0	1 (0.4)	1 (0.4)
Arthritis	0	1 (0.4)	0
Chondromalacia	0	0	1 (0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.4)	1 (0.4)	2 (0.8)
Adenocarcinoma of colon	0	0	1 (0.4)
Invasive breast carcinoma	1 (0.4)	1 (0.4)	0
Small cell carcinoma	0	0	1 (0.4)
Nervous system disorders	0	0	1 (0.4)
Subarachnoid haemorrhage	0	0	1 (0.4)
Psychiatric disorders	1 (0.4)	0	1 (0.4)
Anxiety	1 (0.4)	0	1 (0.4)
Depression	1 (0.4)	0	1 (0.4)
Mental disorder	1 (0.4)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

1975

22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
R&D/21/1542 - CLINICAL/STATISTICAL
TABLE PAGE 5 OF 6

TABLE 14.3 2.1.1.3

Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Psychiatric disorders (Cont.)			
Suicidal ideation	1 (0.4)	0	0
Renal and urinary disorders	0	1 (0.4)	0
Urinary retention	0	1 (0.4)	0
Reproductive system and breast disorders	0	0	2 (0.8)
Cervical dysplasia	0	0	2 (0.8)
Respiratory, thoracic and mediastinal disorders	1 (0.4)	3 (1.2)	2 (0.8)
Acute respiratory failure	1 (0.4)	0	1 (0.4)
Chronic obstructive pulmonary disease	0	1 (0.4)	0
Interstitial lung disease	1 (0.4)	0	0
Noninfective bronchitis	0	0	1 (0.4)
Pulmonary embolism	0	2 (0.8)	0
Skin and subcutaneous tissue disorders	1 (0.4)	1 (0.4)	0
Erythema nodosum	1 (0.4)	0	0
Panniculitis	0	1 (0.4)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
R&D/21/1542 - CLINICAL/STATISTICAL
TABLE PAGE 6 OF 6

TABLE 14.3 2.1.1.3

Subjects with Treatment-Emergent Serious Adverse Events
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Surgical and medical procedures	0	2 (0.8)	0
Abortion induced	0	2 (0.8)	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

1977

Anhang 4-G4: UE, die zum Therapieabbruch führten nach SOC/PT

Anhang 4-G4.1: Induktionsphase

Anhang 4-G4.1.1: U-ACHIEVE Substudie 1

09JUL2021 10:50 <! m14234ae-ss1.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 1
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 2

TABLE 14.3 2.2 A

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Substudy 1 - SA1A Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=46) n (%)	ABT-494 7.5 mg QD (N=47) n (%)	ABT-494 15 mg QD (N=49) n (%)	ABT-494 30 mg QD (N=52) n (%)	ABT-494 45 mg QD (N=56) n (%)	ABT-494 Total (N=204) n (%)
Any adverse event	4 (8.7)	2 (4.3)	2 (4.1)	4 (7.7)	5 (8.9)	13 (6.4)
Blood and lymphatic system disorders	0	0	0	0	1 (1.8)	1 (0.5)
Lymphopenia	0	0	0	0	1 (1.8)	1 (0.5)
Gastrointestinal disorders	3 (6.5)	0	2 (4.1)	4 (7.7)	3 (5.4)	9 (4.4)
Abdominal pain upper	0	0	0	1 (1.9)	0	1 (0.5)
Anal ulcer	0	0	0	0	1 (1.8)	1 (0.5)
Colitis	1 (2.2)	0	0	0	0	0
Colitis ulcerative	2 (4.3)	0	2 (4.1)	3 (5.8)	2 (3.6)	7 (3.4)
Nausea	0	0	0	1 (1.9)	0	1 (0.5)
General disorders and administration site conditions	0	0	0	1 (1.9)	0	1 (0.5)
Chills	0	0	0	1 (1.9)	0	1 (0.5)
Pyrexia	0	0	0	1 (1.9)	0	1 (0.5)
Infections and infestations	0	0	0	0	1 (1.8)	1 (0.5)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Treatment-emergent AEs during Substudy 1 are defined as events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and within 30 days after the last dose of the study medication in Substudy 1 for subjects who discontinued Substudy 1 and are not enrolled into Substudy 3 or study M14-533, or events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and up to the first dose of the study medication in Substudy 3 or study M14-533.

program source code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234ae-ss1.sas

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09JUL2021 10:50 <! m14234ae-ss1.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 1
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 2

TABLE 14.3 2.2 A

Number and Percentage of Subjects with Treatment-Emergent Adverse Events
Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(Substudy 1 - SA1A Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=46) n (%)	ABT-494 7.5 mg QD (N=47) n (%)	ABT-494 15 mg QD (N=49) n (%)	ABT-494 30 mg QD (N=52) n (%)	ABT-494 45 mg QD (N=56) n (%)	ABT-494 Total (N=204) n (%)
Infections and infestations (Cont.)						
Viral pharyngitis	0	0	0	0	1 (1.8)	1 (0.5)
Investigations	0	1 (2.1)	0	0	1 (1.8)	2 (1.0)
Alanine aminotransferase increased	0	1 (2.1)	0	0	0	1 (0.5)
Aspartate aminotransferase increased	0	1 (2.1)	0	0	0	1 (0.5)
Neutrophil count decreased	0	0	0	0	1 (1.8)	1 (0.5)
Metabolism and nutrition disorders	1 (2.2)	0	0	0	0	0
Hypophosphataemia	1 (2.2)	0	0	0	0	0
Nervous system disorders	0	1 (2.1)	0	0	0	1 (0.5)
Headache	0	1 (2.1)	0	0	0	1 (0.5)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Treatment-emergent AEs during Substudy 1 are defined as events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and within 30 days after the last dose of the study medication in Substudy 1 for subjects who discontinued Substudy 1 and are not enrolled into Substudy 3 or study M14-533, or events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and up to the first dose of the study medication in Substudy 3 or study M14-533.

program source code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234ae-ss1.sas

23300

Anhang 4-G4.1.2: U-ACHIEVE Substudie 2

09JUL2021 10:50 <! m14234aesum-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 2

TABLE 14.3_2.2.1_B

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Any adverse event	14 (9.0)	6 (1.9)	5 (5.9)	0
Gastrointestinal disorders	12 (7.7)	3 (0.9)	1 (1.2)	0
Colitis	1 (0.6)	0	0	0
Colitis ulcerative	11 (7.1)	2 (0.6)	1 (1.2)	0
Rectal dysplasia	0	1 (0.3)	0	0
General disorders and administration site conditions	0	1 (0.3)	0	0
Pyrexia	0	1 (0.3)	0	0
Infections and infestations	1 (0.6)	2 (0.6)	2 (2.4)	0
Herpes zoster	0	1 (0.3)	2 (2.4)	0
Muscle abscess	1 (0.6)	0	0	0
Viral infection	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

2721

09JUL2021 10:50 <! m14234aesum-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 2

TABLE 14.3 2.2.1 B

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Investigations	1 (0.6)	0	1 (1.2)	0
Blood creatine phosphokinase increased	0	0	1 (1.2)	0
Haemoglobin decreased	1 (0.6)	0	0	0
Renal and urinary disorders	0	1 (0.3)	0	0
Chronic kidney disease	0	1 (0.3)	0	0
Respiratory, thoracic and mediastinal disorders	0	0	1 (1.2)	0
Alveolitis	0	0	1 (1.2)	0
Skin and subcutaneous tissue disorders	1 (0.6)	0	0	0
Pruritus	1 (0.6)	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

2722

Anhang 4-G4.1.3: U-ACCOMPLISH

10JUN2021 16:30 <! m14675aesum.sas DBV O >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-675
R&D/21/0078 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 3

TABLE 14.3 2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Any adverse event	9 (5.1)	6 (1.7)	2 (1.7)	2 (2.9)
Blood and lymphatic system disorders	0	1 (0.3)	0	0
Lymphopenia	0	1 (0.3)	0	0
Ear and labyrinth disorders	0	1 (0.3)	0	0
Tinnitus	0	1 (0.3)	0	0
Eye disorders	0	1 (0.3)	0	0
Vision blurred	0	1 (0.3)	0	0
Gastrointestinal disorders	6 (3.4)	3 (0.9)	1 (0.9)	2 (2.9)
Colitis ulcerative	5 (2.8)	3 (0.9)	1 (0.9)	2 (2.9)
Large intestine perforation	1 (0.6)	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /homx/SDA/ABT-494/UC/CSR/M14-675/O/14.3/PCMS_RUN/m14675aesum.sas

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10JUN2021 16:30 <! m14675aesum.sas DBV O >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-675
R&D/21/0078 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 3

TABLE 14.3 2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
General disorders and administration site conditions	1 (0.6)	0	1 (0.9)	0
Asthenia	1 (0.6)	0	0	0
Fatigue	1 (0.6)	0	0	0
Pyrexia	0	0	1 (0.9)	0
Infections and infestations	1 (0.6)	0	0	0
Enterococcal infection	1 (0.6)	0	0	0
Escherichia infection	1 (0.6)	0	0	0
Injury, poisoning and procedural complications	1 (0.6)	0	0	0
Gastrointestinal stoma necrosis	1 (0.6)	0	0	0
Musculoskeletal and connective tissue disorders	0	2 (0.6)	0	0
Arthralgia	0	1 (0.3)	0	0
Arthritis	0	1 (0.3)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /homx/SDA/ABT-494/UC/CSR/M14-675/O/14.3/PCMS_RUN/m14675aesum.sas

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UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-675
R&D/21/0078 - CLINICAL/STATISTICAL
TABLE PAGE 3 OF 3

TABLE 14.3_2.2.1

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Trigger finger	0	1 (0.3)	0	0
Nervous system disorders	2 (1.1)	1 (0.3)	0	0
Burning sensation	0	1 (0.3)	0	0
Headache	1 (0.6)	0	0	0
Migraine	1 (0.6)	0	0	0
Respiratory, thoracic and mediastinal disorders	1 (0.6)	0	0	0
Pulmonary embolism	1 (0.6)	0	0	0
Skin and subcutaneous tissue disorders	0	0	1 (0.9)	0
Rash	0	0	1 (0.9)	0
Vascular disorders	1 (0.6)	0	0	0
Pelvic venous thrombosis	1 (0.6)	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /homx/SDA/ABT-494/UC/CSR/M14-675/O/14.3/PCMS_RUN/m14675aesum.sas

1191

Anhang 4-G4.2: Erhaltungsphase

Anhang 4-G4.2.1: U-ACHIEVE Substudie 3

22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
R&D/21/1542 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 4

TABLE 14.3 2.2.1.3

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Any adverse event	25 (10.2)	10 (4.0)	18 (7.2)
Cardiac disorders	1 (0.4)	0	0
Acute myocardial infarction	1 (0.4)	0	0
Gastrointestinal disorders	15 (6.1)	6 (2.4)	3 (1.2)
Colitis ulcerative	13 (5.3)	5 (2.0)	3 (1.2)
Intestinal obstruction	0	1 (0.4)	0
Large intestine perforation	1 (0.4)	0	0
Pancreatitis	1 (0.4)	0	0
General disorders and administration site conditions	1 (0.4)	0	0
Pyrexia	1 (0.4)	0	0
Hepatobiliary disorders	0	0	1 (0.4)
Drug-induced liver injury	0	0	1 (0.4)
Infections and infestations	3 (1.2)	1 (0.4)	5 (2.0)
Abdominal abscess	1 (0.4)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

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22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
R&D/21/1542 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 4

TABLE 14.3 2.2.1.3

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Infections and infestations (Cont.)			
Acute endocarditis	1 (0.4)	0	0
Arthritis bacterial	0	1 (0.4)	0
COVID-19 pneumonia	0	0	1 (0.4)
Herpes zoster	0	0	2 (0.8)
Herpes zoster meningitis	0	0	1 (0.4)
Pneumonia	1 (0.4)	0	0
Pneumonia cryptococcal	0	0	2 (0.8)
Investigations	0	0	4 (1.6)
Blood creatine phosphokinase increased	0	0	1 (0.4)
Haemoglobin decreased	0	0	1 (0.4)
Hepatitis B DNA assay positive	0	0	1 (0.4)
Neutrophil count decreased	0	0	1 (0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.4)	1 (0.4)	2 (0.8)
Adenocarcinoma of colon	0	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

1988

22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
R&D/21/1542 - CLINICAL/STATISTICAL
TABLE PAGE 3 OF 4

TABLE 14.3 2.2.1.3

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Invasive breast carcinoma	1 (0.4)	1 (0.4)	0
Small cell carcinoma	0	0	1 (0.4)
Renal and urinary disorders	0	1 (0.4)	0
Renal impairment	0	1 (0.4)	0
Respiratory, thoracic and mediastinal disorders	1 (0.4)	0	1 (0.4)
Interstitial lung disease	1 (0.4)	0	0
Lung infiltration	0	0	1 (0.4)
Skin and subcutaneous tissue disorders	2 (0.8)	2 (0.8)	1 (0.4)
Erythema	0	1 (0.4)	0
Erythema nodosum	1 (0.4)	0	0
Panniculitis	0	1 (0.4)	0
Pruritus	1 (0.4)	0	0
Seborrhoeic dermatitis	0	0	1 (0.4)
Vascular disorders	2 (0.8)	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

1989

22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
R&D/21/1542 - CLINICAL/STATISTICAL
TABLE PAGE 4 OF 4

TABLE 14.3 2.2.1.3

Subjects with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Vascular disorders (Cont.)			
Deep vein thrombosis	0	0	1 (0.4)
Hypertension	1 (0.4)	0	0
Venous thrombosis	1 (0.4)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

1990

Anhang 4-G5: UE, die zum Tod führten nach SOC/PT

Anhang 4-G5.1: Induktionsphase

Anhang 4-G5.1.1: U-ACHIEVE Substudie 1

09JUL2021 10:50 <! m14234ae-ss1.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 1
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 2

TABLE 14.3 2.4.9 A

Number and Percentage of Subjects with Treatment-Emergent Adverse Events Leading to Death
by Primary MedDRA System Organ Class and Preferred Term
(Substudy 1 - SA1A and SA1B Population)

		ABT-494				
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=46) n (%)	7.5 mg QD (N=47) n (%)	15 mg QD (N=49) n (%)	30 mg QD (N=52) n (%)	45 mg QD (N=56) n (%)	Total (N=204) n (%)
Any adverse event	0	0	0	0	0	0

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Treatment-emergent AEs during Substudy 1 are defined as events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and within 30 days after the last dose of the study medication in Substudy 1 for subjects who discontinued Substudy 1 and are not enrolled into Substudy 3 or study M14-533, or events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and up to the first dose of the study medication in Substudy 3 or study M14-533.

program source code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234ae-ss1.sas

2336

09JUL2021 10:50 <! m14234ae-ss1.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 1
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 2

TABLE 14.3_2.4.9_A

Number and Percentage of Subjects with Treatment-Emergent Adverse Events Leading to Death
by Primary MedDRA System Organ Class and Preferred Term
(Substudy 1 - SA1A and SA1B Population)

	ABT-494		
MedDRA 23.0 System Organ Class Preferred Term	30 mg QD (N=65) n (%)	45 mg QD (N=67) n (%)	Total (N=132) n (%)
Any adverse event	0	0	0

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Treatment-emergent AEs during Substudy 1 are defined as events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and within 30 days after the last dose of the study medication in Substudy 1 for subjects who discontinued Substudy 1 and are not enrolled into Substudy 3 or study M14-533, or events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and up to the first dose of the study medication in Substudy 3 or study M14-533.

program source code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234ae-ss1.sas

2337

Anhang 4-G5.1.2: U-ACHIEVE Substudie 2

09JUL2021 10:50 <! m14234aesum-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.3 2.3.1 B

Subjects with Treatment-Emergent Adverse Events Leading to Death
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Any adverse event	0	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aesum-ss2.sas

2725

Anhang 4-G5.1.3: U-ACCOMPLISH

10JUN2021 16:30 <! m14675aesum.sas DBV O >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-675
R&D/21/0078 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.3 2.3.1

Subjects with Treatment-Emergent Adverse Events Leading to Death
by Primary MedDRA System Organ Class and Preferred Term
(SA1 Population and SA2 Population)

	Part 1		Part 2	
MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Any adverse event	0	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.

Program Source Code: /homx/SDA/ABT-494/UC/CSR/M14-675/O/14.3/PCMS_RUN/m14675aesum.sas

1195

Anhang 4-G5.2: Erhaltungsphase

Anhang 4-G5.2.1: U-ACHIEVE Substudie 3

22FEB2022 11:17 <! m14234aesum-ss3.sas DBV AC >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 3
R&D/21/1542 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.3 2.3.1.3

Subjects with Treatment-Emergent Adverse Events Leading to Death
by Primary MedDRA System Organ Class and Preferred Term
(SA_C Population)

MedDRA 23.0 System Organ Class Preferred Term	Placebo (N=245) n (%)	UPA 15 mg QD (N=250) n (%)	UPA 30 mg QD (N=251) n (%)
Any adverse event	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) are defined as events that begin either on or after the first dose of the study drug in the Maintenance Study and within 30 days after the last dose administration of the study drug for subjects who do not participate in the long-term extension Study M14-533 or until first dose of study drug in the Study M14-533 if the subject is enrolled into Study M14-533.

Program Source Code: /kangtx/SDA/ABT-494/UC/CSR/M14-234/SS3/AC/14.3/PCMS_RUN/m14234aesum-ss3.sas

1999

Anhang 4-G6: UE von speziellem Interesse

Anhang 4-G6.1: Induktionsphase

Anhang 4-G6.1.1: U-ACHIEVE Substudie 1

09JUL2021 10:09 <! m14234aeovp-ss1.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 1
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 2

TABLE 14.3_1.1.2.5_A

Overview of Number and Percentage of Subjects with Treatment-Emergent Adverse Events
ABT-494 Total vs Placebo
(Substudy 1 - SA1A Population)

	Placebo (N=46) n (%)	ABT-494 Total (N=204) n (%)	P-value@ ABT-494 Total vs Placebo
Subjects with:			
Any adverse event (AE)	33 (71.7)	135 (66.2)	
Any AE with reasonable possibility of being related to study drug$	17 (37.0)	59 (28.9)	
Any severe AE	7 (15.2)	12 (5.9)	0.057
Any serious AE	5 (10.9)	8 (3.9)	0.068
Any AE leading to discontinuation of study drug	4 (8.7)	13 (6.4)	
Any AE leading to death	0	0	
Any serious infections	2 (4.3)	3 (1.5)	
Any opportunistic infections	1 (2.2)	0	
Any malignancy	0	0	
Any confirmed malignancy	0	0	
Any non-melanoma skin cancer (NMSC)	0	0	
Any confirmed malignancy excluding NMSC	0	0	
Any lymphoma	0	0	

Note: Treatment-emergent AEs during Substudy 1 are defined as events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and within 30 days after the last dose of the study medication in Substudy 1 for subjects who discontinued Substudy 1 and are not enrolled into Substudy 3 or study M14-533, or events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and up to the first dose of the study medication in Substudy 3 or study M14-533.
$ As assessed by investigator.
# Includes non treatment-emergent deaths.
@ P-value for comparisons among individual treatment groups using Fisher's exact test. Only P-values <= 0.100 are presented.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value < 0.001.

program source code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aeovp-ss1.sas

1605

09JUL2021 10:09 <! m14234aeovp-ss1.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 1
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 2

TABLE 14.3_1.1.2.5_A

Overview of Number and Percentage of Subjects with Treatment-Emergent Adverse Events
ABT-494 Total vs Placebo
(Substudy 1 - SA1A Population)

	Placebo (N=46) n (%)	ABT-494 Total (N=204) n (%)	P-value@ ABT-494 Total vs Placebo
Any hepatic disorder	1 (2.2)	8 (3.9)	
Any gastrointestinal perforations	0	0	
Any anemia	3 (6.5)	7 (3.4)	
Any neutropenia	0	2 (1.0)	
Any lymphopenia	0	4 (2.0)	
Any herpes zoster	0	1 (0.5)	
Any creatine phosphokinase (CPK) elevation	0	10 (4.9)	
Any renal dysfunction	0	0	
Any tuberculosis	0	0	
Any adjudicated cardiovascular events	0	1 (0.5)	
Deaths#	0	0	

Note: Treatment-emergent AEs during Substudy 1 are defined as events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and within 30 days after the last dose of the study medication in Substudy 1 for subjects who discontinued Substudy 1 and are not enrolled into Substudy 3 or study M14-533, or events that begin or worsen either on or after the first dose of the study medication in Substudy 1 and up to the first dose of the study medication in Substudy 3 or study M14-533.
$ As assessed by investigator.
# Includes non treatment-emergent deaths.
@ P-value for comparisons among individual treatment groups using Fisher's exact test. Only P-values <= 0.100 are presented.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value < 0.001.

program source code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aeovp-ss1.sas

1606

Anhang 4-G6.1.2: U-ACHIEVE Substudie 2

09JUL2021 10:16 <! m14234aeov-si-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 2

TABLE 14.3_1.1.3 B

Overview of Treatment-Emergent Adverse Events of Special Interest
(SA1 Population and SA2 Population)

	Part 1			Part 2	
	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Difference UPA - Placebo (95% CI&)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Subjects with:					
Any serious infections	2 (1.3)	5 (1.6)	0.3 (-2.0, 2.5)	0	0
Any opportunistic infection excluding tuberculosis and herpes zoster	0	1 (0.3)	0.3 (-0.3, 0.9)	0	0
Any active tuberculosis	0	0	0.0	0	0
Any herpes zoster	0	1 (0.3)	0.3 (-0.3, 0.9)	5 (5.9)	3 (5.1)
Any neutropenia	1 (0.6)	16 (5.0)	4.4 (1.7, 7.1)	5 (5.9)	1 (1.7)
Any creatine phosphokinase (CPK) elevation	3 (1.9)	16 (5.0)	3.1 (-0.2, 6.3)	5 (5.9)	4 (6.8)
Any possible malignancies	0	1 (0.3)	0.3 (-0.3, 0.9)	0	0
Any malignancy	0	0	0.0	0	0
Any malignancies excluding NMSC	0	0	0.0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0.0	0	0
Any lymphoma	0	0	0.0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
& 95% CI for treatment difference is based on the normal approximation.
* MACE: Major Adverse Cardiovascular Events, defined as cardiovascular death, non-fatal myocardial infarction and non-fatal stroke.
** VTE: Include deep vein thrombosis (DVT) and pulmonary embolism (PE).

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aeov-si-ss2.sas

1847

09JUL2021 10:16 <! m14234aeov-si-ss2.sas >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-234 SUBSTUDY 2
R&D/20/1294 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 2

TABLE 14.3_1.1.3 B

Overview of Treatment-Emergent Adverse Events of Special Interest
(SA1 Population and SA2 Population)

	Part 1			Part 2	
	Placebo (N=155) n (%)	UPA 45 mg QD (N=319) n (%)	Difference UPA - Placebo (95% CI&)	Placebo/ UPA 45 mg QD (N=85) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=59) n (%)
Subjects with:					
Any renal dysfunction	0	0	0.0	0	0
Any hepatic disorder	7 (4.5)	9 (2.8)	-1.7 (-5.4, 2.0)	2 (2.4)	1 (1.7)
Any anemia	14 (9.0)	10 (3.1)	-5.9 (-10.8, -1.0)	7 (8.2)	2 (3.4)
Any lymphopenia	1 (0.6)	10 (3.1)	2.5 (0.2, 4.8)	0	1 (1.7)
Any adjudicated gastrointestinal perforations	0	0	0.0	0	0
Any adjudicated MACE *	0	0	0.0	0	0
Any adjudicated VTE **	0	0	0.0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
& 95% CI for treatment difference is based on the normal approximation.
* MACE: Major Adverse Cardiovascular Events, defined as cardiovascular death, non-fatal myocardial infarction and non-fatal stroke.
** VTE: Include deep vein thrombosis (DVT) and pulmonary embolism (PE).

Program Source Code: /parepbk/SDA/ABT-494/UC/CSR/M14-234/SS1-2/Y/14.3/PCMS_RUN/m14234aeov-si-ss2.sas

1848

Anhang 4-G6.1.3: U-ACCOMPLISH

10JUN2021 16:30 <! m14675aeov-si.sas DBV O >
UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-675
R&D/21/0078 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 2

TABLE 14.3_1.1.3

Overview of Treatment-Emergent Adverse Events of Special Interest
(SA1 Population and SA2 Population)

	Part 1			Part 2	
	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Difference UPA - Placebo (95% CI&)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Subjects with:					
Any serious infections	1 (0.6)	2 (0.6)	0.0 (-1.3, 1.4)	1 (0.9)	0
Any opportunistic infection excluding tuberculosis and herpes zoster	0	2 (0.6)	0.6 (-0.2, 1.4)	0	0
Any active tuberculosis	0	0	0.0	0	0
Any herpes zoster	0	2 (0.6)	0.6 (-0.2, 1.4)	0	1 (1.5)
Any neutropenia	0	15 (4.4)	4.4 (2.2, 6.5)	1 (0.9)	1 (1.5)
Any creatine phosphokinase (CPK) elevation	2 (1.1)	16 (4.7)	3.5 (0.8, 6.2)	5 (4.3)	4 (5.9)
Any possible malignancies	1 (0.6)	1 (0.3)	-0.3 (-1.5, 1.0)	0	0
Any malignancy	0	0	0.0	0	0
Any malignancies excluding NMSC	0	0	0.0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0.0	0	0
Any lymphoma	0	0	0.0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
& 95% CI for treatment difference is based on the normal approximation.
* MACE: Major Adverse Cardiovascular Events, defined as cardiovascular death, non-fatal myocardial infarction and non-fatal stroke.
** VTE: Include deep vein thrombosis (DVT) and pulmonary embolism (PE).

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UPADACITINIB (ULCERATIVE COLITIS)
STUDY M14-675
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TABLE 14.3_1.1.3

Overview of Treatment-Emergent Adverse Events of Special Interest
(SA1 Population and SA2 Population)

	Part 1			Part 2	
	Placebo (N=177) n (%)	UPA 45 mg QD (N=344) n (%)	Difference UPA - Placebo (95% CI&)	Placebo/ UPA 45 mg QD (N=116) n (%)	UPA 45 mg QD/ UPA 45 mg QD (N=68) n (%)
Subjects with:					
Any renal dysfunction	0	0	0.0	0	0
Any hepatic disorder	1 (0.6)	10 (2.9)	2.3 (0.3, 4.4)	2 (1.7)	2 (2.9)
Any anemia	4 (2.3)	15 (4.4)	2.1 (-1.0, 5.2)	4 (3.4)	4 (5.9)
Any lymphopenia	1 (0.6)	6 (1.7)	1.2 (-0.6, 2.9)	1 (0.9)	1 (1.5)
Any adjudicated gastrointestinal perforations	1 (0.6)	0	-0.6 (-1.7, 0.5)	0	0
Any adjudicated MACE *	0	0	0.0	0	0
Any adjudicated VTE **	1 (0.6)	0	-0.6 (-1.7, 0.5)	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent AEs (TEAEs) for Part 1 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 1 and within 30 days after the last dose administration of the study drug for subjects who are not enrolled in Part 2 and do not participate the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in Part 2 if the subject is enrolled into Part 2 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
Treatment-emergent AEs (TEAEs) for Part 2 are defined as events that begin or worsen either on or after the first dose of the study drug in Part 2 and within 30 days after the last dose administration of the study drug for subjects who do not participate in the Maintenance Study M14-234 Substudy 3 and M14-533 or until first dose of study drug in the Maintenance Study M14-234 Substudy 3 if the subject is enrolled into Maintenance Study M14-234 Substudy 3 or until first dose of study drug in M14-533 if the subject is enrolled into M14-533.
& 95% CI for treatment difference is based on the normal approximation.
* MACE: Major Adverse Cardiovascular Events, defined as cardiovascular death, non-fatal myocardial infarction and non-fatal stroke.
** VTE: Include deep vein thrombosis (DVT) and pulmonary embolism (PE).

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