MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
内分泌障害	2 (0.5)	3 (0.7)	5 (0.6)
甲状腺機能正常症候群	0	1 (0.2)	1 (0.1)
甲状腺機能低下症	1 (0.2)	1 (0.2)	2 (0.2)
甲状腺腫瘤	1 (0.2)	1 (0.2)	2 (0.2)
眼障害	25 (5.6)	29 (6.7)	54 (6.1)
眼瞼炎	4 (0.9)	4 (0.9)	8 (0.9)
白内障	0	4 (0.9)	4 (0.5)
霰粒腫	1 (0.2)	2 (0.5)	3 (0.3)
結膜沈着物	0	1 (0.2)	1 (0.1)
結膜充血	0	1 (0.2)	1 (0.1)
結膜刺激	0	1 (0.2)	1 (0.1)
アレルギー性結膜炎	2 (0.5)	3 (0.7)	5 (0.6)
角膜浮腫	1 (0.2)	0	1 (0.1)
ドライアイ	3 (0.7)	2 (0.5)	5 (0.6)
眼瞼紅斑	1 (0.2)	0	1 (0.1)
眼刺激	1 (0.2)	0	1 (0.1)
眼痛	1 (0.2)	1 (0.2)	2 (0.2)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
眼障害 (Cont.)			
眼の異常感覚	0	1 (0.2)	1 (0.1)
眼そう痒症	0	1 (0.2)	1 (0.1)
眼部腫脹	0	2 (0.5)	2 (0.2)
眼瞼障害	0	1 (0.2)	1 (0.1)
緑内障	1 (0.2)	0	1 (0.1)
流涙増加	4 (0.9)	0	4 (0.5)
黄斑症	0	1 (0.2)	1 (0.1)
近視	0	1 (0.2)	1 (0.1)
視神経乳頭浮腫	0	1 (0.2)	1 (0.1)
眼窩周囲浮腫	1 (0.2)	0	1 (0.1)
羞明	0	1 (0.2)	1 (0.1)
屈折障害	1 (0.2)	0	1 (0.1)
網膜剥離	1 (0.2)	1 (0.2)	2 (0.2)
裂孔原性網膜剥離	0	1 (0.2)	1 (0.1)
眼瞼腫脹	1 (0.2)	1 (0.2)	2 (0.2)
潰瘍性角膜炎	1 (0.2)	1 (0.2)	2 (0.2)
春季カタル	0	1 (0.2)	1 (0.1)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
眼障害 (Cont.)			
霧視	3 (0.7)	1 (0.2)	4 (0.5)
視力低下	0	1 (0.2)	1 (0.1)
硝子体剥離	0	1 (0.2)	1 (0.1)
眼球乾燥症	1 (0.2)	0	1 (0.1)
胃腸障害	80 (18.1)	91 (20.9)	171 (19.5)
腹部不快感	3 (0.7)	2 (0.5)	5 (0.6)
腹部膨満	2 (0.5)	2 (0.5)	4 (0.5)
腹痛	12 (2.7)	12 (2.8)	24 (2.7)
下腹部痛	1 (0.2)	0	1 (0.1)
上腹部痛	17 (3.8)	5 (1.1)	22 (2.5)
腹部圧痛	0	1 (0.2)	1 (0.1)
肛門そう痒症	1 (0.2)	0	1 (0.1)
口角口唇炎	0	2 (0.5)	2 (0.2)
肛門直腸不快感	0	1 (0.2)	1 (0.1)
アフタ性潰瘍	1 (0.2)	1 (0.2)	2 (0.2)
便習慣変化	0	2 (0.5)	2 (0.2)
口唇のひび割れ	1 (0.2)	0	1 (0.1)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
胃腸障害 (Cont.)			
慢性胃炎	2 (0.5)	0	2 (0.2)
便秘	7 (1.6)	8 (1.8)	15 (1.7)
齲歯	5 (1.1)	6 (1.4)	11 (1.3)
下痢	15 (3.4)	19 (4.4)	34 (3.9)
口内乾燥	0	2 (0.5)	2 (0.2)
出血性十二指腸潰瘍	1 (0.2)	0	1 (0.1)
消化不良	9 (2.0)	5 (1.1)	14 (1.6)
嚥下障害	0	2 (0.5)	2 (0.2)
変色便	1 (0.2)	0	1 (0.1)
白色便	1 (0.2)	0	1 (0.1)
鼓腸	2 (0.5)	1 (0.2)	3 (0.3)
食中毒	0	1 (0.2)	1 (0.1)
排便回数増加	0	1 (0.2)	1 (0.1)
胃炎	2 (0.5)	3 (0.7)	5 (0.6)
胃腸障害	1 (0.2)	0	1 (0.1)
胃腸粘膜障害	1 (0.2)	0	1 (0.1)
胃食道逆流性疾患	3 (0.7)	10 (2.3)	13 (1.5)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
胃腸障害 (Cont.)			
舌炎	1 (0.2)	0	1 (0.1)
舌痛	0	1 (0.2)	1 (0.1)
痔核	1 (0.2)	1 (0.2)	2 (0.2)
裂孔ヘルニア	0	1 (0.2)	1 (0.1)
胃酸過多	0	1 (0.2)	1 (0.1)
腸閉塞	1 (0.2)	0	1 (0.1)
過敏性腸症候群	0	2 (0.5)	2 (0.2)
口唇水疱	1 (0.2)	0	1 (0.1)
口腔内出血	0	1 (0.2)	1 (0.1)
口腔内潰瘍形成	2 (0.5)	1 (0.2)	3 (0.3)
悪心	15 (3.4)	17 (3.9)	32 (3.6)
嚥下痛	2 (0.5)	0	2 (0.2)
口腔瘻	1 (0.2)	0	1 (0.1)
口腔そう痒症	0	1 (0.2)	1 (0.1)
膵炎	1 (0.2)	0	1 (0.1)
歯周病	1 (0.2)	0	1 (0.1)
無髄歯	0	1 (0.2)	1 (0.1)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
胃腸障害 (Cont.)			
レッチング	0	1 (0.2)	1 (0.1)
口内炎	1 (0.2)	0	1 (0.1)
生歯	1 (0.2)	0	1 (0.1)
歯の障害	1 (0.2)	1 (0.2)	2 (0.2)
埋伏歯	2 (0.5)	3 (0.7)	5 (0.6)
歯痛	3 (0.7)	9 (2.1)	12 (1.4)
嘔吐	5 (1.1)	8 (1.8)	13 (1.5)
一般・全身障害および投与部位の状態	54 (12.2)	57 (13.1)	111 (12.6)
胸部不快感	2 (0.5)	1 (0.2)	3 (0.3)
胸痛	5 (1.1)	4 (0.9)	9 (1.0)
悪寒	3 (0.7)	0	3 (0.3)
嚢胞	1 (0.2)	1 (0.2)	2 (0.2)
顔面浮腫	1 (0.2)	0	1 (0.1)
顔面痛	3 (0.7)	0	3 (0.3)
疲労	10 (2.3)	6 (1.4)	16 (1.8)
熱感	1 (0.2)	0	1 (0.1)
肉芽腫	0	1 (0.2)	1 (0.1)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
ヘルニア	0	1 (0.2)	1 (0.1)
低体温	0	1 (0.2)	1 (0.1)
治癒不良	0	1 (0.2)	1 (0.1)
炎症	0	1 (0.2)	1 (0.1)
インフルエンザ様疾患	12 (2.7)	16 (3.7)	28 (3.2)
倦怠感	2 (0.5)	1 (0.2)	3 (0.3)
小結節	0	1 (0.2)	1 (0.1)
非心臓性胸痛	0	1 (0.2)	1 (0.1)
末梢性浮腫	3 (0.7)	0	3 (0.3)
疼痛	4 (0.9)	2 (0.5)	6 (0.7)
末梢腫脹	1 (0.2)	1 (0.2)	2 (0.2)
発熱	19 (4.3)	18 (4.1)	37 (4.2)
腫脹	3 (0.7)	1 (0.2)	4 (0.5)
顔面腫脹	3 (0.7)	1 (0.2)	4 (0.5)
血管穿刺部位内出血	0	1 (0.2)	1 (0.1)
肝胆道系障害	8 (1.8)	6 (1.4)	14 (1.6)
肝機能異常	5 (1.1)	2 (0.5)	7 (0.8)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
肝胆道系障害 (Cont.)			
脂肪肝	3 (0.7)	1 (0.2)	4 (0.5)
肝細胞損傷	0	1 (0.2)	1 (0.1)
肝腫大	0	1 (0.2)	1 (0.1)
高ビリルビン血症	1 (0.2)	0	1 (0.1)
非アルコール性脂肪性肝炎	0	1 (0.2)	1 (0.1)
免疫系障害	8 (1.8)	12 (2.8)	20 (2.3)
アレルギー性浮腫	0	1 (0.2)	1 (0.1)
動物アレルギー	0	1 (0.2)	1 (0.1)
アナフィラキシー反応	0	1 (0.2)	1 (0.1)
薬物過敏症	1 (0.2)	0	1 (0.1)
食物アレルギー	1 (0.2)	2 (0.5)	3 (0.3)
過敏症	3 (0.7)	4 (0.9)	7 (0.8)
季節性アレルギー	4 (0.9)	3 (0.7)	7 (0.8)
血清病	0	1 (0.2)	1 (0.1)
感染症および寄生虫症	263 (59.4)	278 (63.8)	541 (61.5)
四肢膿瘍	0	1 (0.2)	1 (0.1)
口腔膿瘍	0	1 (0.2)	1 (0.1)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
感染症および寄生虫症 (Cont.)			
ダニ皮膚炎	1 (0.2)	1 (0.2)	2 (0.2)
膿疱性ざ瘡	1 (0.2)	2 (0.5)	3 (0.3)
急性副鼻腔炎	1 (0.2)	0	1 (0.1)
肛門膿瘍	1 (0.2)	0	1 (0.1)
虫垂炎	1 (0.2)	0	1 (0.1)
細菌性疾患キャリアー	1 (0.2)	0	1 (0.1)
細菌感染	3 (0.7)	2 (0.5)	5 (0.6)
細菌性膣症	1 (0.2)	0	1 (0.1)
細菌尿	0	1 (0.2)	1 (0.1)
バルトネラ症	1 (0.2)	0	1 (0.1)
体部白癬	2 (0.5)	6 (1.4)	8 (0.9)
気管支炎	8 (1.8)	13 (3.0)	21 (2.4)
ウイルス性気管支炎	0	1 (0.2)	1 (0.1)
水疱性膿痂疹	1 (0.2)	0	1 (0.1)
感染性滑液包炎	0	1 (0.2)	1 (0.1)
カンジダ感染	0	1 (0.2)	1 (0.1)
蜂巣炎	3 (0.7)	4 (0.9)	7 (0.8)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
感染症および寄生虫症 (Cont.)			
条虫感染	1 (0.2)	0	1 (0.1)
クラミジア感染	0	1 (0.2)	1 (0.1)
慢性副鼻腔炎	1 (0.2)	0	1 (0.1)
結膜炎	12 (2.7)	10 (2.3)	22 (2.5)
細菌性結膜炎	1 (0.2)	1 (0.2)	2 (0.2)
ウイルス性結膜炎	1 (0.2)	1 (0.2)	2 (0.2)
コロナウイルス感染	10 (2.3)	10 (2.3)	20 (2.3)
膀胱炎	2 (0.5)	2 (0.5)	4 (0.5)
涙嚢炎	1 (0.2)	0	1 (0.1)
医療機器関連感染	1 (0.2)	0	1 (0.1)
感染性下痢	0	1 (0.2)	1 (0.1)
赤痢	1 (0.2)	0	1 (0.1)
耳感染	3 (0.7)	1 (0.2)	4 (0.5)
ブドウ球菌性耳感染	0	1 (0.2)	1 (0.1)
ヘルペス性状湿疹	5 (1.1)	10 (2.3)	15 (1.7)
膿痂疹性湿疹	2 (0.5)	2 (0.5)	4 (0.5)
感染性湿疹	0	1 (0.2)	1 (0.1)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
感染症および寄生虫症 (Cont.)			
エンテロバクター感染	1 (0.2)	0	1 (0.1)
蟯虫症	1 (0.2)	0	1 (0.1)
丹毒	1 (0.2)	0	1 (0.1)
眼感染	1 (0.2)	0	1 (0.1)
ブドウ球菌性眼感染	1 (0.2)	1 (0.2)	2 (0.2)
ウイルス性眼感染	1 (0.2)	0	1 (0.1)
眼瞼感染	2 (0.5)	0	2 (0.2)
糸状虫症	0	1 (0.2)	1 (0.1)
毛包炎	19 (4.3)	21 (4.8)	40 (4.6)
真菌感染	3 (0.7)	0	3 (0.3)
皮膚真菌感染	3 (0.7)	4 (0.9)	7 (0.8)
せつ	4 (0.9)	5 (1.1)	9 (1.0)
ウイルス性胃炎	1 (0.2)	0	1 (0.1)
胃腸炎	12 (2.7)	13 (3.0)	25 (2.8)
ウイルス性胃腸炎	0	6 (1.4)	6 (0.7)
消化管感染	1 (0.2)	0	1 (0.1)
陰部ヘルペス	0	2 (0.5)	2 (0.2)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
感染症および寄生虫症 (Cont.)			
陰部単純ヘルペス	0	3 (0.7)	3 (0.3)
ジアルジア症	1 (0.2)	0	1 (0.1)
歯肉炎	1 (0.2)	1 (0.2)	2 (0.2)
ヘルペス眼感染	1 (0.2)	3 (0.7)	4 (0.5)
単純ヘルペス	23 (5.2)	24 (5.5)	47 (5.3)
帯状疱疹	18 (4.1)	28 (6.4)	46 (5.2)
皮膚播種性帯状疱疹	1 (0.2)	0	1 (0.1)
播種性帯状疱疹	0	1 (0.2)	1 (0.1)
耳帯状疱疹	0	2 (0.5)	2 (0.2)
麦粒腫	6 (1.4)	5 (1.1)	11 (1.3)
膿痂疹	13 (2.9)	10 (2.3)	23 (2.6)
切開部位蜂巣炎	1 (0.2)	0	1 (0.1)
感染性嚢腫	1 (0.2)	0	1 (0.1)
感染性皮膚嚢腫	0	1 (0.2)	1 (0.1)
感染	1 (0.2)	1 (0.2)	2 (0.2)
寄生虫感染	1 (0.2)	0	1 (0.1)
インフルエンザ	15 (3.4)	11 (2.5)	26 (3.0)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
感染症および寄生虫症 (Cont.)			
関節膿瘍	0	1 (0.2)	1 (0.1)
カポジ水痘様発疹	1 (0.2)	4 (0.9)	5 (0.6)
ウイルス性角膜炎	1 (0.2)	0	1 (0.1)
腎感染	1 (0.2)	0	1 (0.1)
大腸感染	1 (0.2)	0	1 (0.1)
喉頭炎	1 (0.2)	0	1 (0.1)
潜伏結核	1 (0.2)	3 (0.7)	4 (0.5)
シラミ寄生	0	1 (0.2)	1 (0.1)
マラセチア感染	1 (0.2)	1 (0.2)	2 (0.2)
細菌性乳腺炎	1 (0.2)	0	1 (0.1)
ウイルス性髄膜炎	1 (0.2)	0	1 (0.1)
メタニューモウイルス感染	1 (0.2)	0	1 (0.1)
伝染性軟属腫	4 (0.9)	4 (0.9)	8 (0.9)
鼻ヘルペス	1 (0.2)	3 (0.7)	4 (0.5)
上咽頭炎	76 (17.2)	73 (16.7)	149 (17.0)
爪真菌症	2 (0.5)	3 (0.7)	5 (0.6)
眼部単純ヘルペス	6 (1.4)	9 (2.1)	15 (1.7)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
感染症および寄生虫症 (Cont.)			
眼帯状疱疹	0	1 (0.2)	1 (0.1)
口腔カンジダ症	1 (0.2)	3 (0.7)	4 (0.5)
口腔ヘルペス	20 (4.5)	36 (8.3)	56 (6.4)
外耳炎	4 (0.9)	4 (0.9)	8 (0.9)
中耳炎	3 (0.7)	2 (0.5)	5 (0.6)
急性中耳炎	1 (0.2)	1 (0.2)	2 (0.2)
爪囲炎	3 (0.7)	2 (0.5)	5 (0.6)
インプラント周囲炎	1 (0.2)	0	1 (0.1)
軟骨膜炎	1 (0.2)	0	1 (0.1)
歯周炎	1 (0.2)	0	1 (0.1)
眼窩周囲蜂巣炎	1 (0.2)	0	1 (0.1)
扁桃周囲膿瘍	1 (0.2)	0	1 (0.1)
咽頭炎	10 (2.3)	12 (2.8)	22 (2.5)
レンサ球菌性咽頭炎	2 (0.5)	2 (0.5)	4 (0.5)
肺炎	4 (0.9)	4 (0.9)	8 (0.9)
マイコプラズマ性肺炎	0	2 (0.5)	2 (0.2)
ウイルス感染後疲労症候群	0	1 (0.2)	1 (0.1)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
感染症および寄生虫症 (Cont.)			
術後創感染	0	2 (0.5)	2 (0.2)
歯髄炎	0	1 (0.2)	1 (0.1)
化膿性分泌物	1 (0.2)	0	1 (0.1)
膿疱	1 (0.2)	3 (0.7)	4 (0.5)
腎盂腎炎	1 (0.2)	1 (0.2)	2 (0.2)
膿疱性皮疹	0	2 (0.5)	2 (0.2)
気道感染	3 (0.7)	1 (0.2)	4 (0.5)
ウイルス性気道感染	2 (0.5)	1 (0.2)	3 (0.3)
鼻炎	3 (0.7)	1 (0.2)	4 (0.5)
鼻咽頭炎	0	1 (0.2)	1 (0.1)
ライノウイルス感染	0	1 (0.2)	1 (0.1)
副鼻腔炎	5 (1.1)	7 (1.6)	12 (1.4)
皮膚細菌感染	3 (0.7)	1 (0.2)	4 (0.5)
皮膚感染	7 (1.6)	4 (0.9)	11 (1.3)
膿性痰	1 (0.2)	0	1 (0.1)
ブドウ球菌性膿瘍	1 (0.2)	0	1 (0.1)
ブドウ球菌性膿痂疹	1 (0.2)	0	1 (0.1)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
感染症および寄生虫症 (Cont.)			
ブドウ球菌感染	3 (0.7)	3 (0.7)	6 (0.7)
ブドウ球菌皮膚感染	4 (0.9)	7 (1.6)	11 (1.3)
細菌重複感染	0	1 (0.2)	1 (0.1)
真菌重複感染	1 (0.2)	0	1 (0.1)
股部白癬	0	2 (0.5)	2 (0.2)
白癬感染	1 (0.2)	2 (0.5)	3 (0.3)
足部白癬	6 (1.4)	9 (2.1)	15 (1.7)
癜風	1 (0.2)	4 (0.9)	5 (0.6)
扁桃炎	4 (0.9)	6 (1.4)	10 (1.1)
歯感染	4 (0.9)	5 (1.1)	9 (1.0)
気管炎	2 (0.5)	1 (0.2)	3 (0.3)
気管気管支炎	1 (0.2)	0	1 (0.1)
トリコモナス症	0	1 (0.2)	1 (0.1)
トリコフィトン感染症	1 (0.2)	0	1 (0.1)
上気道感染	45 (10.2)	45 (10.3)	90 (10.2)
ウレアプラズマ感染	1 (0.2)	0	1 (0.1)
尿道炎	1 (0.2)	0	1 (0.1)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
感染症および寄生虫症 (Cont.)			
尿路感染	11 (2.5)	21 (4.8)	32 (3.6)
細菌性尿路感染	0	1 (0.2)	1 (0.1)
腟感染	2 (0.5)	1 (0.2)	3 (0.3)
ウイルス感染	1 (0.2)	3 (0.7)	4 (0.5)
ウイルス性咽頭炎	2 (0.5)	2 (0.5)	4 (0.5)
ウイルス性上気道感染	5 (1.1)	10 (2.3)	15 (1.7)
外陰部腟カンジダ症	3 (0.7)	1 (0.2)	4 (0.5)
外陰腟真菌感染	1 (0.2)	2 (0.5)	3 (0.3)
トリコモナス外陰腟炎	1 (0.2)	0	1 (0.1)
傷害、中毒および処置合併症	37 (8.4)	44 (10.1)	81 (9.2)
事故	1 (0.2)	1 (0.2)	2 (0.2)
動物咬傷	1 (0.2)	0	1 (0.1)
足関節部骨折	0	1 (0.2)	1 (0.1)
節足動物咬傷	0	2 (0.5)	2 (0.2)
節足動物刺傷	2 (0.5)	0	2 (0.2)
骨挫傷	0	1 (0.2)	1 (0.1)
軟骨損傷	1 (0.2)	1 (0.2)	2 (0.2)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
傷害、中毒および処置合併症 (Cont.)			
胸部損傷	0	1 (0.2)	1 (0.1)
鎖骨骨折	0	1 (0.2)	1 (0.1)
挫傷	2 (0.5)	3 (0.7)	5 (0.6)
角膜擦過傷	0	1 (0.2)	1 (0.1)
頭蓋脳損傷	1 (0.2)	1 (0.2)	2 (0.2)
胸骨脱臼	0	1 (0.2)	1 (0.1)
上顆炎	0	1 (0.2)	1 (0.1)
眼挫傷	0	1 (0.2)	1 (0.1)
眼外傷	0	1 (0.2)	1 (0.1)
転倒	2 (0.5)	5 (1.1)	7 (0.8)
大腿骨骨折	0	1 (0.2)	1 (0.1)
足骨折	3 (0.7)	1 (0.2)	4 (0.5)
尾骨骨折	1 (0.2)	0	1 (0.1)
頭部損傷	1 (0.2)	0	1 (0.1)
熱疲労	0	1 (0.2)	1 (0.1)
上腕骨骨折	0	1 (0.2)	1 (0.1)
腸骨骨折	1 (0.2)	0	1 (0.1)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
傷害、中毒および処置合併症 (Cont.)			
損傷	2 (0.5)	1 (0.2)	3 (0.3)
関節脱臼	0	1 (0.2)	1 (0.1)
関節損傷	1 (0.2)	4 (0.9)	5 (0.6)
靭帯損傷	1 (0.2)	0	1 (0.1)
靭帯断裂	0	1 (0.2)	1 (0.1)
靭帯捻挫	1 (0.2)	1 (0.2)	2 (0.2)
四肢損傷	4 (0.9)	1 (0.2)	5 (0.6)
半月板損傷	1 (0.2)	0	1 (0.1)
筋損傷	0	1 (0.2)	1 (0.1)
肉離れ	2 (0.5)	5 (1.1)	7 (0.8)
開放骨折	0	1 (0.2)	1 (0.1)
処置による疼痛	1 (0.2)	2 (0.5)	3 (0.3)
橈骨骨折	0	3 (0.7)	3 (0.3)
肋骨骨折	3 (0.7)	1 (0.2)	4 (0.5)
交通事故	0	3 (0.7)	3 (0.3)
瘢痕	1 (0.2)	0	1 (0.1)
皮膚擦過傷	2 (0.5)	1 (0.2)	3 (0.3)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
傷害、中毒および処置合併症 (Cont.)			
皮膚裂傷	3 (0.7)	1 (0.2)	4 (0.5)
脊椎骨折	1 (0.2)	0	1 (0.1)
スポーツ損傷	1 (0.2)	0	1 (0.1)
胸骨骨折	1 (0.2)	0	1 (0.1)
サンバーン	1 (0.2)	1 (0.2)	2 (0.2)
腱損傷	0	1 (0.2)	1 (0.1)
腱断裂	1 (0.2)	0	1 (0.1)
熱傷	1 (0.2)	0	1 (0.1)
歯牙破折	2 (0.5)	2 (0.5)	4 (0.5)
外傷性血腫	1 (0.2)	0	1 (0.1)
上肢骨折	0	1 (0.2)	1 (0.1)
創傷	0	1 (0.2)	1 (0.1)
創部分泌	0	1 (0.2)	1 (0.1)
手首関節骨折	1 (0.2)	0	1 (0.1)
臨床検査	88 (19.9)	94 (21.6)	182 (20.7)
アラニンアミノトランスフェラーゼ増加	12 (2.7)	8 (1.8)	20 (2.3)
アスパラギン酸アミノトランスフェラーゼ異常	1 (0.2)	0	1 (0.1)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
臨床検査 (Cont.)			
アスパラギン酸アミノトランスフェラーゼ増加	8 (1.8)	7 (1.6)	15 (1.7)
血中アルカリホスファターゼ増加	1 (0.2)	0	1 (0.1)
血中重炭酸塩減少	0	1 (0.2)	1 (0.1)
血中ビリルビン増加	1 (0.2)	1 (0.2)	2 (0.2)
血中コレステロール	1 (0.2)	0	1 (0.1)
血中コレステロール増加	4 (0.9)	2 (0.5)	6 (0.7)
血中クレアチンホスホキナーゼ増加	37 (8.4)	49 (11.2)	86 (9.8)
血中クレアチニン増加	1 (0.2)	2 (0.5)	3 (0.3)
血中葉酸減少	1 (0.2)	0	1 (0.1)
血中ブドウ糖増加	1 (0.2)	1 (0.2)	2 (0.2)
血中免疫グロブリンＥ増加	1 (0.2)	0	1 (0.1)
血中鉄減少	0	1 (0.2)	1 (0.1)
血中リン減少	1 (0.2)	0	1 (0.1)
血中カリウム減少	0	1 (0.2)	1 (0.1)
血圧上昇	5 (1.1)	2 (0.5)	7 (0.8)
血中遊離テストステロン減少	1 (0.2)	0	1 (0.1)
血中トリグリセリド増加	2 (0.5)	3 (0.7)	5 (0.6)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
臨床検査 (Cont.)			
血中尿素増加	0	1 (0.2)	1 (0.1)
血中尿酸増加	3 (0.7)	0	3 (0.3)
尿中血陽性	0	1 (0.2)	1 (0.1)
体温上昇	0	1 (0.2)	1 (0.1)
心電図 QT 間隔異常	1 (0.2)	0	1 (0.1)
好酸球数増加	3 (0.7)	1 (0.2)	4 (0.5)
好酸球百分率増加	1 (0.2)	0	1 (0.1)
便量増加	0	1 (0.2)	1 (0.1)
真菌検査陽性	1 (0.2)	0	1 (0.1)
ヘモグロビン減少	1 (0.2)	6 (1.4)	7 (0.8)
ヘリコバクター検査陽性	1 (0.2)	0	1 (0.1)
肝酵素上昇	1 (0.2)	0	1 (0.1)
肝機能検査異常	1 (0.2)	1 (0.2)	2 (0.2)
低比重リポ蛋白増加	1 (0.2)	3 (0.7)	4 (0.5)
リンパ球数減少	1 (0.2)	0	1 (0.1)
リンパ球数増加	1 (0.2)	0	1 (0.1)
平均赤血球容積増加	1 (0.2)	0	1 (0.1)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
臨床検査 (Cont.)			
単球数増加	0	1 (0.2)	1 (0.1)
結核菌群検査陽性	2 (0.5)	0	2 (0.2)
好中球数減少	8 (1.8)	5 (1.1)	13 (1.5)
好中球数増加	1 (0.2)	0	1 (0.1)
好中球百分率減少	1 (0.2)	0	1 (0.1)
好中球百分率増加	1 (0.2)	0	1 (0.1)
ポリオーマウイルス検査陽性	1 (0.2)	0	1 (0.1)
尿中蛋白陽性	3 (0.7)	1 (0.2)	4 (0.5)
赤血球数減少	1 (0.2)	1 (0.2)	2 (0.2)
ブドウ球菌検査陽性	3 (0.7)	0	3 (0.3)
トランスアミナーゼ上昇	0	1 (0.2)	1 (0.1)
トロポニン増加	0	1 (0.2)	1 (0.1)
ビタミン B12 減少	1 (0.2)	0	1 (0.1)
ビタミン D 減少	0	1 (0.2)	1 (0.1)
体重減少	2 (0.5)	0	2 (0.2)
体重増加	9 (2.0)	14 (3.2)	23 (2.6)
白血球数減少	3 (0.7)	4 (0.9)	7 (0.8)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
臨床検査 (Cont.)			
白血球数増加	0	1 (0.2)	1 (0.1)
尿中白血球陽性	1 (0.2)	2 (0.5)	3 (0.3)
代謝および栄養障害	20 (4.5)	22 (5.0)	42 (4.8)
食欲減退	2 (0.5)	0	2 (0.2)
脱水	0	2 (0.5)	2 (0.2)
糖尿病	0	2 (0.5)	2 (0.2)
脂質異常症	0	2 (0.5)	2 (0.2)
水分過負荷	0	1 (0.2)	1 (0.1)
食物不耐性	1 (0.2)	0	1 (0.1)
耐糖能障害	1 (0.2)	0	1 (0.1)
グルテン過敏症	0	1 (0.2)	1 (0.1)
痛風	1 (0.2)	1 (0.2)	2 (0.2)
高コレステロール血症	3 (0.7)	4 (0.9)	7 (0.8)
高血糖	3 (0.7)	2 (0.5)	5 (0.6)
高ホモシステイン血症	1 (0.2)	0	1 (0.1)
高カリウム血症	1 (0.2)	0	1 (0.1)
高脂血症	1 (0.2)	5 (1.1)	6 (0.7)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
代謝および栄養障害 (Cont.)			
高ナトリウム血症	1 (0.2)	0	1 (0.1)
高トリグリセリド血症	1 (0.2)	2 (0.5)	3 (0.3)
高尿酸血症	4 (0.9)	2 (0.5)	6 (0.7)
低カリウム血症	0	1 (0.2)	1 (0.1)
低マグネシウム血症	1 (0.2)	0	1 (0.1)
低ナトリウム血症	1 (0.2)	1 (0.2)	2 (0.2)
食欲亢進	0	2 (0.5)	2 (0.2)
鉄欠乏	0	1 (0.2)	1 (0.1)
肥満	1 (0.2)	0	1 (0.1)
ビタミン B12 欠乏	1 (0.2)	0	1 (0.1)
ビタミン D 欠乏	1 (0.2)	2 (0.5)	3 (0.3)
筋骨格系および結合組織障害	40 (9.0)	60 (13.8)	100 (11.4)
関節痛	10 (2.3)	9 (2.1)	19 (2.2)
関節炎	2 (0.5)	4 (0.9)	6 (0.7)
背部痛	9 (2.0)	12 (2.8)	21 (2.4)
骨痛	0	1 (0.2)	1 (0.1)
滑液包炎	2 (0.5)	5 (1.1)	7 (0.8)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
筋骨格系および結合組織障害 (Cont.)			
尾骨痛	0	1 (0.2)	1 (0.1)
外骨腫	1 (0.2)	0	1 (0.1)
出血性関節症	0	1 (0.2)	1 (0.1)
椎間板突出	0	4 (0.9)	4 (0.5)
関節ロック	0	1 (0.2)	1 (0.1)
関節腫脹	0	1 (0.2)	1 (0.1)
四肢不快感	1 (0.2)	0	1 (0.1)
筋痙縮	1 (0.2)	6 (1.4)	7 (0.8)
筋攣縮	0	1 (0.2)	1 (0.1)
筋骨格系胸痛	2 (0.5)	3 (0.7)	5 (0.6)
筋骨格痛	1 (0.2)	3 (0.7)	4 (0.5)
筋骨格硬直	0	1 (0.2)	1 (0.1)
筋肉痛	5 (1.1)	4 (0.9)	9 (1.0)
頚部腫瘤	0	1 (0.2)	1 (0.1)
頚部痛	5 (1.1)	2 (0.5)	7 (0.8)
骨減少症	0	1 (0.2)	1 (0.1)
骨粗鬆症	0	1 (0.2)	1 (0.1)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
筋骨格系および結合組織障害 (Cont.)			
四肢痛	4 (0.9)	7 (1.6)	11 (1.3)
顎痛	0	1 (0.2)	1 (0.1)
膝蓋大腿関節痛症候群	1 (0.2)	0	1 (0.1)
足底筋膜炎	1 (0.2)	0	1 (0.1)
脊柱管狭窄症	0	1 (0.2)	1 (0.1)
脊椎すべり症	0	1 (0.2)	1 (0.1)
軟骨下脆弱性骨折	0	1 (0.2)	1 (0.1)
滑液嚢腫	0	1 (0.2)	1 (0.1)
顎関節症候群	1 (0.2)	1 (0.2)	2 (0.2)
腱炎	1 (0.2)	2 (0.5)	3 (0.3)
腱鞘炎	0	1 (0.2)	1 (0.1)
斜頚	2 (0.5)	0	2 (0.2)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	15 (3.4)	15 (3.4)	30 (3.4)
結腸腺癌	0	1 (0.2)	1 (0.1)
肛門性器疣贅	0	2 (0.5)	2 (0.2)
良性新生物	0	1 (0.2)	1 (0.1)
精巣の良性新生物	0	1 (0.2)	1 (0.1)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)			
異形成母斑	1 (0.2)	0	1 (0.1)
血管腫	1 (0.2)	1 (0.2)	2 (0.2)
ケラトアカントーマ	0	1 (0.2)	1 (0.1)
表皮内悪性黒色腫	0	1 (0.2)	1 (0.1)
メラノサイト性母斑	1 (0.2)	0	1 (0.1)
結節性筋膜炎	1 (0.2)	0	1 (0.1)
化膿性肉芽腫	0	1 (0.2)	1 (0.1)
脂漏性角化症	1 (0.2)	1 (0.2)	2 (0.2)
皮膚乳頭腫	8 (1.8)	5 (1.1)	13 (1.5)
口腔内扁平上皮癌	1 (0.2)	0	1 (0.1)
子宮平滑筋腫	1 (0.2)	1 (0.2)	2 (0.2)
神経系障害	49 (11.1)	52 (11.9)	101 (11.5)
手根管症候群	1 (0.2)	0	1 (0.1)
馬尾症候群	0	1 (0.2)	1 (0.1)
脳血管発作	0	1 (0.2)	1 (0.1)
浮動性めまい	8 (1.8)	7 (1.6)	15 (1.7)
味覚不全	0	2 (0.5)	2 (0.2)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
神経系障害 (Cont.)			
てんかん	0	1 (0.2)	1 (0.1)
労作性頭痛	1 (0.2)	0	1 (0.1)
全身性強直性間代性発作	0	1 (0.2)	1 (0.1)
頭部不快感	0	1 (0.2)	1 (0.1)
頭痛	29 (6.5)	28 (6.4)	57 (6.5)
過眠症	0	1 (0.2)	1 (0.1)
筋緊張亢進	0	1 (0.2)	1 (0.1)
感覚鈍麻	2 (0.5)	1 (0.2)	3 (0.3)
嗜眠	0	1 (0.2)	1 (0.1)
片頭痛	5 (1.1)	3 (0.7)	8 (0.9)
前兆を伴う片頭痛	1 (0.2)	0	1 (0.1)
多発性硬化症	0	1 (0.2)	1 (0.1)
多発性硬化症再発	0	1 (0.2)	1 (0.1)
神経圧迫	0	1 (0.2)	1 (0.1)
末梢性ニューロパチー	1 (0.2)	1 (0.2)	2 (0.2)
錯感覚	2 (0.5)	1 (0.2)	3 (0.3)
嗅覚錯誤	0	1 (0.2)	1 (0.1)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
神経系障害 (Cont.)			
末梢神経不全麻痺	1 (0.2)	0	1 (0.1)
ヘルペス後神経痛	2 (0.5)	1 (0.2)	3 (0.3)
失神寸前の状態	1 (0.2)	1 (0.2)	2 (0.2)
坐骨神経痛	1 (0.2)	2 (0.5)	3 (0.3)
傾眠	0	1 (0.2)	1 (0.1)
くも膜下出血	1 (0.2)	0	1 (0.1)
失神	0	1 (0.2)	1 (0.1)
足根管症候群	1 (0.2)	0	1 (0.1)
緊張性頭痛	0	1 (0.2)	1 (0.1)
三叉神経痛	0	1 (0.2)	1 (0.1)
トンネル状視野	0	1 (0.2)	1 (0.1)
妊娠、産褥および周産期の状態	0	1 (0.2)	1 (0.1)
自然流産	0	1 (0.2)	1 (0.1)
精神障害	27 (6.1)	29 (6.7)	56 (6.4)
感情不安定	2 (0.5)	0	2 (0.2)
アルコール使用障害	0	1 (0.2)	1 (0.1)
不安	6 (1.4)	4 (0.9)	10 (1.1)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
精神障害 (Cont.)			
注意欠陥多動性障害	1 (0.2)	2 (0.5)	3 (0.3)
双極性障害	0	1 (0.2)	1 (0.1)
抑うつ気分	4 (0.9)	3 (0.7)	7 (0.8)
うつ病	3 (0.7)	4 (0.9)	7 (0.8)
抑うつ症状	1 (0.2)	0	1 (0.1)
全般性不安障害	1 (0.2)	0	1 (0.1)
不眠症	4 (0.9)	6 (1.4)	10 (1.1)
易刺激性	1 (0.2)	0	1 (0.1)
リビドー減退	0	1 (0.2)	1 (0.1)
リビドー亢進	1 (0.2)	0	1 (0.1)
精神障害	0	1 (0.2)	1 (0.1)
混合性不安抑うつ障害	0	1 (0.2)	1 (0.1)
悪夢	1 (0.2)	0	1 (0.1)
パニック発作	1 (0.2)	1 (0.2)	2 (0.2)
心的外傷後ストレス障害	0	1 (0.2)	1 (0.1)
睡眠障害	0	2 (0.5)	2 (0.2)
ストレス	2 (0.5)	2 (0.5)	4 (0.5)

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精神障害 (Cont.)			
自殺念慮	0	1 (0.2)	1 (0.1)
自殺企図	1 (0.2)	0	1 (0.1)
腎および尿路障害	13 (2.9)	14 (3.2)	27 (3.1)
急性腎障害	1 (0.2)	0	1 (0.1)
アルブミン尿	2 (0.5)	1 (0.2)	3 (0.3)
尿路結石	1 (0.2)	0	1 (0.1)
出血性膀胱炎	0	1 (0.2)	1 (0.1)
排尿困難	3 (0.7)	0	3 (0.3)
糖尿	1 (0.2)	0	1 (0.1)
血尿	2 (0.5)	5 (1.1)	7 (0.8)
水腎症	1 (0.2)	0	1 (0.1)
緊張性膀胱	0	1 (0.2)	1 (0.1)
腎結石症	1 (0.2)	2 (0.5)	3 (0.3)
夜間頻尿	1 (0.2)	0	1 (0.1)
頻尿	0	2 (0.5)	2 (0.2)
多尿	1 (0.2)	0	1 (0.1)
蛋白尿	1 (0.2)	3 (0.7)	4 (0.5)

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腎および尿路障害 (Cont.)			
腎仙痛	0	1 (0.2)	1 (0.1)
生殖系および乳房障害	16 (3.6)	20 (4.6)	36 (4.1)
無月経	1 (0.2)	1 (0.2)	2 (0.2)
萎縮性外陰腟炎	0	1 (0.2)	1 (0.1)
乳房嚢胞	2 (0.5)	0	2 (0.2)
子宮頚部上皮異形成	2 (0.5)	2 (0.5)	4 (0.5)
月経困難症	1 (0.2)	0	1 (0.1)
子宮内膜症	0	2 (0.5)	2 (0.2)
勃起不全	1 (0.2)	3 (0.7)	4 (0.5)
女性化乳房	0	1 (0.2)	1 (0.1)
過少月経	1 (0.2)	0	1 (0.1)
月経過多	1 (0.2)	0	1 (0.1)
月経障害	1 (0.2)	0	1 (0.1)
不規則月経	1 (0.2)	2 (0.5)	3 (0.3)
不正子宮出血	0	1 (0.2)	1 (0.1)
骨盤痛	0	1 (0.2)	1 (0.1)
多嚢胞性卵巣	0	1 (0.2)	1 (0.1)

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生殖系および乳房障害 (Cont.)			
前立腺炎	1 (0.2)	0	1 (0.1)
精巣障害	0	1 (0.2)	1 (0.1)
精巣腫瘤	0	2 (0.5)	2 (0.2)
精巣痛	1 (0.2)	3 (0.7)	4 (0.5)
腟分泌物	2 (0.5)	0	2 (0.2)
腟出血	1 (0.2)	1 (0.2)	2 (0.2)
女性外陰部潰瘍	0	1 (0.2)	1 (0.1)
外陰腟乾燥	1 (0.2)	0	1 (0.1)
呼吸器、胸郭および縦隔障害	70 (15.8)	70 (16.1)	140 (15.9)
急性呼吸窮迫症候群	0	1 (0.2)	1 (0.1)
アレルギー性気管支炎	1 (0.2)	0	1 (0.1)
失声症	1 (0.2)	0	1 (0.1)
喘息	12 (2.7)	9 (2.1)	21 (2.4)
無気肺	1 (0.2)	0	1 (0.1)
カタル	6 (1.4)	5 (1.1)	11 (1.3)
慢性閉塞性肺疾患	0	1 (0.2)	1 (0.1)
咳嗽	23 (5.2)	26 (6.0)	49 (5.6)

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呼吸器、胸郭および縦隔障害 (Cont.)			
呼吸困難	5 (1.1)	5 (1.1)	10 (1.1)
鼻出血	6 (1.4)	6 (1.4)	12 (1.4)
喀血	2 (0.5)	0	2 (0.2)
しゃっくり	0	1 (0.2)	1 (0.1)
肺浸潤	1 (0.2)	0	1 (0.1)
縦隔血腫	1 (0.2)	0	1 (0.1)
鼻閉	1 (0.2)	1 (0.2)	2 (0.2)
鼻茸	1 (0.2)	0	1 (0.1)
鼻中隔弯曲	1 (0.2)	0	1 (0.1)
口腔咽頭痛	10 (2.3)	11 (2.5)	21 (2.4)
咽頭腫脹	0	1 (0.2)	1 (0.1)
胸水	1 (0.2)	0	1 (0.1)
胸膜痛	0	1 (0.2)	1 (0.1)
湿性咳嗽	1 (0.2)	0	1 (0.1)
肺塞栓症	1 (0.2)	0	1 (0.1)
肺肉芽腫	0	1 (0.2)	1 (0.1)
肺腫瘤	1 (0.2)	2 (0.5)	3 (0.3)

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呼吸器、胸郭および縦隔障害 (Cont.)			
気道うっ血	0	2 (0.5)	2 (0.2)
アレルギー性鼻炎	0	3 (0.7)	3 (0.3)
鼻漏	7 (1.6)	5 (1.1)	12 (1.4)
副鼻腔うっ血	1 (0.2)	2 (0.5)	3 (0.3)
睡眠時無呼吸症候群	1 (0.2)	0	1 (0.1)
くしゃみ	0	1 (0.2)	1 (0.1)
喘息発作重積	1 (0.2)	0	1 (0.1)
咽喉刺激感	0	1 (0.2)	1 (0.1)
上気道うっ血	1 (0.2)	0	1 (0.1)
喘鳴	1 (0.2)	1 (0.2)	2 (0.2)
皮膚および皮下組織障害	162 (36.6)	152 (34.9)	314 (35.7)
ざ瘡	62 (14.0)	81 (18.6)	143 (16.3)
嚢胞性ざ瘡	0	1 (0.2)	1 (0.1)
後天性ブラシュコ皮膚炎	1 (0.2)	0	1 (0.1)
光線角化症	0	1 (0.2)	1 (0.1)
脱毛症	2 (0.5)	1 (0.2)	3 (0.3)
血管浮腫	0	2 (0.5)	2 (0.2)

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皮膚および皮下組織障害 (Cont.)			
水疱	2 (0.5)	2 (0.5)	4 (0.5)
冷汗	0	1 (0.2)	1 (0.1)
皮膚嚢腫	1 (0.2)	1 (0.2)	2 (0.2)
皮膚炎	4 (0.9)	2 (0.5)	6 (0.7)
ざ瘡様皮膚炎	5 (1.1)	4 (0.9)	9 (1.0)
アレルギー性皮膚炎	2 (0.5)	2 (0.5)	4 (0.5)
アトピー性皮膚炎	47 (10.6)	29 (6.7)	76 (8.6)
接触皮膚炎	4 (0.9)	6 (1.4)	10 (1.1)
疱疹状皮膚炎	0	1 (0.2)	1 (0.1)
乾癬様皮膚炎	1 (0.2)	0	1 (0.1)
薬疹	1 (0.2)	0	1 (0.1)
皮膚乾燥	0	1 (0.2)	1 (0.1)
異汗性湿疹	3 (0.7)	0	3 (0.3)
斑状出血	0	2 (0.5)	2 (0.2)
湿疹	12 (2.7)	8 (1.8)	20 (2.3)
小水疱性湿疹	0	1 (0.2)	1 (0.1)
紅斑	3 (0.7)	2 (0.5)	5 (0.6)

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皮膚および皮下組織障害 (Cont.)			
過剰肉芽組織	1 (0.2)	0	1 (0.1)
毛髪成長異常	1 (0.2)	1 (0.2)	2 (0.2)
多汗症	3 (0.7)	1 (0.2)	4 (0.5)
過角化	3 (0.7)	1 (0.2)	4 (0.5)
多毛症	1 (0.2)	1 (0.2)	2 (0.2)
特発性蕁麻疹	0	1 (0.2)	1 (0.1)
嵌入爪	0	2 (0.5)	2 (0.2)
間擦疹	0	1 (0.2)	1 (0.1)
苔癬化	0	1 (0.2)	1 (0.1)
網状皮斑	0	1 (0.2)	1 (0.1)
稗粒腫	0	1 (0.2)	1 (0.1)
汗疹	4 (0.9)	2 (0.5)	6 (0.7)
神経皮膚炎	0	1 (0.2)	1 (0.1)
寝汗	1 (0.2)	1 (0.2)	2 (0.2)
爪破損	0	1 (0.2)	1 (0.1)
皮膚疼痛	1 (0.2)	0	1 (0.1)
丘疹	0	1 (0.2)	1 (0.1)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
皮膚および皮下組織障害 (Cont.)			
丘疹膿疱性酒さ	0	1 (0.2)	1 (0.1)
口囲皮膚炎	2 (0.5)	3 (0.7)	5 (0.6)
光線過敏性反応	0	2 (0.5)	2 (0.2)
白色粃糠疹	1 (0.2)	0	1 (0.1)
進行性黄斑メラニン減少症	1 (0.2)	0	1 (0.1)
そう痒症	7 (1.6)	1 (0.2)	8 (0.9)
偽毛包炎	1 (0.2)	0	1 (0.1)
紫斑	2 (0.5)	0	2 (0.2)
発疹	2 (0.5)	4 (0.9)	6 (0.7)
斑状丘疹状皮疹	0	1 (0.2)	1 (0.1)
丘疹性皮疹	1 (0.2)	1 (0.2)	2 (0.2)
そう痒性皮疹	1 (0.2)	0	1 (0.1)
小水疱性皮疹	1 (0.2)	1 (0.2)	2 (0.2)
酒さ	3 (0.7)	6 (1.4)	9 (1.0)
痂皮	0	2 (0.5)	2 (0.2)
脂漏	1 (0.2)	1 (0.2)	2 (0.2)
脂漏性皮膚炎	1 (0.2)	2 (0.5)	3 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
皮膚および皮下組織障害 (Cont.)			
敏感肌	1 (0.2)	0	1 (0.1)
皮膚灼熱感	0	1 (0.2)	1 (0.1)
皮膚変色	0	1 (0.2)	1 (0.1)
皮膚障害	0	1 (0.2)	1 (0.1)
皮膚剥脱	2 (0.5)	0	2 (0.2)
皮膚亀裂	1 (0.2)	3 (0.7)	4 (0.5)
皮膚刺激	2 (0.5)	1 (0.2)	3 (0.3)
皮膚腫瘤	3 (0.7)	2 (0.5)	5 (0.6)
皮膚線条	3 (0.7)	0	3 (0.3)
皮膚腫脹	0	1 (0.2)	1 (0.1)
皮膚潰瘍	1 (0.2)	2 (0.5)	3 (0.3)
皮膚熱感	1 (0.2)	0	1 (0.1)
日光黒子	1 (0.2)	0	1 (0.1)
蕁麻疹	13 (2.9)	12 (2.8)	25 (2.8)
圧迫性蕁麻疹	0	1 (0.2)	1 (0.1)
社会環境	1 (0.2)	0	1 (0.1)
歯科補てつ物使用者	1 (0.2)	0	1 (0.1)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
外科および内科処置	1 (0.2)	3 (0.7)	4 (0.5)
人工流産	0	1 (0.2)	1 (0.1)
子宮頚部円錐切除	1 (0.2)	0	1 (0.1)
避妊用インプラント	0	1 (0.2)	1 (0.1)
歯科手術	0	1 (0.2)	1 (0.1)
ポリープ切除	0	1 (0.2)	1 (0.1)
血管障害	13 (2.9)	12 (2.8)	25 (2.8)
大動脈瘤	0	1 (0.2)	1 (0.1)
大動脈解離	0	1 (0.2)	1 (0.1)
血腫	1 (0.2)	1 (0.2)	2 (0.2)
ほてり	0	1 (0.2)	1 (0.1)
高血圧	10 (2.3)	8 (1.8)	18 (2.0)
起立性低血圧	1 (0.2)	0	1 (0.1)
レイノー現象	0	1 (0.2)	1 (0.1)
四肢静脈血栓症	1 (0.2)	0	1 (0.1)

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Program Source Code: [redacted]

相互参照：M16-047 試験 CSR W52 Table 14.3__1.5.1.1

表 2. ウパダシチニブ投与期間中に有害事象を発現した被験者数及び発現割合：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団，青少年）

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) n (%)	UPA 30 mg QD + TCS (N=54) n (%)	Total (N=112) n (%)
Any adverse event	51 (87.9)	44 (81.5)	95 (84.8)
血液およびリンパ系障害	5 (8.6)	4 (7.4)	9 (8.0)
貧血	2 (3.4)	0	2 (1.8)
好酸球増加症	0	1 (1.9)	1 (0.9)
白血球減少症	0	2 (3.7)	2 (1.8)
リンパ節症	2 (3.4)	1 (1.9)	3 (2.7)
大赤血球症	1 (1.7)	0	1 (0.9)
単球減少症	0	1 (1.9)	1 (0.9)
好中球減少症	0	2 (3.7)	2 (1.8)
耳および迷路障害	1 (1.7)	1 (1.9)	2 (1.8)
難聴	0	1 (1.9)	1 (0.9)
耳痛	1 (1.7)	0	1 (0.9)
耳鳴	0	1 (1.9)	1 (0.9)
内分泌障害	0	1 (1.9)	1 (0.9)
甲状腺機能正常症候群	0	1 (1.9)	1 (0.9)
眼障害	1 (1.7)	3 (5.6)	4 (3.6)
眼瞼炎	0	1 (1.9)	1 (0.9)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) n (%)	UPA 30 mg QD + TCS (N=54) n (%)	Total (N=112) n (%)
眼障害 (Cont.)			
霰粒腫	1 (1.7)	0	1 (0.9)
眼痛	0	1 (1.9)	1 (0.9)
春季カタル	0	1 (1.9)	1 (0.9)
胃腸障害	10 (17.2)	15 (27.8)	25 (22.3)
腹痛	2 (3.4)	5 (9.3)	7 (6.3)
上腹部痛	2 (3.4)	2 (3.7)	4 (3.6)
便秘	0	1 (1.9)	1 (0.9)
下痢	1 (1.7)	5 (9.3)	6 (5.4)
消化不良	2 (3.4)	1 (1.9)	3 (2.7)
変色便	1 (1.7)	0	1 (0.9)
胃食道逆流性疾患	0	2 (3.7)	2 (1.8)
腸閉塞	1 (1.7)	0	1 (0.9)
悪心	3 (5.2)	4 (7.4)	7 (6.3)
歯の障害	1 (1.7)	0	1 (0.9)
嘔吐	2 (3.4)	4 (7.4)	6 (5.4)
一般・全身障害および投与部位の状態	4 (6.9)	8 (14.8)	12 (10.7)
顔面痛	1 (1.7)	0	1 (0.9)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) n (%)	UPA 30 mg QD + TCS (N=54) n (%)	Total (N=112) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
疲労	1 (1.7)	1 (1.9)	2 (1.8)
インフルエンザ様疾患	1 (1.7)	3 (5.6)	4 (3.6)
発熱	1 (1.7)	3 (5.6)	4 (3.6)
腫脹	1 (1.7)	0	1 (0.9)
顔面腫脹	0	1 (1.9)	1 (0.9)
肝胆道系障害	2 (3.4)	0	2 (1.8)
肝機能異常	2 (3.4)	0	2 (1.8)
免疫系障害	2 (3.4)	2 (3.7)	4 (3.6)
食物アレルギー	1 (1.7)	1 (1.9)	2 (1.8)
過敏症	1 (1.7)	1 (1.9)	2 (1.8)
感染症および寄生虫症	33 (56.9)	35 (64.8)	68 (60.7)
膿疱性ざ瘡	1 (1.7)	2 (3.7)	3 (2.7)
細菌性疾患キャリアー	1 (1.7)	0	1 (0.9)
細菌感染	1 (1.7)	1 (1.9)	2 (1.8)
バルトネラ症	1 (1.7)	0	1 (0.9)
気管支炎	1 (1.7)	0	1 (0.9)
結膜炎	2 (3.4)	2 (3.7)	4 (3.6)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) n (%)	UPA 30 mg QD + TCS (N=54) n (%)	Total (N=112) n (%)
感染症および寄生虫症 (Cont.)			
コロナウイルス感染	2 (3.4)	1 (1.9)	3 (2.7)
赤痢	1 (1.7)	0	1 (0.9)
耳感染	2 (3.4)	0	2 (1.8)
感染性湿疹	0	1 (1.9)	1 (0.9)
エンテロバクター感染	1 (1.7)	0	1 (0.9)
毛包炎	2 (3.4)	2 (3.7)	4 (3.6)
真菌感染	1 (1.7)	0	1 (0.9)
せつ	2 (3.4)	1 (1.9)	3 (2.7)
胃腸炎	1 (1.7)	1 (1.9)	2 (1.8)
ウイルス性胃腸炎	0	1 (1.9)	1 (0.9)
単純ヘルペス	5 (8.6)	2 (3.7)	7 (6.3)
帯状疱疹	0	2 (3.7)	2 (1.8)
膿痂疹	4 (6.9)	2 (3.7)	6 (5.4)
インフルエンザ	1 (1.7)	2 (3.7)	3 (2.7)
シラミ寄生	0	1 (1.9)	1 (0.9)
伝染性軟属腫	1 (1.7)	2 (3.7)	3 (2.7)
鼻ヘルペス	1 (1.7)	0	1 (0.9)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) n (%)	UPA 30 mg QD + TCS (N=54) n (%)	Total (N=112) n (%)
感染症および寄生虫症 (Cont.)			
上咽頭炎	9 (15.5)	6 (11.1)	15 (13.4)
爪真菌症	1 (1.7)	0	1 (0.9)
眼部単純ヘルペス	1 (1.7)	0	1 (0.9)
口腔ヘルペス	1 (1.7)	1 (1.9)	2 (1.8)
爪囲炎	1 (1.7)	0	1 (0.9)
咽頭炎	2 (3.4)	3 (5.6)	5 (4.5)
レンサ球菌性咽頭炎	0	2 (3.7)	2 (1.8)
肺炎	0	1 (1.9)	1 (0.9)
ウイルス性気道感染	1 (1.7)	0	1 (0.9)
副鼻腔炎	0	1 (1.9)	1 (0.9)
皮膚感染	2 (3.4)	1 (1.9)	3 (2.7)
ブドウ球菌性膿瘍	1 (1.7)	0	1 (0.9)
ブドウ球菌性膿痂疹	1 (1.7)	0	1 (0.9)
ブドウ球菌感染	1 (1.7)	0	1 (0.9)
ブドウ球菌皮膚感染	1 (1.7)	3 (5.6)	4 (3.6)
白癬感染	0	1 (1.9)	1 (0.9)
足部白癬	1 (1.7)	0	1 (0.9)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) n (%)	UPA 30 mg QD + TCS (N=54) n (%)	Total (N=112) n (%)
感染症および寄生虫症 (Cont.)			
癜風	0	1 (1.9)	1 (0.9)
扁桃炎	0	2 (3.7)	2 (1.8)
上気道感染	4 (6.9)	7 (13.0)	11 (9.8)
尿路感染	1 (1.7)	3 (5.6)	4 (3.6)
ウイルス性咽頭炎	1 (1.7)	0	1 (0.9)
ウイルス性上気道感染	0	3 (5.6)	3 (2.7)
外陰部腟カンジダ症	1 (1.7)	0	1 (0.9)
傷害、中毒および処置合併症	5 (8.6)	4 (7.4)	9 (8.0)
事故	0	1 (1.9)	1 (0.9)
挫傷	1 (1.7)	0	1 (0.9)
足骨折	0	1 (1.9)	1 (0.9)
損傷	0	1 (1.9)	1 (0.9)
靭帯断裂	0	1 (1.9)	1 (0.9)
四肢損傷	1 (1.7)	0	1 (0.9)
橈骨骨折	0	1 (1.9)	1 (0.9)
交通事故	0	1 (1.9)	1 (0.9)
瘢痕	1 (1.7)	0	1 (0.9)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) n (%)	UPA 30 mg QD + TCS (N=54) n (%)	Total (N=112) n (%)
傷害、中毒および処置合併症 (Cont.)			
スポーツ損傷	1 (1.7)	0	1 (0.9)
サンバーン	1 (1.7)	1 (1.9)	2 (1.8)
熱傷	1 (1.7)	0	1 (0.9)
臨床検査	13 (22.4)	16 (29.6)	29 (25.9)
アラニンアミノトランスフェラーゼ増加	2 (3.4)	0	2 (1.8)
アスパラギン酸アミノトランスフェラーゼ増加	2 (3.4)	0	2 (1.8)
血中アルカリホスファターゼ増加	1 (1.7)	0	1 (0.9)
血中コレステロール増加	1 (1.7)	0	1 (0.9)
血中クレアチンホスホキナーゼ増加	4 (6.9)	7 (13.0)	11 (9.8)
血中クレアチニン増加	0	1 (1.9)	1 (0.9)
血中葉酸減少	1 (1.7)	0	1 (0.9)
血中トリグリセリド増加	1 (1.7)	1 (1.9)	2 (1.8)
血中尿酸増加	2 (3.4)	0	2 (1.8)
心電図 QT 間隔異常	1 (1.7)	0	1 (0.9)
好酸球数増加	1 (1.7)	0	1 (0.9)
好酸球百分率増加	1 (1.7)	0	1 (0.9)
ヘモグロビン減少	0	1 (1.9)	1 (0.9)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) n (%)	UPA 30 mg QD + TCS (N=54) n (%)	Total (N=112) n (%)
臨床検査 (Cont.)			
平均赤血球容積増加	1 (1.7)	0	1 (0.9)
結核菌群検査陽性	1 (1.7)	0	1 (0.9)
好中球数減少	2 (3.4)	3 (5.6)	5 (4.5)
好中球百分率減少	1 (1.7)	0	1 (0.9)
尿中蛋白陽性	1 (1.7)	0	1 (0.9)
ブドウ球菌検査陽性	1 (1.7)	0	1 (0.9)
体重増加	0	3 (5.6)	3 (2.7)
白血球数減少	1 (1.7)	2 (3.7)	3 (2.7)
尿中白血球陽性	1 (1.7)	1 (1.9)	2 (1.8)
代謝および栄養障害	5 (8.6)	1 (1.9)	6 (5.4)
食欲減退	2 (3.4)	0	2 (1.8)
食物不耐性	1 (1.7)	0	1 (0.9)
高コレステロール血症	1 (1.7)	0	1 (0.9)
高トリグリセリド血症	1 (1.7)	0	1 (0.9)
鉄欠乏	0	1 (1.9)	1 (0.9)
肥満	1 (1.7)	0	1 (0.9)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) n (%)	UPA 30 mg QD + TCS (N=54) n (%)	Total (N=112) n (%)
筋骨格系および結合組織障害	2 (3.4)	3 (5.6)	5 (4.5)
背部痛	0	1 (1.9)	1 (0.9)
筋骨格系胸痛	0	1 (1.9)	1 (0.9)
頚部痛	1 (1.7)	0	1 (0.9)
四肢痛	0	1 (1.9)	1 (0.9)
顎関節症候群	1 (1.7)	0	1 (0.9)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2 (3.4)	0	2 (1.8)
異形成母斑	1 (1.7)	0	1 (0.9)
皮膚乳頭腫	1 (1.7)	0	1 (0.9)
神経系障害	7 (12.1)	7 (13.0)	14 (12.5)
浮動性めまい	1 (1.7)	1 (1.9)	2 (1.8)
頭痛	7 (12.1)	4 (7.4)	11 (9.8)
片頭痛	0	2 (3.7)	2 (1.8)
失神寸前の状態	0	1 (1.9)	1 (0.9)
精神障害	3 (5.2)	3 (5.6)	6 (5.4)
不安	1 (1.7)	0	1 (0.9)
注意欠陥多動性障害	0	1 (1.9)	1 (0.9)
抑うつ気分	0	1 (1.9)	1 (0.9)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) n (%)	UPA 30 mg QD + TCS (N=54) n (%)	Total (N=112) n (%)
精神障害 (Cont.)			
うつ病	1 (1.7)	1 (1.9)	2 (1.8)
悪夢	1 (1.7)	0	1 (0.9)
腎および尿路障害	1 (1.7)	0	1 (0.9)
蛋白尿	1 (1.7)	0	1 (0.9)
呼吸器、胸郭および縦隔障害	13 (22.4)	10 (18.5)	23 (20.5)
アレルギー性気管支炎	1 (1.7)	0	1 (0.9)
喘息	3 (5.2)	1 (1.9)	4 (3.6)
カタル	4 (6.9)	5 (9.3)	9 (8.0)
咳嗽	4 (6.9)	2 (3.7)	6 (5.4)
呼吸困難	1 (1.7)	0	1 (0.9)
鼻出血	1 (1.7)	0	1 (0.9)
しゃっくり	0	1 (1.9)	1 (0.9)
口腔咽頭痛	2 (3.4)	1 (1.9)	3 (2.7)
アレルギー性鼻炎	0	1 (1.9)	1 (0.9)
鼻漏	3 (5.2)	2 (3.7)	5 (4.5)
副鼻腔うっ血	1 (1.7)	0	1 (0.9)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) n (%)	UPA 30 mg QD + TCS (N=54) n (%)	Total (N=112) n (%)
皮膚および皮下組織障害	28 (48.3)	16 (29.6)	44 (39.3)
ざ瘡	12 (20.7)	13 (24.1)	25 (22.3)
脱毛症	1 (1.7)	0	1 (0.9)
皮膚炎	1 (1.7)	1 (1.9)	2 (1.8)
ざ瘡様皮膚炎	1 (1.7)	1 (1.9)	2 (1.8)
アトピー性皮膚炎	7 (12.1)	3 (5.6)	10 (8.9)
接触皮膚炎	1 (1.7)	1 (1.9)	2 (1.8)
乾癬様皮膚炎	1 (1.7)	0	1 (0.9)
異汗性湿疹	2 (3.4)	0	2 (1.8)
湿疹	1 (1.7)	0	1 (0.9)
紅斑	1 (1.7)	1 (1.9)	2 (1.8)
過角化	1 (1.7)	0	1 (0.9)
間擦疹	0	1 (1.9)	1 (0.9)
丘疹	0	1 (1.9)	1 (0.9)
白色粃糠疹	1 (1.7)	0	1 (0.9)
そう痒症	3 (5.2)	1 (1.9)	4 (3.6)
発疹	0	1 (1.9)	1 (0.9)
丘疹性皮疹	1 (1.7)	0	1 (0.9)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) n (%)	UPA 30 mg QD + TCS (N=54) n (%)	Total (N=112) n (%)
皮膚および皮下組織障害 (Cont.)			
皮膚変色	0	1 (1.9)	1 (0.9)
皮膚剥脱	1 (1.7)	0	1 (0.9)
皮膚線条	1 (1.7)	0	1 (0.9)
蕁麻疹	1 (1.7)	2 (3.7)	3 (2.7)
血管障害	0	1 (1.9)	1 (0.9)
高血圧	0	1 (1.9)	1 (0.9)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

相互参照：M16-047 試験 CSR W52 Table 14.3__1.5.1.2

表 3. ウパダシチニブ投与期間中に有害事象を発現した被験者数及び発現割合：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団，成人）

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
Any adverse event	305 (79.2)	331 (86.6)	636 (82.9)
*** Not coded ***	1 (0.3)	0	1 (0.1)
*** Not coded ***	1 (0.3)	0	1 (0.1)
血液およびリンパ系障害	10 (2.6)	21 (5.5)	31 (4.0)
貧血	1 (0.3)	5 (1.3)	6 (0.8)
大球性貧血	0	1 (0.3)	1 (0.1)
皮膚病性リンパ節症	1 (0.3)	0	1 (0.1)
好酸球増加症	1 (0.3)	0	1 (0.1)
赤血球減少症	0	1 (0.3)	1 (0.1)
内出血発生の増加傾向	0	2 (0.5)	2 (0.3)
鉄欠乏性貧血	0	1 (0.3)	1 (0.1)
白血球増加症	2 (0.5)	0	2 (0.3)
白血球減少症	0	2 (0.5)	2 (0.3)
リンパ節石灰化	1 (0.3)	0	1 (0.1)
リンパ節症	2 (0.5)	2 (0.5)	4 (0.5)
リンパ球増加症	0	1 (0.3)	1 (0.1)
リンパ組織過形成	0	1 (0.3)	1 (0.1)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
血液およびリンパ系障害 (Cont.)			
リンパ球減少症	1 (0.3)	1 (0.3)	2 (0.3)
好中球減少症	1 (0.3)	4 (1.0)	5 (0.7)
汎血球減少症	0	1 (0.3)	1 (0.1)
血小板減少症	0	1 (0.3)	1 (0.1)
血小板増加症	0	1 (0.3)	1 (0.1)
心臓障害	6 (1.6)	8 (2.1)	14 (1.8)
急性冠動脈症候群	0	1 (0.3)	1 (0.1)
心房細動	0	1 (0.3)	1 (0.1)
第一度房室ブロック	1 (0.3)	0	1 (0.1)
徐脈	0	1 (0.3)	1 (0.1)
うっ血性心不全	0	1 (0.3)	1 (0.1)
左室肥大	1 (0.3)	0	1 (0.1)
僧帽弁閉鎖不全症	0	1 (0.3)	1 (0.1)
動悸	1 (0.3)	3 (0.8)	4 (0.5)
洞性徐脈	2 (0.5)	1 (0.3)	3 (0.4)
頻脈	2 (0.5)	0	2 (0.3)
心室性頻脈	0	1 (0.3)	1 (0.1)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
先天性、家族性および遺伝性障害	3 (0.8)	2 (0.5)	5 (0.7)
先天性メラノサイト性母斑	0	1 (0.3)	1 (0.1)
表皮母斑	1 (0.3)	0	1 (0.1)
ジルベール症候群	0	1 (0.3)	1 (0.1)
色素性網膜炎	1 (0.3)	0	1 (0.1)
2a 型高脂血症	1 (0.3)	0	1 (0.1)
耳および迷路障害	6 (1.6)	6 (1.6)	12 (1.6)
耳の障害	1 (0.3)	0	1 (0.1)
耳痛	2 (0.5)	2 (0.5)	4 (0.5)
耳垢分泌過多	1 (0.3)	0	1 (0.1)
聴力低下	0	1 (0.3)	1 (0.1)
耳鳴	0	1 (0.3)	1 (0.1)
回転性めまい	2 (0.5)	2 (0.5)	4 (0.5)
頭位性回転性めまい	1 (0.3)	0	1 (0.1)
内分泌障害	2 (0.5)	2 (0.5)	4 (0.5)
甲状腺機能低下症	1 (0.3)	1 (0.3)	2 (0.3)
甲状腺腫瘤	1 (0.3)	1 (0.3)	2 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
眼障害	24 (6.2)	26 (6.8)	50 (6.5)
眼瞼炎	4 (1.0)	3 (0.8)	7 (0.9)
白内障	0	4 (1.0)	4 (0.5)
霰粒腫	0	2 (0.5)	2 (0.3)
結膜沈着物	0	1 (0.3)	1 (0.1)
結膜充血	0	1 (0.3)	1 (0.1)
結膜刺激	0	1 (0.3)	1 (0.1)
アレルギー性結膜炎	2 (0.5)	3 (0.8)	5 (0.7)
角膜浮腫	1 (0.3)	0	1 (0.1)
ドライアイ	3 (0.8)	2 (0.5)	5 (0.7)
眼瞼紅斑	1 (0.3)	0	1 (0.1)
眼刺激	1 (0.3)	0	1 (0.1)
眼痛	1 (0.3)	0	1 (0.1)
眼の異常感覚	0	1 (0.3)	1 (0.1)
眼そう痒症	0	1 (0.3)	1 (0.1)
眼部腫脹	0	2 (0.5)	2 (0.3)
眼瞼障害	0	1 (0.3)	1 (0.1)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
眼障害 (Cont.)			
緑内障	1 (0.3)	0	1 (0.1)
流涙増加	4 (1.0)	0	4 (0.5)
黄斑症	0	1 (0.3)	1 (0.1)
近視	0	1 (0.3)	1 (0.1)
視神経乳頭浮腫	0	1 (0.3)	1 (0.1)
眼窩周囲浮腫	1 (0.3)	0	1 (0.1)
羞明	0	1 (0.3)	1 (0.1)
屈折障害	1 (0.3)	0	1 (0.1)
網膜剥離	1 (0.3)	1 (0.3)	2 (0.3)
裂孔原性網膜剥離	0	1 (0.3)	1 (0.1)
眼瞼腫脹	1 (0.3)	1 (0.3)	2 (0.3)
潰瘍性角膜炎	1 (0.3)	1 (0.3)	2 (0.3)
霧視	3 (0.8)	1 (0.3)	4 (0.5)
視力低下	0	1 (0.3)	1 (0.1)
硝子体剥離	0	1 (0.3)	1 (0.1)
眼球乾燥症	1 (0.3)	0	1 (0.1)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
胃腸障害	70 (18.2)	76 (19.9)	146 (19.0)
腹部不快感	3 (0.8)	2 (0.5)	5 (0.7)
腹部膨満	2 (0.5)	2 (0.5)	4 (0.5)
腹痛	10 (2.6)	7 (1.8)	17 (2.2)
下腹部痛	1 (0.3)	0	1 (0.1)
上腹部痛	15 (3.9)	3 (0.8)	18 (2.3)
腹部圧痛	0	1 (0.3)	1 (0.1)
肛門そう痒症	1 (0.3)	0	1 (0.1)
口角口唇炎	0	2 (0.5)	2 (0.3)
肛門直腸不快感	0	1 (0.3)	1 (0.1)
アフタ性潰瘍	1 (0.3)	1 (0.3)	2 (0.3)
便習慣変化	0	2 (0.5)	2 (0.3)
口唇のひび割れ	1 (0.3)	0	1 (0.1)
慢性胃炎	2 (0.5)	0	2 (0.3)
便秘	7 (1.8)	7 (1.8)	14 (1.8)
齲歯	5 (1.3)	6 (1.6)	11 (1.4)
下痢	14 (3.6)	14 (3.7)	28 (3.7)
口内乾燥	0	2 (0.5)	2 (0.3)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
胃腸障害 (Cont.)			
出血性十二指腸潰瘍	1 (0.3)	0	1 (0.1)
消化不良	7 (1.8)	4 (1.0)	11 (1.4)
嚥下障害	0	2 (0.5)	2 (0.3)
白色便	1 (0.3)	0	1 (0.1)
鼓腸	2 (0.5)	1 (0.3)	3 (0.4)
食中毒	0	1 (0.3)	1 (0.1)
排便回数増加	0	1 (0.3)	1 (0.1)
胃炎	2 (0.5)	3 (0.8)	5 (0.7)
胃腸障害	1 (0.3)	0	1 (0.1)
胃腸粘膜障害	1 (0.3)	0	1 (0.1)
胃食道逆流性疾患	3 (0.8)	8 (2.1)	11 (1.4)
舌炎	1 (0.3)	0	1 (0.1)
舌痛	0	1 (0.3)	1 (0.1)
痔核	1 (0.3)	1 (0.3)	2 (0.3)
裂孔ヘルニア	0	1 (0.3)	1 (0.1)
胃酸過多	0	1 (0.3)	1 (0.1)
過敏性腸症候群	0	2 (0.5)	2 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
胃腸障害 (Cont.)			
口唇水疱	1 (0.3)	0	1 (0.1)
口腔内出血	0	1 (0.3)	1 (0.1)
口腔内潰瘍形成	2 (0.5)	1 (0.3)	3 (0.4)
悪心	12 (3.1)	13 (3.4)	25 (3.3)
嚥下痛	2 (0.5)	0	2 (0.3)
口腔瘻	1 (0.3)	0	1 (0.1)
口腔そう痒症	0	1 (0.3)	1 (0.1)
膵炎	1 (0.3)	0	1 (0.1)
歯周病	1 (0.3)	0	1 (0.1)
無髄歯	0	1 (0.3)	1 (0.1)
レッチング	0	1 (0.3)	1 (0.1)
口内炎	1 (0.3)	0	1 (0.1)
生歯	1 (0.3)	0	1 (0.1)
歯の障害	0	1 (0.3)	1 (0.1)
埋伏歯	2 (0.5)	3 (0.8)	5 (0.7)
歯痛	3 (0.8)	9 (2.4)	12 (1.6)
嘔吐	3 (0.8)	4 (1.0)	7 (0.9)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
一般・全身障害および投与部位の状態	50 (13.0)	49 (12.8)	99 (12.9)
胸部不快感	2 (0.5)	1 (0.3)	3 (0.4)
胸痛	5 (1.3)	4 (1.0)	9 (1.2)
悪寒	3 (0.8)	0	3 (0.4)
嚢胞	1 (0.3)	1 (0.3)	2 (0.3)
顔面浮腫	1 (0.3)	0	1 (0.1)
顔面痛	2 (0.5)	0	2 (0.3)
疲労	9 (2.3)	5 (1.3)	14 (1.8)
熱感	1 (0.3)	0	1 (0.1)
肉芽腫	0	1 (0.3)	1 (0.1)
ヘルニア	0	1 (0.3)	1 (0.1)
低体温	0	1 (0.3)	1 (0.1)
治癒不良	0	1 (0.3)	1 (0.1)
炎症	0	1 (0.3)	1 (0.1)
インフルエンザ様疾患	11 (2.9)	13 (3.4)	24 (3.1)
倦怠感	2 (0.5)	1 (0.3)	3 (0.4)
小結節	0	1 (0.3)	1 (0.1)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
非心臓性胸痛	0	1 (0.3)	1 (0.1)
末梢性浮腫	3 (0.8)	0	3 (0.4)
疼痛	4 (1.0)	2 (0.5)	6 (0.8)
末梢腫脹	1 (0.3)	1 (0.3)	2 (0.3)
発熱	18 (4.7)	15 (3.9)	33 (4.3)
腫脹	2 (0.5)	1 (0.3)	3 (0.4)
顔面腫脹	3 (0.8)	0	3 (0.4)
血管穿刺部位内出血	0	1 (0.3)	1 (0.1)
肝胆道系障害	6 (1.6)	6 (1.6)	12 (1.6)
肝機能異常	3 (0.8)	2 (0.5)	5 (0.7)
脂肪肝	3 (0.8)	1 (0.3)	4 (0.5)
肝細胞損傷	0	1 (0.3)	1 (0.1)
肝腫大	0	1 (0.3)	1 (0.1)
高ビリルビン血症	1 (0.3)	0	1 (0.1)
非アルコール性脂肪性肝炎	0	1 (0.3)	1 (0.1)
免疫系障害	6 (1.6)	10 (2.6)	16 (2.1)
アレルギー性浮腫	0	1 (0.3)	1 (0.1)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
免疫系障害 (Cont.)			
動物アレルギー	0	1 (0.3)	1 (0.1)
アナフィラキシー反応	0	1 (0.3)	1 (0.1)
薬物過敏症	1 (0.3)	0	1 (0.1)
食物アレルギー	0	1 (0.3)	1 (0.1)
過敏症	2 (0.5)	3 (0.8)	5 (0.7)
季節性アレルギー	4 (1.0)	3 (0.8)	7 (0.9)
血清病	0	1 (0.3)	1 (0.1)
感染症および寄生虫症	230 (59.7)	243 (63.6)	473 (61.7)
四肢膿瘍	0	1 (0.3)	1 (0.1)
口腔膿瘍	0	1 (0.3)	1 (0.1)
ダニ皮膚炎	1 (0.3)	1 (0.3)	2 (0.3)
急性副鼻腔炎	1 (0.3)	0	1 (0.1)
肛門膿瘍	1 (0.3)	0	1 (0.1)
虫垂炎	1 (0.3)	0	1 (0.1)
細菌感染	2 (0.5)	1 (0.3)	3 (0.4)
細菌性膣症	1 (0.3)	0	1 (0.1)
細菌尿	0	1 (0.3)	1 (0.1)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
感染症および寄生虫症 (Cont.)			
体部白癬	2 (0.5)	6 (1.6)	8 (1.0)
気管支炎	7 (1.8)	13 (3.4)	20 (2.6)
ウイルス性気管支炎	0	1 (0.3)	1 (0.1)
水疱性膿痂疹	1 (0.3)	0	1 (0.1)
感染性滑液包炎	0	1 (0.3)	1 (0.1)
カンジダ感染	0	1 (0.3)	1 (0.1)
蜂巣炎	3 (0.8)	4 (1.0)	7 (0.9)
条虫感染	1 (0.3)	0	1 (0.1)
クラミジア感染	0	1 (0.3)	1 (0.1)
慢性副鼻腔炎	1 (0.3)	0	1 (0.1)
結膜炎	10 (2.6)	8 (2.1)	18 (2.3)
細菌性結膜炎	1 (0.3)	1 (0.3)	2 (0.3)
ウイルス性結膜炎	1 (0.3)	1 (0.3)	2 (0.3)
コロナウイルス感染	8 (2.1)	9 (2.4)	17 (2.2)
膀胱炎	2 (0.5)	2 (0.5)	4 (0.5)
涙嚢炎	1 (0.3)	0	1 (0.1)
医療機器関連感染	1 (0.3)	0	1 (0.1)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
感染症および寄生虫症 (Cont.)			
感染性下痢	0	1 (0.3)	1 (0.1)
耳感染	1 (0.3)	1 (0.3)	2 (0.3)
ブドウ球菌性耳感染	0	1 (0.3)	1 (0.1)
ヘルペス性状湿疹	5 (1.3)	10 (2.6)	15 (2.0)
膿痂疹性湿疹	2 (0.5)	2 (0.5)	4 (0.5)
蟯虫症	1 (0.3)	0	1 (0.1)
丹毒	1 (0.3)	0	1 (0.1)
眼感染	1 (0.3)	0	1 (0.1)
ブドウ球菌性眼感染	1 (0.3)	1 (0.3)	2 (0.3)
ウイルス性眼感染	1 (0.3)	0	1 (0.1)
眼瞼感染	2 (0.5)	0	2 (0.3)
糸状虫症	0	1 (0.3)	1 (0.1)
毛包炎	17 (4.4)	19 (5.0)	36 (4.7)
真菌感染	2 (0.5)	0	2 (0.3)
皮膚真菌感染	3 (0.8)	4 (1.0)	7 (0.9)
せつ	2 (0.5)	4 (1.0)	6 (0.8)
ウイルス性胃炎	1 (0.3)	0	1 (0.1)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
感染症および寄生虫症 (Cont.)			
胃腸炎	11 (2.9)	12 (3.1)	23 (3.0)
ウイルス性胃腸炎	0	5 (1.3)	5 (0.7)
消化管感染	1 (0.3)	0	1 (0.1)
陰部ヘルペス	0	2 (0.5)	2 (0.3)
陰部単純ヘルペス	0	3 (0.8)	3 (0.4)
ジアルジア症	1 (0.3)	0	1 (0.1)
歯肉炎	1 (0.3)	1 (0.3)	2 (0.3)
ヘルペス眼感染	1 (0.3)	3 (0.8)	4 (0.5)
単純ヘルペス	18 (4.7)	22 (5.8)	40 (5.2)
帯状疱疹	18 (4.7)	26 (6.8)	44 (5.7)
皮膚播種性帯状疱疹	1 (0.3)	0	1 (0.1)
播種性帯状疱疹	0	1 (0.3)	1 (0.1)
耳帯状疱疹	0	2 (0.5)	2 (0.3)
麦粒腫	6 (1.6)	5 (1.3)	11 (1.4)
膿痂疹	9 (2.3)	8 (2.1)	17 (2.2)
切開部位蜂巣炎	1 (0.3)	0	1 (0.1)
感染性嚢腫	1 (0.3)	0	1 (0.1)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
感染症および寄生虫症 (Cont.)			
感染性皮膚嚢腫	0	1 (0.3)	1 (0.1)
感染	1 (0.3)	1 (0.3)	2 (0.3)
寄生虫感染	1 (0.3)	0	1 (0.1)
インフルエンザ	14 (3.6)	9 (2.4)	23 (3.0)
関節膿瘍	0	1 (0.3)	1 (0.1)
カポジ水痘様発疹	1 (0.3)	4 (1.0)	5 (0.7)
ウイルス性角膜炎	1 (0.3)	0	1 (0.1)
腎感染	1 (0.3)	0	1 (0.1)
大腸感染	1 (0.3)	0	1 (0.1)
喉頭炎	1 (0.3)	0	1 (0.1)
潜伏結核	1 (0.3)	3 (0.8)	4 (0.5)
マラセチア感染	1 (0.3)	1 (0.3)	2 (0.3)
細菌性乳腺炎	1 (0.3)	0	1 (0.1)
ウイルス性髄膜炎	1 (0.3)	0	1 (0.1)
メタニューモウイルス感染	1 (0.3)	0	1 (0.1)
伝染性軟属腫	3 (0.8)	2 (0.5)	5 (0.7)
鼻ヘルペス	0	3 (0.8)	3 (0.4)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
感染症および寄生虫症 (Cont.)			
上咽頭炎	67 (17.4)	67 (17.5)	134 (17.5)
爪真菌症	1 (0.3)	3 (0.8)	4 (0.5)
眼部単純ヘルペス	5 (1.3)	9 (2.4)	14 (1.8)
眼帯状疱疹	0	1 (0.3)	1 (0.1)
口腔カンジダ症	1 (0.3)	3 (0.8)	4 (0.5)
口腔ヘルペス	19 (4.9)	35 (9.2)	54 (7.0)
外耳炎	4 (1.0)	4 (1.0)	8 (1.0)
中耳炎	3 (0.8)	2 (0.5)	5 (0.7)
急性中耳炎	1 (0.3)	1 (0.3)	2 (0.3)
爪囲炎	2 (0.5)	2 (0.5)	4 (0.5)
インプラント周囲炎	1 (0.3)	0	1 (0.1)
軟骨膜炎	1 (0.3)	0	1 (0.1)
歯周炎	1 (0.3)	0	1 (0.1)
眼窩周囲蜂巣炎	1 (0.3)	0	1 (0.1)
扁桃周囲膿瘍	1 (0.3)	0	1 (0.1)
咽頭炎	8 (2.1)	9 (2.4)	17 (2.2)
レンサ球菌性咽頭炎	2 (0.5)	0	2 (0.3)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
感染症および寄生虫症 (Cont.)			
肺炎	4 (1.0)	3 (0.8)	7 (0.9)
マイコプラズマ性肺炎	0	2 (0.5)	2 (0.3)
ウイルス感染後疲労症候群	0	1 (0.3)	1 (0.1)
術後創感染	0	2 (0.5)	2 (0.3)
歯髄炎	0	1 (0.3)	1 (0.1)
化膿性分泌物	1 (0.3)	0	1 (0.1)
膿疱	1 (0.3)	3 (0.8)	4 (0.5)
腎盂腎炎	1 (0.3)	1 (0.3)	2 (0.3)
膿疱性皮疹	0	2 (0.5)	2 (0.3)
気道感染	3 (0.8)	1 (0.3)	4 (0.5)
ウイルス性気道感染	1 (0.3)	1 (0.3)	2 (0.3)
鼻炎	3 (0.8)	1 (0.3)	4 (0.5)
鼻喉頭炎	0	1 (0.3)	1 (0.1)
ライノウイルス感染	0	1 (0.3)	1 (0.1)
副鼻腔炎	5 (1.3)	6 (1.6)	11 (1.4)
皮膚細菌感染	3 (0.8)	1 (0.3)	4 (0.5)
皮膚感染	5 (1.3)	3 (0.8)	8 (1.0)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
感染症および寄生虫症 (Cont.)			
膿性痰	1 (0.3)	0	1 (0.1)
ブドウ球菌感染	2 (0.5)	3 (0.8)	5 (0.7)
ブドウ球菌皮膚感染	3 (0.8)	4 (1.0)	7 (0.9)
細菌重複感染	0	1 (0.3)	1 (0.1)
真菌重複感染	1 (0.3)	0	1 (0.1)
股部白癬	0	2 (0.5)	2 (0.3)
白癬感染	1 (0.3)	1 (0.3)	2 (0.3)
足部白癬	5 (1.3)	9 (2.4)	14 (1.8)
癜風	1 (0.3)	3 (0.8)	4 (0.5)
扁桃炎	4 (1.0)	4 (1.0)	8 (1.0)
歯感染	4 (1.0)	5 (1.3)	9 (1.2)
気管炎	2 (0.5)	1 (0.3)	3 (0.4)
気管気管支炎	1 (0.3)	0	1 (0.1)
トリコモナス症	0	1 (0.3)	1 (0.1)
トリコフィトン感染症	1 (0.3)	0	1 (0.1)
上気道感染	41 (10.6)	38 (9.9)	79 (10.3)
ウレアプラズマ感染	1 (0.3)	0	1 (0.1)

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感染症および寄生虫症 (Cont.)			
尿道炎	1 (0.3)	0	1 (0.1)
尿路感染	10 (2.6)	18 (4.7)	28 (3.7)
細菌性尿路感染	0	1 (0.3)	1 (0.1)
腟感染	2 (0.5)	1 (0.3)	3 (0.4)
ウイルス感染	1 (0.3)	3 (0.8)	4 (0.5)
ウイルス性咽頭炎	1 (0.3)	2 (0.5)	3 (0.4)
ウイルス性上気道感染	5 (1.3)	7 (1.8)	12 (1.6)
外陰部腟カンジダ症	2 (0.5)	1 (0.3)	3 (0.4)
外陰腟真菌感染	1 (0.3)	2 (0.5)	3 (0.4)
トリコモナス外陰腟炎	1 (0.3)	0	1 (0.1)
傷害、中毒および処置合併症	32 (8.3)	40 (10.5)	72 (9.4)
事故	1 (0.3)	0	1 (0.1)
動物咬傷	1 (0.3)	0	1 (0.1)
足関節部骨折	0	1 (0.3)	1 (0.1)
節足動物咬傷	0	2 (0.5)	2 (0.3)
節足動物刺傷	2 (0.5)	0	2 (0.3)
骨挫傷	0	1 (0.3)	1 (0.1)

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傷害、中毒および処置合併症 (Cont.)			
軟骨損傷	1 (0.3)	1 (0.3)	2 (0.3)
胸部損傷	0	1 (0.3)	1 (0.1)
鎖骨骨折	0	1 (0.3)	1 (0.1)
挫傷	1 (0.3)	3 (0.8)	4 (0.5)
角膜擦過傷	0	1 (0.3)	1 (0.1)
頭蓋脳損傷	1 (0.3)	1 (0.3)	2 (0.3)
胸骨脱臼	0	1 (0.3)	1 (0.1)
上顆炎	0	1 (0.3)	1 (0.1)
眼挫傷	0	1 (0.3)	1 (0.1)
眼外傷	0	1 (0.3)	1 (0.1)
転倒	2 (0.5)	5 (1.3)	7 (0.9)
大腿骨骨折	0	1 (0.3)	1 (0.1)
足骨折	3 (0.8)	0	3 (0.4)
尾骨骨折	1 (0.3)	0	1 (0.1)
頭部損傷	1 (0.3)	0	1 (0.1)
熱疲労	0	1 (0.3)	1 (0.1)
上腕骨骨折	0	1 (0.3)	1 (0.1)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
傷害、中毒および処置合併症 (Cont.)			
腸骨骨折	1 (0.3)	0	1 (0.1)
損傷	2 (0.5)	0	2 (0.3)
関節脱臼	0	1 (0.3)	1 (0.1)
関節損傷	1 (0.3)	4 (1.0)	5 (0.7)
靭帯損傷	1 (0.3)	0	1 (0.1)
靭帯捻挫	1 (0.3)	1 (0.3)	2 (0.3)
四肢損傷	3 (0.8)	1 (0.3)	4 (0.5)
半月板損傷	1 (0.3)	0	1 (0.1)
筋損傷	0	1 (0.3)	1 (0.1)
肉離れ	2 (0.5)	5 (1.3)	7 (0.9)
開放骨折	0	1 (0.3)	1 (0.1)
処置による疼痛	1 (0.3)	2 (0.5)	3 (0.4)
橈骨骨折	0	2 (0.5)	2 (0.3)
肋骨骨折	3 (0.8)	1 (0.3)	4 (0.5)
交通事故	0	2 (0.5)	2 (0.3)
皮膚擦過傷	2 (0.5)	1 (0.3)	3 (0.4)
皮膚裂傷	3 (0.8)	1 (0.3)	4 (0.5)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
傷害、中毒および処置合併症 (Cont.)			
脊椎骨折	1 (0.3)	0	1 (0.1)
胸骨骨折	1 (0.3)	0	1 (0.1)
腱損傷	0	1 (0.3)	1 (0.1)
腱断裂	1 (0.3)	0	1 (0.1)
歯牙破折	2 (0.5)	2 (0.5)	4 (0.5)
外傷性血腫	1 (0.3)	0	1 (0.1)
上肢骨折	0	1 (0.3)	1 (0.1)
創傷	0	1 (0.3)	1 (0.1)
創部分泌	0	1 (0.3)	1 (0.1)
手首関節骨折	1 (0.3)	0	1 (0.1)
臨床検査	75 (19.5)	78 (20.4)	153 (19.9)
アラニンアミノトランスフェラーゼ増加	10 (2.6)	8 (2.1)	18 (2.3)
アスパラギン酸アミノトランスフェラーゼ異常	1 (0.3)	0	1 (0.1)
アスパラギン酸アミノトランスフェラーゼ増加	6 (1.6)	7 (1.8)	13 (1.7)
血中重炭酸塩減少	0	1 (0.3)	1 (0.1)
血中ビリルビン増加	1 (0.3)	1 (0.3)	2 (0.3)
血中コレステロール	1 (0.3)	0	1 (0.1)

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臨床検査 (Cont.)			
血中コレステロール増加	3 (0.8)	2 (0.5)	5 (0.7)
血中クレアチンホスホキナーゼ増加	33 (8.6)	42 (11.0)	75 (9.8)
血中クレアチニン増加	1 (0.3)	1 (0.3)	2 (0.3)
血中ブドウ糖増加	1 (0.3)	1 (0.3)	2 (0.3)
血中免疫グロブリンＥ増加	1 (0.3)	0	1 (0.1)
血中鉄減少	0	1 (0.3)	1 (0.1)
血中リン減少	1 (0.3)	0	1 (0.1)
血中カリウム減少	0	1 (0.3)	1 (0.1)
血圧上昇	5 (1.3)	2 (0.5)	7 (0.9)
血中遊離テストステロン減少	1 (0.3)	0	1 (0.1)
血中トリグリセリド増加	1 (0.3)	2 (0.5)	3 (0.4)
血中尿素増加	0	1 (0.3)	1 (0.1)
血中尿酸増加	1 (0.3)	0	1 (0.1)
尿中血陽性	0	1 (0.3)	1 (0.1)
体温上昇	0	1 (0.3)	1 (0.1)
好酸球数増加	2 (0.5)	1 (0.3)	3 (0.4)
便量増加	0	1 (0.3)	1 (0.1)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
臨床検査 (Cont.)			
真菌検査陽性	1 (0.3)	0	1 (0.1)
ヘモグロビン減少	1 (0.3)	5 (1.3)	6 (0.8)
ヘリコバクター検査陽性	1 (0.3)	0	1 (0.1)
肝酵素上昇	1 (0.3)	0	1 (0.1)
肝機能検査異常	1 (0.3)	1 (0.3)	2 (0.3)
低比重リポ蛋白増加	1 (0.3)	3 (0.8)	4 (0.5)
リンパ球数減少	1 (0.3)	0	1 (0.1)
リンパ球数増加	1 (0.3)	0	1 (0.1)
単球数増加	0	1 (0.3)	1 (0.1)
結核菌群検査陽性	1 (0.3)	0	1 (0.1)
好中球数減少	6 (1.6)	2 (0.5)	8 (1.0)
好中球数増加	1 (0.3)	0	1 (0.1)
好中球百分率増加	1 (0.3)	0	1 (0.1)
ポリオーマウイルス検査陽性	1 (0.3)	0	1 (0.1)
尿中蛋白陽性	2 (0.5)	1 (0.3)	3 (0.4)
赤血球数減少	1 (0.3)	1 (0.3)	2 (0.3)
ブドウ球菌検査陽性	2 (0.5)	0	2 (0.3)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
臨床検査 (Cont.)			
トランスアミナーゼ上昇	0	1 (0.3)	1 (0.1)
トロポニン増加	0	1 (0.3)	1 (0.1)
ビタミン B12 減少	1 (0.3)	0	1 (0.1)
ビタミン D 減少	0	1 (0.3)	1 (0.1)
体重減少	2 (0.5)	0	2 (0.3)
体重増加	9 (2.3)	11 (2.9)	20 (2.6)
白血球数減少	2 (0.5)	2 (0.5)	4 (0.5)
白血球数増加	0	1 (0.3)	1 (0.1)
尿中白血球陽性	0	1 (0.3)	1 (0.1)
代謝および栄養障害	15 (3.9)	21 (5.5)	36 (4.7)
脱水	0	2 (0.5)	2 (0.3)
糖尿病	0	2 (0.5)	2 (0.3)
脂質異常症	0	2 (0.5)	2 (0.3)
水分過負荷	0	1 (0.3)	1 (0.1)
耐糖能障害	1 (0.3)	0	1 (0.1)
グルテン過敏症	0	1 (0.3)	1 (0.1)
痛風	1 (0.3)	1 (0.3)	2 (0.3)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
代謝および栄養障害 (Cont.)			
高コレステロール血症	2 (0.5)	4 (1.0)	6 (0.8)
高血糖	3 (0.8)	2 (0.5)	5 (0.7)
高ホモシステイン血症	1 (0.3)	0	1 (0.1)
高カリウム血症	1 (0.3)	0	1 (0.1)
高脂血症	1 (0.3)	5 (1.3)	6 (0.8)
高ナトリウム血症	1 (0.3)	0	1 (0.1)
高トリグリセリド血症	0	2 (0.5)	2 (0.3)
高尿酸血症	4 (1.0)	2 (0.5)	6 (0.8)
低カリウム血症	0	1 (0.3)	1 (0.1)
低マグネシウム血症	1 (0.3)	0	1 (0.1)
低ナトリウム血症	1 (0.3)	1 (0.3)	2 (0.3)
食欲亢進	0	2 (0.5)	2 (0.3)
ビタミン B12 欠乏	1 (0.3)	0	1 (0.1)
ビタミン D 欠乏	1 (0.3)	2 (0.5)	3 (0.4)
筋骨格系および結合組織障害	38 (9.9)	57 (14.9)	95 (12.4)
関節痛	10 (2.6)	9 (2.4)	19 (2.5)
関節炎	2 (0.5)	4 (1.0)	6 (0.8)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
筋骨格系および結合組織障害 (Cont.)			
背部痛	9 (2.3)	11 (2.9)	20 (2.6)
骨痛	0	1 (0.3)	1 (0.1)
滑液包炎	2 (0.5)	5 (1.3)	7 (0.9)
尾骨痛	0	1 (0.3)	1 (0.1)
外骨腫	1 (0.3)	0	1 (0.1)
出血性関節症	0	1 (0.3)	1 (0.1)
椎間板突出	0	4 (1.0)	4 (0.5)
関節ロック	0	1 (0.3)	1 (0.1)
関節腫脹	0	1 (0.3)	1 (0.1)
四肢不快感	1 (0.3)	0	1 (0.1)
筋痙縮	1 (0.3)	6 (1.6)	7 (0.9)
筋攣縮	0	1 (0.3)	1 (0.1)
筋骨格系胸痛	2 (0.5)	2 (0.5)	4 (0.5)
筋骨格痛	1 (0.3)	3 (0.8)	4 (0.5)
筋骨格硬直	0	1 (0.3)	1 (0.1)
筋肉痛	5 (1.3)	4 (1.0)	9 (1.2)
頚部腫瘤	0	1 (0.3)	1 (0.1)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
筋骨格系および結合組織障害 (Cont.)			
頚部痛	4 (1.0)	2 (0.5)	6 (0.8)
骨減少症	0	1 (0.3)	1 (0.1)
骨粗鬆症	0	1 (0.3)	1 (0.1)
四肢痛	4 (1.0)	6 (1.6)	10 (1.3)
顎痛	0	1 (0.3)	1 (0.1)
膝蓋大腿関節痛症候群	1 (0.3)	0	1 (0.1)
足底筋膜炎	1 (0.3)	0	1 (0.1)
脊柱管狭窄症	0	1 (0.3)	1 (0.1)
脊椎すべり症	0	1 (0.3)	1 (0.1)
軟骨下脆弱性骨折	0	1 (0.3)	1 (0.1)
滑液嚢腫	0	1 (0.3)	1 (0.1)
顎関節症候群	0	1 (0.3)	1 (0.1)
腱炎	1 (0.3)	2 (0.5)	3 (0.4)
腱鞘炎	0	1 (0.3)	1 (0.1)
斜頚	2 (0.5)	0	2 (0.3)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	13 (3.4)	15 (3.9)	28 (3.7)
結腸腺癌	0	1 (0.3)	1 (0.1)

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良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)			
肛門性器疣贅	0	2 (0.5)	2 (0.3)
良性新生物	0	1 (0.3)	1 (0.1)
精巣の良性新生物	0	1 (0.3)	1 (0.1)
血管腫	1 (0.3)	1 (0.3)	2 (0.3)
ケラトアカントーマ	0	1 (0.3)	1 (0.1)
表皮内悪性黒色腫	0	1 (0.3)	1 (0.1)
メラノサイト性母斑	1 (0.3)	0	1 (0.1)
結節性筋膜炎	1 (0.3)	0	1 (0.1)
化膿性肉芽腫	0	1 (0.3)	1 (0.1)
脂漏性角化症	1 (0.3)	1 (0.3)	2 (0.3)
皮膚乳頭腫	7 (1.8)	5 (1.3)	12 (1.6)
口腔内扁平上皮癌	1 (0.3)	0	1 (0.1)
子宮平滑筋腫	1 (0.3)	1 (0.3)	2 (0.3)
神経系障害	42 (10.9)	45 (11.8)	87 (11.3)
手根管症候群	1 (0.3)	0	1 (0.1)
馬尾症候群	0	1 (0.3)	1 (0.1)
脳血管発作	0	1 (0.3)	1 (0.1)

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神経系障害 (Cont.)			
浮動性めまい	7 (1.8)	6 (1.6)	13 (1.7)
味覚不全	0	2 (0.5)	2 (0.3)
てんかん	0	1 (0.3)	1 (0.1)
労作性頭痛	1 (0.3)	0	1 (0.1)
全身性強直性間代性発作	0	1 (0.3)	1 (0.1)
頭部不快感	0	1 (0.3)	1 (0.1)
頭痛	22 (5.7)	24 (6.3)	46 (6.0)
過眠症	0	1 (0.3)	1 (0.1)
筋緊張亢進	0	1 (0.3)	1 (0.1)
感覚鈍麻	2 (0.5)	1 (0.3)	3 (0.4)
嗜眠	0	1 (0.3)	1 (0.1)
片頭痛	5 (1.3)	1 (0.3)	6 (0.8)
前兆を伴う片頭痛	1 (0.3)	0	1 (0.1)
多発性硬化症	0	1 (0.3)	1 (0.1)
多発性硬化症再発	0	1 (0.3)	1 (0.1)
神経圧迫	0	1 (0.3)	1 (0.1)
末梢性ニューロパチー	1 (0.3)	1 (0.3)	2 (0.3)

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神経系障害 (Cont.)			
錯感覚	2 (0.5)	1 (0.3)	3 (0.4)
嗅覚錯誤	0	1 (0.3)	1 (0.1)
末梢神経不全麻痺	1 (0.3)	0	1 (0.1)
ヘルペス後神経痛	2 (0.5)	1 (0.3)	3 (0.4)
失神寸前の状態	1 (0.3)	0	1 (0.1)
坐骨神経痛	1 (0.3)	2 (0.5)	3 (0.4)
傾眠	0	1 (0.3)	1 (0.1)
くも膜下出血	1 (0.3)	0	1 (0.1)
失神	0	1 (0.3)	1 (0.1)
足根管症候群	1 (0.3)	0	1 (0.1)
緊張性頭痛	0	1 (0.3)	1 (0.1)
三叉神経痛	0	1 (0.3)	1 (0.1)
トンネル状視野	0	1 (0.3)	1 (0.1)
妊娠、産褥および周産期の状態	0	1 (0.3)	1 (0.1)
自然流産	0	1 (0.3)	1 (0.1)
精神障害	24 (6.2)	26 (6.8)	50 (6.5)
感情不安定	2 (0.5)	0	2 (0.3)

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精神障害 (Cont.)			
アルコール使用障害	0	1 (0.3)	1 (0.1)
不安	5 (1.3)	4 (1.0)	9 (1.2)
注意欠陥多動性障害	1 (0.3)	1 (0.3)	2 (0.3)
双極性障害	0	1 (0.3)	1 (0.1)
抑うつ気分	4 (1.0)	2 (0.5)	6 (0.8)
うつ病	2 (0.5)	3 (0.8)	5 (0.7)
抑うつ症状	1 (0.3)	0	1 (0.1)
全般性不安障害	1 (0.3)	0	1 (0.1)
不眠症	4 (1.0)	6 (1.6)	10 (1.3)
易刺激性	1 (0.3)	0	1 (0.1)
リビドー減退	0	1 (0.3)	1 (0.1)
リビドー亢進	1 (0.3)	0	1 (0.1)
精神障害	0	1 (0.3)	1 (0.1)
混合性不安抑うつ障害	0	1 (0.3)	1 (0.1)
パニック発作	1 (0.3)	1 (0.3)	2 (0.3)
心的外傷後ストレス障害	0	1 (0.3)	1 (0.1)
睡眠障害	0	2 (0.5)	2 (0.3)

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精神障害 (Cont.)			
ストレス	2 (0.5)	2 (0.5)	4 (0.5)
自殺念慮	0	1 (0.3)	1 (0.1)
自殺企図	1 (0.3)	0	1 (0.1)
腎および尿路障害	12 (3.1)	14 (3.7)	26 (3.4)
急性腎障害	1 (0.3)	0	1 (0.1)
アルブミン尿	2 (0.5)	1 (0.3)	3 (0.4)
尿路結石	1 (0.3)	0	1 (0.1)
出血性膀胱炎	0	1 (0.3)	1 (0.1)
排尿困難	3 (0.8)	0	3 (0.4)
糖尿	1 (0.3)	0	1 (0.1)
血尿	2 (0.5)	5 (1.3)	7 (0.9)
水腎症	1 (0.3)	0	1 (0.1)
緊張性膀胱	0	1 (0.3)	1 (0.1)
腎結石症	1 (0.3)	2 (0.5)	3 (0.4)
夜間頻尿	1 (0.3)	0	1 (0.1)
頻尿	0	2 (0.5)	2 (0.3)
多尿	1 (0.3)	0	1 (0.1)

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腎および尿路障害 (Cont.)			
蛋白尿	0	3 (0.8)	3 (0.4)
腎仙痛	0	1 (0.3)	1 (0.1)
生殖系および乳房障害	16 (4.2)	20 (5.2)	36 (4.7)
無月経	1 (0.3)	1 (0.3)	2 (0.3)
萎縮性外陰腟炎	0	1 (0.3)	1 (0.1)
乳房嚢胞	2 (0.5)	0	2 (0.3)
子宮頚部上皮異形成	2 (0.5)	2 (0.5)	4 (0.5)
月経困難症	1 (0.3)	0	1 (0.1)
子宮内膜症	0	2 (0.5)	2 (0.3)
勃起不全	1 (0.3)	3 (0.8)	4 (0.5)
女性化乳房	0	1 (0.3)	1 (0.1)
過少月経	1 (0.3)	0	1 (0.1)
月経過多	1 (0.3)	0	1 (0.1)
月経障害	1 (0.3)	0	1 (0.1)
不規則月経	1 (0.3)	2 (0.5)	3 (0.4)
不正子宮出血	0	1 (0.3)	1 (0.1)
骨盤痛	0	1 (0.3)	1 (0.1)

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生殖系および乳房障害 (Cont.)			
多嚢胞性卵巣	0	1 (0.3)	1 (0.1)
前立腺炎	1 (0.3)	0	1 (0.1)
精巣障害	0	1 (0.3)	1 (0.1)
精巣腫瘤	0	2 (0.5)	2 (0.3)
精巣痛	1 (0.3)	3 (0.8)	4 (0.5)
腟分泌物	2 (0.5)	0	2 (0.3)
腟出血	1 (0.3)	1 (0.3)	2 (0.3)
女性外陰部潰瘍	0	1 (0.3)	1 (0.1)
外陰腟乾燥	1 (0.3)	0	1 (0.1)
呼吸器、胸郭および縦隔障害	57 (14.8)	60 (15.7)	117 (15.3)
急性呼吸窮迫症候群	0	1 (0.3)	1 (0.1)
失声症	1 (0.3)	0	1 (0.1)
喘息	9 (2.3)	8 (2.1)	17 (2.2)
無気肺	1 (0.3)	0	1 (0.1)
カタル	2 (0.5)	0	2 (0.3)
慢性閉塞性肺疾患	0	1 (0.3)	1 (0.1)
咳嗽	19 (4.9)	24 (6.3)	43 (5.6)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)			
呼吸困難	4 (1.0)	5 (1.3)	9 (1.2)
鼻出血	5 (1.3)	6 (1.6)	11 (1.4)
喀血	2 (0.5)	0	2 (0.3)
肺浸潤	1 (0.3)	0	1 (0.1)
縦隔血腫	1 (0.3)	0	1 (0.1)
鼻閉	1 (0.3)	1 (0.3)	2 (0.3)
鼻茸	1 (0.3)	0	1 (0.1)
鼻中隔弯曲	1 (0.3)	0	1 (0.1)
口腔咽頭痛	8 (2.1)	10 (2.6)	18 (2.3)
咽頭腫脹	0	1 (0.3)	1 (0.1)
胸水	1 (0.3)	0	1 (0.1)
胸膜痛	0	1 (0.3)	1 (0.1)
湿性咳嗽	1 (0.3)	0	1 (0.1)
肺塞栓症	1 (0.3)	0	1 (0.1)
肺肉芽腫	0	1 (0.3)	1 (0.1)
肺腫瘤	1 (0.3)	2 (0.5)	3 (0.4)
気道うっ血	0	2 (0.5)	2 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)			
アレルギー性鼻炎	0	2 (0.5)	2 (0.3)
鼻漏	4 (1.0)	3 (0.8)	7 (0.9)
副鼻腔うっ血	0	2 (0.5)	2 (0.3)
睡眠時無呼吸症候群	1 (0.3)	0	1 (0.1)
くしゃみ	0	1 (0.3)	1 (0.1)
喘息発作重積	1 (0.3)	0	1 (0.1)
咽喉刺激感	0	1 (0.3)	1 (0.1)
上気道うっ血	1 (0.3)	0	1 (0.1)
喘鳴	1 (0.3)	1 (0.3)	2 (0.3)
皮膚および皮下組織障害	134 (34.8)	136 (35.6)	270 (35.2)
ざ瘡	50 (13.0)	68 (17.8)	118 (15.4)
嚢胞性ざ瘡	0	1 (0.3)	1 (0.1)
後天性ブラシュコ皮膚炎	1 (0.3)	0	1 (0.1)
光線角化症	0	1 (0.3)	1 (0.1)
脱毛症	1 (0.3)	1 (0.3)	2 (0.3)
血管浮腫	0	2 (0.5)	2 (0.3)
水疱	2 (0.5)	2 (0.5)	4 (0.5)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
皮膚および皮下組織障害 (Cont.)			
冷汗	0	1 (0.3)	1 (0.1)
皮膚嚢腫	1 (0.3)	1 (0.3)	2 (0.3)
皮膚炎	3 (0.8)	1 (0.3)	4 (0.5)
ざ瘡様皮膚炎	4 (1.0)	3 (0.8)	7 (0.9)
アレルギー性皮膚炎	2 (0.5)	2 (0.5)	4 (0.5)
アトピー性皮膚炎	40 (10.4)	26 (6.8)	66 (8.6)
接触皮膚炎	3 (0.8)	5 (1.3)	8 (1.0)
疱疹状皮膚炎	0	1 (0.3)	1 (0.1)
薬疹	1 (0.3)	0	1 (0.1)
皮膚乾燥	0	1 (0.3)	1 (0.1)
異汗性湿疹	1 (0.3)	0	1 (0.1)
斑状出血	0	2 (0.5)	2 (0.3)
湿疹	11 (2.9)	8 (2.1)	19 (2.5)
小水疱性湿疹	0	1 (0.3)	1 (0.1)
紅斑	2 (0.5)	1 (0.3)	3 (0.4)
過剰肉芽組織	1 (0.3)	0	1 (0.1)
毛髪成長異常	1 (0.3)	1 (0.3)	2 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
皮膚および皮下組織障害 (Cont.)			
多汗症	3 (0.8)	1 (0.3)	4 (0.5)
過角化	2 (0.5)	1 (0.3)	3 (0.4)
多毛症	1 (0.3)	1 (0.3)	2 (0.3)
特発性蕁麻疹	0	1 (0.3)	1 (0.1)
嵌入爪	0	2 (0.5)	2 (0.3)
苔癬化	0	1 (0.3)	1 (0.1)
網状皮斑	0	1 (0.3)	1 (0.1)
稗粒腫	0	1 (0.3)	1 (0.1)
汗疹	4 (1.0)	2 (0.5)	6 (0.8)
神経皮膚炎	0	1 (0.3)	1 (0.1)
寝汗	1 (0.3)	1 (0.3)	2 (0.3)
爪破損	0	1 (0.3)	1 (0.1)
皮膚疼痛	1 (0.3)	0	1 (0.1)
丘疹膿疱性酒さ	0	1 (0.3)	1 (0.1)
口囲皮膚炎	2 (0.5)	3 (0.8)	5 (0.7)
光線過敏性反応	0	2 (0.5)	2 (0.3)
進行性黄斑メラニン減少症	1 (0.3)	0	1 (0.1)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
皮膚および皮下組織障害 (Cont.)			
そう痒症	4 (1.0)	0	4 (0.5)
偽毛包炎	1 (0.3)	0	1 (0.1)
紫斑	2 (0.5)	0	2 (0.3)
発疹	2 (0.5)	3 (0.8)	5 (0.7)
斑状丘疹状皮疹	0	1 (0.3)	1 (0.1)
丘疹性皮疹	0	1 (0.3)	1 (0.1)
そう痒性皮疹	1 (0.3)	0	1 (0.1)
小水疱性皮疹	1 (0.3)	1 (0.3)	2 (0.3)
酒さ	3 (0.8)	6 (1.6)	9 (1.2)
痂皮	0	2 (0.5)	2 (0.3)
脂漏	1 (0.3)	1 (0.3)	2 (0.3)
脂漏性皮膚炎	1 (0.3)	2 (0.5)	3 (0.4)
敏感肌	1 (0.3)	0	1 (0.1)
皮膚灼熱感	0	1 (0.3)	1 (0.1)
皮膚障害	0	1 (0.3)	1 (0.1)
皮膚剥脱	1 (0.3)	0	1 (0.1)
皮膚亀裂	1 (0.3)	3 (0.8)	4 (0.5)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
皮膚および皮下組織障害 (Cont.)			
皮膚刺激	2 (0.5)	1 (0.3)	3 (0.4)
皮膚腫瘤	3 (0.8)	2 (0.5)	5 (0.7)
皮膚線条	2 (0.5)	0	2 (0.3)
皮膚腫脹	0	1 (0.3)	1 (0.1)
皮膚潰瘍	1 (0.3)	2 (0.5)	3 (0.4)
皮膚熱感	1 (0.3)	0	1 (0.1)
日光黒子	1 (0.3)	0	1 (0.1)
蕁麻疹	12 (3.1)	10 (2.6)	22 (2.9)
圧迫性蕁麻疹	0	1 (0.3)	1 (0.1)
社会環境	1 (0.3)	0	1 (0.1)
歯科補てつ物使用者	1 (0.3)	0	1 (0.1)
外科および内科処置	1 (0.3)	3 (0.8)	4 (0.5)
人工流産	0	1 (0.3)	1 (0.1)
子宮頚部円錐切除	1 (0.3)	0	1 (0.1)
避妊用インプラント	0	1 (0.3)	1 (0.1)
歯科手術	0	1 (0.3)	1 (0.1)
ポリープ切除	0	1 (0.3)	1 (0.1)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) n (%)	UPA 30 mg QD + TCS (N=382) n (%)	Total (N=767) n (%)
血管障害	13 (3.4)	11 (2.9)	24 (3.1)
大動脈瘤	0	1 (0.3)	1 (0.1)
大動脈解離	0	1 (0.3)	1 (0.1)
血腫	1 (0.3)	1 (0.3)	2 (0.3)
ほてり	0	1 (0.3)	1 (0.1)
高血圧	10 (2.6)	7 (1.8)	17 (2.2)
起立性低血圧	1 (0.3)	0	1 (0.1)
レイノー現象	0	1 (0.3)	1 (0.1)
四肢静脈血栓症	1 (0.3)	0	1 (0.1)

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Program Source Code: [redacted]

相互参照：M16-047 試験 CSR W52 Table 14.3__1.5.1.3

表 4. ウパダシチニブ投与期間中の有害事象の 100 人年あたりの発現率：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団）

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
Any adverse event	1730 (338.0)	1848 (346.6)	3578 (342.4)
*** Not coded ***	1 (0.2)	0	1 (<0.1)
*** Not coded ***	1 (0.2)	0	1 (<0.1)
血液およびリンパ系障害	17 (3.3)	33 (6.2)	50 (4.8)
貧血	5 (1.0)	5 (0.9)	10 (1.0)
大球性貧血	0	1 (0.2)	1 (<0.1)
皮膚病性リンパ節症	1 (0.2)	0	1 (<0.1)
好酸球増加症	1 (0.2)	1 (0.2)	2 (0.2)
赤血球減少症	0	1 (0.2)	1 (<0.1)
内出血発生の増加傾向	0	2 (0.4)	2 (0.2)
鉄欠乏性貧血	0	1 (0.2)	1 (<0.1)
白血球増加症	2 (0.4)	0	2 (0.2)
白血球減少症	0	4 (0.8)	4 (0.4)
リンパ節石灰化	1 (0.2)	0	1 (<0.1)
リンパ節症	4 (0.8)	3 (0.6)	7 (0.7)
リンパ球増加症	0	1 (0.2)	1 (<0.1)
リンパ組織過形成	0	1 (0.2)	1 (<0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
血液およびリンパ系障害 (Cont.)			
リンパ球減少症	1 (0.2)	1 (0.2)	2 (0.2)
大赤血球症	1 (0.2)	0	1 (<0.1)
単球減少症	0	1 (0.2)	1 (<0.1)
好中球減少症	1 (0.2)	8 (1.5)	9 (0.9)
汎血球減少症	0	1 (0.2)	1 (<0.1)
血小板減少症	0	1 (0.2)	1 (<0.1)
血小板増加症	0	1 (0.2)	1 (<0.1)
心臓障害	7 (1.4)	11 (2.1)	18 (1.7)
急性冠動脈症候群	0	1 (0.2)	1 (<0.1)
心房細動	0	1 (0.2)	1 (<0.1)
第一度房室ブロック	1 (0.2)	0	1 (<0.1)
徐脈	0	1 (0.2)	1 (<0.1)
うっ血性心不全	0	1 (0.2)	1 (<0.1)
左室肥大	1 (0.2)	0	1 (<0.1)
僧帽弁閉鎖不全症	0	1 (0.2)	1 (<0.1)
動悸	1 (0.2)	4 (0.8)	5 (0.5)
洞性徐脈	2 (0.4)	1 (0.2)	3 (0.3)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
心臓障害 (Cont.)			
頻脈	2 (0.4)	0	2 (0.2)
心室性頻脈	0	1 (0.2)	1 (<0.1)
先天性、家族性および遺伝性障害	3 (0.6)	2 (0.4)	5 (0.5)
先天性メラノサイト性母斑	0	1 (0.2)	1 (<0.1)
表皮母斑	1 (0.2)	0	1 (<0.1)
ジルベール症候群	0	1 (0.2)	1 (<0.1)
色素性網膜炎	1 (0.2)	0	1 (<0.1)
2a 型高脂血症	1 (0.2)	0	1 (<0.1)
耳および迷路障害	9 (1.8)	8 (1.5)	17 (1.6)
難聴	0	1 (0.2)	1 (<0.1)
耳の障害	1 (0.2)	0	1 (<0.1)
耳痛	4 (0.8)	2 (0.4)	6 (0.6)
耳垢分泌過多	1 (0.2)	0	1 (<0.1)
聴力低下	0	1 (0.2)	1 (<0.1)
耳鳴	0	2 (0.4)	2 (0.2)
回転性めまい	2 (0.4)	2 (0.4)	4 (0.4)
頭位性回転性めまい	1 (0.2)	0	1 (<0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
内分泌障害	2 (0.4)	3 (0.6)	5 (0.5)
甲状腺機能正常症候群	0	1 (0.2)	1 (<0.1)
甲状腺機能低下症	1 (0.2)	1 (0.2)	2 (0.2)
甲状腺腫瘤	1 (0.2)	1 (0.2)	2 (0.2)
眼障害	29 (5.7)	38 (7.1)	67 (6.4)
眼瞼炎	4 (0.8)	4 (0.8)	8 (0.8)
白内障	0	4 (0.8)	4 (0.4)
霰粒腫	1 (0.2)	3 (0.6)	4 (0.4)
結膜沈着物	0	1 (0.2)	1 (<0.1)
結膜充血	0	1 (0.2)	1 (<0.1)
結膜刺激	0	1 (0.2)	1 (<0.1)
アレルギー性結膜炎	2 (0.4)	3 (0.6)	5 (0.5)
角膜浮腫	1 (0.2)	0	1 (<0.1)
ドライアイ	3 (0.6)	2 (0.4)	5 (0.5)
眼瞼紅斑	1 (0.2)	0	1 (<0.1)
眼刺激	1 (0.2)	0	1 (<0.1)
眼痛	1 (0.2)	1 (0.2)	2 (0.2)

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E/100PY = Events per 100 patient-years.

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
眼障害 (Cont.)			
眼の異常感覚	0	1 (0.2)	1 (<0.1)
眼そう痒症	0	1 (0.2)	1 (<0.1)
眼部腫脹	0	2 (0.4)	2 (0.2)
眼瞼障害	0	1 (0.2)	1 (<0.1)
緑内障	1 (0.2)	0	1 (<0.1)
流涙増加	4 (0.8)	0	4 (0.4)
黄斑症	0	1 (0.2)	1 (<0.1)
近視	0	1 (0.2)	1 (<0.1)
視神経乳頭浮腫	0	1 (0.2)	1 (<0.1)
眼窩周囲浮腫	1 (0.2)	0	1 (<0.1)
羞明	0	1 (0.2)	1 (<0.1)
屈折障害	1 (0.2)	0	1 (<0.1)
網膜剥離	1 (0.2)	1 (0.2)	2 (0.2)
裂孔原性網膜剥離	0	2 (0.4)	2 (0.2)
眼瞼腫脹	2 (0.4)	1 (0.2)	3 (0.3)
潰瘍性角膜炎	1 (0.2)	1 (0.2)	2 (0.2)
春季カタル	0	1 (0.2)	1 (<0.1)

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E/100PY = Events per 100 patient-years.

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
眼障害 (Cont.)			
霧視	3 (0.6)	1 (0.2)	4 (0.4)
視力低下	0	1 (0.2)	1 (<0.1)
硝子体剥離	0	1 (0.2)	1 (<0.1)
眼球乾燥症	1 (0.2)	0	1 (<0.1)
胃腸障害	139 (27.2)	158 (29.6)	297 (28.4)
腹部不快感	3 (0.6)	2 (0.4)	5 (0.5)
腹部膨満	2 (0.4)	2 (0.4)	4 (0.4)
腹痛	16 (3.1)	15 (2.8)	31 (3.0)
下腹部痛	1 (0.2)	0	1 (<0.1)
上腹部痛	18 (3.5)	6 (1.1)	24 (2.3)
腹部圧痛	0	1 (0.2)	1 (<0.1)
肛門そう痒症	1 (0.2)	0	1 (<0.1)
口角口唇炎	0	2 (0.4)	2 (0.2)
肛門直腸不快感	0	1 (0.2)	1 (<0.1)
アフタ性潰瘍	2 (0.4)	2 (0.4)	4 (0.4)
便習慣変化	0	2 (0.4)	2 (0.2)
口唇のひび割れ	1 (0.2)	0	1 (<0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
胃腸障害 (Cont.)			
慢性胃炎	2 (0.4)	0	2 (0.2)
便秘	7 (1.4)	8 (1.5)	15 (1.4)
齲歯	5 (1.0)	6 (1.1)	11 (1.1)
下痢	17 (3.3)	36 (6.8)	53 (5.1)
口内乾燥	0	2 (0.4)	2 (0.2)
出血性十二指腸潰瘍	1 (0.2)	0	1 (<0.1)
消化不良	10 (2.0)	5 (0.9)	15 (1.4)
嚥下障害	0	2 (0.4)	2 (0.2)
変色便	1 (0.2)	0	1 (<0.1)
白色便	1 (0.2)	0	1 (<0.1)
鼓腸	2 (0.4)	1 (0.2)	3 (0.3)
食中毒	0	1 (0.2)	1 (<0.1)
排便回数増加	0	1 (0.2)	1 (<0.1)
胃炎	2 (0.4)	3 (0.6)	5 (0.5)
胃腸障害	1 (0.2)	0	1 (<0.1)
胃腸粘膜障害	1 (0.2)	0	1 (<0.1)
胃食道逆流性疾患	3 (0.6)	10 (1.9)	13 (1.2)

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胃腸障害 (Cont.)			
舌炎	1 (0.2)	0	1 (<0.1)
舌痛	0	1 (0.2)	1 (<0.1)
痔核	1 (0.2)	1 (0.2)	2 (0.2)
裂孔ヘルニア	0	1 (0.2)	1 (<0.1)
胃酸過多	0	1 (0.2)	1 (<0.1)
腸閉塞	1 (0.2)	0	1 (<0.1)
過敏性腸症候群	0	2 (0.4)	2 (0.2)
口唇水疱	1 (0.2)	0	1 (<0.1)
口腔内出血	0	1 (0.2)	1 (<0.1)
口腔内潰瘍形成	2 (0.4)	1 (0.2)	3 (0.3)
悪心	17 (3.3)	18 (3.4)	35 (3.3)
嚥下痛	2 (0.4)	0	2 (0.2)
口腔瘻	1 (0.2)	0	1 (<0.1)
口腔そう痒症	0	1 (0.2)	1 (<0.1)
膵炎	2 (0.4)	0	2 (0.2)
歯周病	1 (0.2)	0	1 (<0.1)
無髄歯	0	1 (0.2)	1 (<0.1)

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胃腸障害 (Cont.)			
レッチング	0	1 (0.2)	1 (<0.1)
口内炎	1 (0.2)	0	1 (<0.1)
生歯	1 (0.2)	0	1 (<0.1)
歯の障害	1 (0.2)	1 (0.2)	2 (0.2)
埋伏歯	2 (0.4)	3 (0.6)	5 (0.5)
歯痛	3 (0.6)	9 (1.7)	12 (1.1)
嘔吐	5 (1.0)	8 (1.5)	13 (1.2)
一般・全身障害および投与部位の状態	80 (15.6)	75 (14.1)	155 (14.8)
胸部不快感	2 (0.4)	1 (0.2)	3 (0.3)
胸痛	5 (1.0)	4 (0.8)	9 (0.9)
悪寒	3 (0.6)	0	3 (0.3)
嚢胞	1 (0.2)	1 (0.2)	2 (0.2)
顔面浮腫	1 (0.2)	0	1 (<0.1)
顔面痛	4 (0.8)	0	4 (0.4)
疲労	10 (2.0)	6 (1.1)	16 (1.5)
熱感	1 (0.2)	0	1 (<0.1)
肉芽腫	0	1 (0.2)	1 (<0.1)

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一般・全身障害および投与部位の状態 (Cont.)			
ヘルニア	0	1 (0.2)	1 (<0.1)
低体温	0	1 (0.2)	1 (<0.1)
治癒不良	0	1 (0.2)	1 (<0.1)
炎症	0	1 (0.2)	1 (<0.1)
インフルエンザ様疾患	15 (2.9)	23 (4.3)	38 (3.6)
倦怠感	2 (0.4)	1 (0.2)	3 (0.3)
小結節	0	2 (0.4)	2 (0.2)
非心臓性胸痛	0	1 (0.2)	1 (<0.1)
末梢性浮腫	3 (0.6)	0	3 (0.3)
疼痛	5 (1.0)	2 (0.4)	7 (0.7)
末梢腫脹	1 (0.2)	1 (0.2)	2 (0.2)
発熱	21 (4.1)	22 (4.1)	43 (4.1)
腫脹	3 (0.6)	1 (0.2)	4 (0.4)
顔面腫脹	3 (0.6)	1 (0.2)	4 (0.4)
血管穿刺部位内出血	0	4 (0.8)	4 (0.4)
肝胆道系障害	10 (2.0)	7 (1.3)	17 (1.6)
肝機能異常	6 (1.2)	3 (0.6)	9 (0.9)

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肝胆道系障害 (Cont.)			
脂肪肝	3 (0.6)	1 (0.2)	4 (0.4)
肝細胞損傷	0	1 (0.2)	1 (<0.1)
肝腫大	0	1 (0.2)	1 (<0.1)
高ビリルビン血症	1 (0.2)	0	1 (<0.1)
非アルコール性脂肪性肝炎	0	1 (0.2)	1 (<0.1)
免疫系障害	9 (1.8)	14 (2.6)	23 (2.2)
アレルギー性浮腫	0	1 (0.2)	1 (<0.1)
動物アレルギー	0	1 (0.2)	1 (<0.1)
アナフィラキシー反応	0	1 (0.2)	1 (<0.1)
薬物過敏症	1 (0.2)	0	1 (<0.1)
食物アレルギー	1 (0.2)	3 (0.6)	4 (0.4)
過敏症	3 (0.6)	4 (0.8)	7 (0.7)
季節性アレルギー	4 (0.8)	3 (0.6)	7 (0.7)
血清病	0	1 (0.2)	1 (<0.1)
感染症および寄生虫症	638 (124.6)	646 (121.2)	1284 (122.9)
四肢膿瘍	0	1 (0.2)	1 (<0.1)
口腔膿瘍	0	1 (0.2)	1 (<0.1)

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感染症および寄生虫症 (Cont.)			
ダニ皮膚炎	1 (0.2)	1 (0.2)	2 (0.2)
膿疱性ざ瘡	1 (0.2)	2 (0.4)	3 (0.3)
急性副鼻腔炎	1 (0.2)	0	1 (<0.1)
肛門膿瘍	1 (0.2)	0	1 (<0.1)
虫垂炎	1 (0.2)	0	1 (<0.1)
細菌性疾患キャリアー	1 (0.2)	0	1 (<0.1)
細菌感染	3 (0.6)	2 (0.4)	5 (0.5)
細菌性膣症	2 (0.4)	0	2 (0.2)
細菌尿	0	1 (0.2)	1 (<0.1)
バルトネラ症	1 (0.2)	0	1 (<0.1)
体部白癬	2 (0.4)	6 (1.1)	8 (0.8)
気管支炎	10 (2.0)	15 (2.8)	25 (2.4)
ウイルス性気管支炎	0	1 (0.2)	1 (<0.1)
水疱性膿痂疹	2 (0.4)	0	2 (0.2)
感染性滑液包炎	0	1 (0.2)	1 (<0.1)
カンジダ感染	0	1 (0.2)	1 (<0.1)
蜂巣炎	3 (0.6)	5 (0.9)	8 (0.8)

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感染症および寄生虫症 (Cont.)			
条虫感染	1 (0.2)	0	1 (<0.1)
クラミジア感染	0	1 (0.2)	1 (<0.1)
慢性副鼻腔炎	1 (0.2)	0	1 (<0.1)
結膜炎	13 (2.5)	10 (1.9)	23 (2.2)
細菌性結膜炎	2 (0.4)	1 (0.2)	3 (0.3)
ウイルス性結膜炎	1 (0.2)	1 (0.2)	2 (0.2)
コロナウイルス感染	10 (2.0)	11 (2.1)	21 (2.0)
膀胱炎	6 (1.2)	2 (0.4)	8 (0.8)
涙嚢炎	1 (0.2)	0	1 (<0.1)
医療機器関連感染	2 (0.4)	0	2 (0.2)
感染性下痢	0	1 (0.2)	1 (<0.1)
赤痢	1 (0.2)	0	1 (<0.1)
耳感染	3 (0.6)	1 (0.2)	4 (0.4)
ブドウ球菌性耳感染	0	1 (0.2)	1 (<0.1)
ヘルペス性状湿疹	6 (1.2)	12 (2.3)	18 (1.7)
膿痂疹性湿疹	3 (0.6)	2 (0.4)	5 (0.5)
感染性湿疹	0	1 (0.2)	1 (<0.1)

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感染症および寄生虫症 (Cont.)			
エンテロバクター感染	1 (0.2)	0	1 (<0.1)
蟯虫症	1 (0.2)	0	1 (<0.1)
丹毒	1 (0.2)	0	1 (<0.1)
眼感染	1 (0.2)	0	1 (<0.1)
ブドウ球菌性眼感染	1 (0.2)	1 (0.2)	2 (0.2)
ウイルス性眼感染	1 (0.2)	0	1 (<0.1)
眼瞼感染	2 (0.4)	0	2 (0.2)
糸状虫症	0	1 (0.2)	1 (<0.1)
毛包炎	22 (4.3)	23 (4.3)	45 (4.3)
真菌感染	3 (0.6)	0	3 (0.3)
皮膚真菌感染	4 (0.8)	5 (0.9)	9 (0.9)
せつ	4 (0.8)	9 (1.7)	13 (1.2)
ウイルス性胃炎	1 (0.2)	0	1 (<0.1)
胃腸炎	13 (2.5)	16 (3.0)	29 (2.8)
ウイルス性胃腸炎	0	6 (1.1)	6 (0.6)
消化管感染	1 (0.2)	0	1 (<0.1)
陰部ヘルペス	0	3 (0.6)	3 (0.3)

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感染症および寄生虫症 (Cont.)			
陰部単純ヘルペス	0	3 (0.6)	3 (0.3)
ジアルジア症	1 (0.2)	0	1 (<0.1)
歯肉炎	1 (0.2)	1 (0.2)	2 (0.2)
ヘルペス眼感染	1 (0.2)	3 (0.6)	4 (0.4)
単純ヘルペス	42 (8.2)	31 (5.8)	73 (7.0)
帯状疱疹	18 (3.5)	28 (5.3)	46 (4.4)
皮膚播種性帯状疱疹	1 (0.2)	0	1 (<0.1)
播種性帯状疱疹	0	1 (0.2)	1 (<0.1)
耳帯状疱疹	0	2 (0.4)	2 (0.2)
麦粒腫	6 (1.2)	5 (0.9)	11 (1.1)
膿痂疹	16 (3.1)	11 (2.1)	27 (2.6)
切開部位蜂巣炎	1 (0.2)	0	1 (<0.1)
感染性嚢腫	1 (0.2)	0	1 (<0.1)
感染性皮膚嚢腫	0	1 (0.2)	1 (<0.1)
感染	1 (0.2)	1 (0.2)	2 (0.2)
寄生虫感染	1 (0.2)	0	1 (<0.1)
インフルエンザ	16 (3.1)	11 (2.1)	27 (2.6)

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感染症および寄生虫症 (Cont.)			
関節膿瘍	0	1 (0.2)	1 (<0.1)
カポジ水痘様発疹	1 (0.2)	6 (1.1)	7 (0.7)
ウイルス性角膜炎	1 (0.2)	0	1 (<0.1)
腎感染	1 (0.2)	0	1 (<0.1)
大腸感染	1 (0.2)	0	1 (<0.1)
喉頭炎	1 (0.2)	0	1 (<0.1)
潜伏結核	1 (0.2)	3 (0.6)	4 (0.4)
シラミ寄生	0	1 (0.2)	1 (<0.1)
マラセチア感染	1 (0.2)	1 (0.2)	2 (0.2)
細菌性乳腺炎	1 (0.2)	0	1 (<0.1)
ウイルス性髄膜炎	1 (0.2)	0	1 (<0.1)
メタニューモウイルス感染	1 (0.2)	0	1 (<0.1)
伝染性軟属腫	5 (1.0)	4 (0.8)	9 (0.9)
鼻ヘルペス	1 (0.2)	3 (0.6)	4 (0.4)
上咽頭炎	128 (25.0)	90 (16.9)	218 (20.9)
爪真菌症	2 (0.4)	3 (0.6)	5 (0.5)
眼部単純ヘルペス	9 (1.8)	11 (2.1)	20 (1.9)

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感染症および寄生虫症 (Cont.)			
眼帯状疱疹	0	1 (0.2)	1 (<0.1)
口腔カンジダ症	1 (0.2)	3 (0.6)	4 (0.4)
口腔ヘルペス	42 (8.2)	66 (12.4)	108 (10.3)
外耳炎	4 (0.8)	4 (0.8)	8 (0.8)
中耳炎	3 (0.6)	2 (0.4)	5 (0.5)
急性中耳炎	1 (0.2)	1 (0.2)	2 (0.2)
爪囲炎	3 (0.6)	2 (0.4)	5 (0.5)
インプラント周囲炎	1 (0.2)	0	1 (<0.1)
軟骨膜炎	1 (0.2)	0	1 (<0.1)
歯周炎	1 (0.2)	0	1 (<0.1)
眼窩周囲蜂巣炎	2 (0.4)	0	2 (0.2)
扁桃周囲膿瘍	1 (0.2)	0	1 (<0.1)
咽頭炎	12 (2.3)	13 (2.4)	25 (2.4)
レンサ球菌性咽頭炎	2 (0.4)	2 (0.4)	4 (0.4)
肺炎	4 (0.8)	5 (0.9)	9 (0.9)
マイコプラズマ性肺炎	0	2 (0.4)	2 (0.2)
ウイルス感染後疲労症候群	0	1 (0.2)	1 (<0.1)

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感染症および寄生虫症 (Cont.)			
術後創感染	0	2 (0.4)	2 (0.2)
歯髄炎	0	1 (0.2)	1 (<0.1)
化膿性分泌物	1 (0.2)	0	1 (<0.1)
膿疱	1 (0.2)	3 (0.6)	4 (0.4)
腎盂腎炎	1 (0.2)	1 (0.2)	2 (0.2)
膿疱性皮疹	0	2 (0.4)	2 (0.2)
気道感染	4 (0.8)	1 (0.2)	5 (0.5)
ウイルス性気道感染	2 (0.4)	1 (0.2)	3 (0.3)
鼻炎	4 (0.8)	1 (0.2)	5 (0.5)
鼻喉頭炎	0	1 (0.2)	1 (<0.1)
ライノウイルス感染	0	1 (0.2)	1 (<0.1)
副鼻腔炎	5 (1.0)	8 (1.5)	13 (1.2)
皮膚細菌感染	3 (0.6)	1 (0.2)	4 (0.4)
皮膚感染	9 (1.8)	5 (0.9)	14 (1.3)
膿性痰	1 (0.2)	0	1 (<0.1)
ブドウ球菌性膿瘍	1 (0.2)	0	1 (<0.1)
ブドウ球菌性膿痂疹	1 (0.2)	0	1 (<0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
ブドウ球菌感染	5 (1.0)	3 (0.6)	8 (0.8)
ブドウ球菌皮膚感染	5 (1.0)	10 (1.9)	15 (1.4)
細菌重複感染	0	1 (0.2)	1 (<0.1)
真菌重複感染	1 (0.2)	0	1 (<0.1)
股部白癬	0	3 (0.6)	3 (0.3)
白癬感染	1 (0.2)	2 (0.4)	3 (0.3)
足部白癬	7 (1.4)	10 (1.9)	17 (1.6)
癜風	1 (0.2)	4 (0.8)	5 (0.5)
扁桃炎	5 (1.0)	6 (1.1)	11 (1.1)
歯感染	5 (1.0)	5 (0.9)	10 (1.0)
気管炎	2 (0.4)	2 (0.4)	4 (0.4)
気管気管支炎	1 (0.2)	0	1 (<0.1)
トリコモナス症	0	1 (0.2)	1 (<0.1)
トリコフィトン感染症	1 (0.2)	0	1 (<0.1)
上気道感染	58 (11.3)	58 (10.9)	116 (11.1)
ウレアプラズマ感染	1 (0.2)	0	1 (<0.1)
尿道炎	1 (0.2)	0	1 (<0.1)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
尿路感染	19 (3.7)	23 (4.3)	42 (4.0)
細菌性尿路感染	0	1 (0.2)	1 (<0.1)
腟感染	2 (0.4)	1 (0.2)	3 (0.3)
ウイルス感染	1 (0.2)	3 (0.6)	4 (0.4)
ウイルス性咽頭炎	2 (0.4)	2 (0.4)	4 (0.4)
ウイルス性上気道感染	8 (1.6)	12 (2.3)	20 (1.9)
外陰部腟カンジダ症	3 (0.6)	1 (0.2)	4 (0.4)
外陰腟真菌感染	1 (0.2)	2 (0.4)	3 (0.3)
トリコモナス外陰腟炎	1 (0.2)	0	1 (<0.1)
傷害、中毒および処置合併症	52 (10.2)	63 (11.8)	115 (11.0)
事故	1 (0.2)	2 (0.4)	3 (0.3)
動物咬傷	1 (0.2)	0	1 (<0.1)
足関節部骨折	0	1 (0.2)	1 (<0.1)
節足動物咬傷	0	2 (0.4)	2 (0.2)
節足動物刺傷	2 (0.4)	0	2 (0.2)
骨挫傷	0	1 (0.2)	1 (<0.1)
軟骨損傷	1 (0.2)	1 (0.2)	2 (0.2)

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傷害、中毒および処置合併症 (Cont.)			
胸部損傷	0	1 (0.2)	1 (<0.1)
鎖骨骨折	0	1 (0.2)	1 (<0.1)
挫傷	2 (0.4)	4 (0.8)	6 (0.6)
角膜擦過傷	0	1 (0.2)	1 (<0.1)
頭蓋脳損傷	1 (0.2)	1 (0.2)	2 (0.2)
胸骨脱臼	0	1 (0.2)	1 (<0.1)
上顆炎	0	1 (0.2)	1 (<0.1)
眼挫傷	0	1 (0.2)	1 (<0.1)
眼外傷	0	1 (0.2)	1 (<0.1)
転倒	2 (0.4)	5 (0.9)	7 (0.7)
大腿骨骨折	0	1 (0.2)	1 (<0.1)
足骨折	3 (0.6)	1 (0.2)	4 (0.4)
尾骨骨折	1 (0.2)	0	1 (<0.1)
頭部損傷	1 (0.2)	0	1 (<0.1)
熱疲労	0	1 (0.2)	1 (<0.1)
上腕骨骨折	0	1 (0.2)	1 (<0.1)
腸骨骨折	1 (0.2)	0	1 (<0.1)

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傷害、中毒および処置合併症 (Cont.)			
損傷	3 (0.6)	1 (0.2)	4 (0.4)
関節脱臼	0	1 (0.2)	1 (<0.1)
関節損傷	1 (0.2)	5 (0.9)	6 (0.6)
靭帯損傷	2 (0.4)	0	2 (0.2)
靭帯断裂	0	1 (0.2)	1 (<0.1)
靭帯捻挫	1 (0.2)	1 (0.2)	2 (0.2)
四肢損傷	4 (0.8)	1 (0.2)	5 (0.5)
半月板損傷	1 (0.2)	0	1 (<0.1)
筋損傷	0	1 (0.2)	1 (<0.1)
肉離れ	3 (0.6)	5 (0.9)	8 (0.8)
開放骨折	0	1 (0.2)	1 (<0.1)
処置による疼痛	1 (0.2)	2 (0.4)	3 (0.3)
橈骨骨折	0	3 (0.6)	3 (0.3)
肋骨骨折	3 (0.6)	1 (0.2)	4 (0.4)
交通事故	0	3 (0.6)	3 (0.3)
瘢痕	1 (0.2)	0	1 (<0.1)
皮膚擦過傷	2 (0.4)	1 (0.2)	3 (0.3)

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傷害、中毒および処置合併症 (Cont.)			
皮膚裂傷	3 (0.6)	1 (0.2)	4 (0.4)
脊椎骨折	1 (0.2)	0	1 (<0.1)
スポーツ損傷	1 (0.2)	0	1 (<0.1)
胸骨骨折	1 (0.2)	0	1 (<0.1)
サンバーン	1 (0.2)	1 (0.2)	2 (0.2)
腱損傷	0	1 (0.2)	1 (<0.1)
腱断裂	1 (0.2)	0	1 (<0.1)
熱傷	1 (0.2)	0	1 (<0.1)
歯牙破折	3 (0.6)	2 (0.4)	5 (0.5)
外傷性血腫	1 (0.2)	0	1 (<0.1)
上肢骨折	0	1 (0.2)	1 (<0.1)
創傷	0	1 (0.2)	1 (<0.1)
創部分泌	0	1 (0.2)	1 (<0.1)
手首関節骨折	1 (0.2)	0	1 (<0.1)
臨床検査	151 (29.5)	138 (25.9)	289 (27.7)
アラニンアミノトランスフェラーゼ増加	17 (3.3)	8 (1.5)	25 (2.4)
アスパラギン酸アミノトランスフェラーゼ異常	1 (0.2)	0	1 (<0.1)

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臨床検査 (Cont.)			
アスパラギン酸アミノトランスフェラーゼ増加	9 (1.8)	7 (1.3)	16 (1.5)
血中アルカリホスファターゼ増加	1 (0.2)	0	1 (<0.1)
血中重炭酸塩減少	0	1 (0.2)	1 (<0.1)
血中ビリルビン増加	2 (0.4)	1 (0.2)	3 (0.3)
血中コレステロール	1 (0.2)	0	1 (<0.1)
血中コレステロール増加	4 (0.8)	3 (0.6)	7 (0.7)
血中クレアチンホスホキナーゼ増加	45 (8.8)	54 (10.1)	99 (9.5)
血中クレアチニン増加	1 (0.2)	2 (0.4)	3 (0.3)
血中葉酸減少	1 (0.2)	0	1 (<0.1)
血中ブドウ糖増加	1 (0.2)	1 (0.2)	2 (0.2)
血中免疫グロブリン E 増加	1 (0.2)	0	1 (<0.1)
血中鉄減少	0	1 (0.2)	1 (<0.1)
血中リン減少	1 (0.2)	0	1 (<0.1)
血中カリウム減少	0	1 (0.2)	1 (<0.1)
血圧上昇	5 (1.0)	2 (0.4)	7 (0.7)
血中遊離テストステロン減少	1 (0.2)	0	1 (<0.1)
血中トリグリセリド増加	2 (0.4)	4 (0.8)	6 (0.6)

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臨床検査 (Cont.)			
血中尿素増加	0	1 (0.2)	1 (<0.1)
血中尿酸増加	4 (0.8)	0	4 (0.4)
尿中血陽性	0	1 (0.2)	1 (<0.1)
体温上昇	0	1 (0.2)	1 (<0.1)
心電図 QT 間隔異常	1 (0.2)	0	1 (<0.1)
好酸球数増加	3 (0.6)	1 (0.2)	4 (0.4)
好酸球百分率増加	1 (0.2)	0	1 (<0.1)
便量増加	0	1 (0.2)	1 (<0.1)
真菌検査陽性	1 (0.2)	0	1 (<0.1)
ヘモグロビン減少	1 (0.2)	6 (1.1)	7 (0.7)
ヘリコバクター検査陽性	1 (0.2)	0	1 (<0.1)
肝酵素上昇	1 (0.2)	0	1 (<0.1)
肝機能検査異常	1 (0.2)	1 (0.2)	2 (0.2)
低比重リポ蛋白増加	1 (0.2)	3 (0.6)	4 (0.4)
リンパ球数減少	1 (0.2)	0	1 (<0.1)
リンパ球数増加	1 (0.2)	0	1 (<0.1)
平均赤血球容積増加	1 (0.2)	0	1 (<0.1)

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臨床検査 (Cont.)			
単球数増加	0	1 (0.2)	1 (<0.1)
結核菌群検査陽性	2 (0.4)	0	2 (0.2)
好中球数減少	8 (1.6)	7 (1.3)	15 (1.4)
好中球数増加	1 (0.2)	0	1 (<0.1)
好中球百分率減少	1 (0.2)	0	1 (<0.1)
好中球百分率増加	1 (0.2)	0	1 (<0.1)
ポリオーマウイルス検査陽性	1 (0.2)	0	1 (<0.1)
尿中蛋白陽性	5 (1.0)	1 (0.2)	6 (0.6)
赤血球数減少	1 (0.2)	1 (0.2)	2 (0.2)
ブドウ球菌検査陽性	4 (0.8)	0	4 (0.4)
トランスアミナーゼ上昇	0	2 (0.4)	2 (0.2)
トロポニン増加	0	1 (0.2)	1 (<0.1)
ビタミン B12 減少	1 (0.2)	0	1 (<0.1)
ビタミン D 減少	0	1 (0.2)	1 (<0.1)
体重減少	2 (0.4)	0	2 (0.2)
体重増加	9 (1.8)	16 (3.0)	25 (2.4)
白血球数減少	3 (0.6)	4 (0.8)	7 (0.7)

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臨床検査 (Cont.)			
白血球数増加	0	1 (0.2)	1 (<0.1)
尿中白血球陽性	1 (0.2)	3 (0.6)	4 (0.4)
代謝および栄養障害	30 (5.9)	38 (7.1)	68 (6.5)
食欲減退	2 (0.4)	0	2 (0.2)
脱水	0	2 (0.4)	2 (0.2)
糖尿病	0	2 (0.4)	2 (0.2)
脂質異常症	0	2 (0.4)	2 (0.2)
水分過負荷	0	1 (0.2)	1 (<0.1)
食物不耐性	1 (0.2)	0	1 (<0.1)
耐糖能障害	1 (0.2)	0	1 (<0.1)
グルテン過敏症	0	1 (0.2)	1 (<0.1)
痛風	1 (0.2)	1 (0.2)	2 (0.2)
高コレステロール血症	4 (0.8)	6 (1.1)	10 (1.0)
高血糖	3 (0.6)	2 (0.4)	5 (0.5)
高ホモシステイン血症	1 (0.2)	0	1 (<0.1)
高カリウム血症	1 (0.2)	0	1 (<0.1)
高脂血症	1 (0.2)	6 (1.1)	7 (0.7)

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代謝および栄養障害 (Cont.)			
高ナトリウム血症	2 (0.4)	0	2 (0.2)
高トリグリセリド血症	2 (0.4)	5 (0.9)	7 (0.7)
高尿酸血症	6 (1.2)	3 (0.6)	9 (0.9)
低カリウム血症	0	1 (0.2)	1 (<0.1)
低マグネシウム血症	1 (0.2)	0	1 (<0.1)
低ナトリウム血症	1 (0.2)	1 (0.2)	2 (0.2)
食欲亢進	0	2 (0.4)	2 (0.2)
鉄欠乏	0	1 (0.2)	1 (<0.1)
肥満	1 (0.2)	0	1 (<0.1)
ビタミン B12 欠乏	1 (0.2)	0	1 (<0.1)
ビタミン D 欠乏	1 (0.2)	2 (0.4)	3 (0.3)
筋骨格系および結合組織障害	53 (10.4)	84 (15.8)	137 (13.1)
関節痛	10 (2.0)	12 (2.3)	22 (2.1)
関節炎	2 (0.4)	4 (0.8)	6 (0.6)
背部痛	9 (1.8)	12 (2.3)	21 (2.0)
骨痛	0	1 (0.2)	1 (<0.1)
滑液包炎	2 (0.4)	5 (0.9)	7 (0.7)

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筋骨格系および結合組織障害 (Cont.)			
尾骨痛	0	1 (0.2)	1 (<0.1)
外骨腫	1 (0.2)	0	1 (<0.1)
出血性関節症	0	1 (0.2)	1 (<0.1)
椎間板突出	0	4 (0.8)	4 (0.4)
関節ロック	0	1 (0.2)	1 (<0.1)
関節腫脹	0	1 (0.2)	1 (<0.1)
四肢不快感	1 (0.2)	0	1 (<0.1)
筋痙縮	2 (0.4)	7 (1.3)	9 (0.9)
筋攣縮	0	1 (0.2)	1 (<0.1)
筋骨格系胸痛	2 (0.4)	3 (0.6)	5 (0.5)
筋骨格痛	1 (0.2)	3 (0.6)	4 (0.4)
筋骨格硬直	0	1 (0.2)	1 (<0.1)
筋肉痛	7 (1.4)	4 (0.8)	11 (1.1)
頚部腫瘤	0	1 (0.2)	1 (<0.1)
頚部痛	5 (1.0)	2 (0.4)	7 (0.7)
骨減少症	0	1 (0.2)	1 (<0.1)
骨粗鬆症	0	1 (0.2)	1 (<0.1)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)			
四肢痛	5 (1.0)	8 (1.5)	13 (1.2)
顎痛	0	1 (0.2)	1 (<0.1)
膝蓋大腿関節痛症候群	1 (0.2)	0	1 (<0.1)
足底筋膜炎	1 (0.2)	0	1 (<0.1)
脊柱管狭窄症	0	1 (0.2)	1 (<0.1)
脊椎すべり症	0	1 (0.2)	1 (<0.1)
軟骨下脆弱性骨折	0	1 (0.2)	1 (<0.1)
滑液嚢腫	0	1 (0.2)	1 (<0.1)
顎関節症候群	1 (0.2)	2 (0.4)	3 (0.3)
腱炎	1 (0.2)	2 (0.4)	3 (0.3)
腱鞘炎	0	1 (0.2)	1 (<0.1)
斜頚	2 (0.4)	0	2 (0.2)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	15 (2.9)	16 (3.0)	31 (3.0)
結腸腺癌	0	1 (0.2)	1 (<0.1)
肛門性器疣贅	0	2 (0.4)	2 (0.2)
良性新生物	0	1 (0.2)	1 (<0.1)
精巣の良性新生物	0	1 (0.2)	1 (<0.1)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）（Cont.）			
異形成母斑	1 (0.2)	0	1 (<0.1)
血管腫	1 (0.2)	1 (0.2)	2 (0.2)
ケラトアカントーマ	0	1 (0.2)	1 (<0.1)
表皮内悪性黒色腫	0	1 (0.2)	1 (<0.1)
メラノサイト性母斑	1 (0.2)	0	1 (<0.1)
結節性筋膜炎	1 (0.2)	0	1 (<0.1)
化膿性肉芽腫	0	1 (0.2)	1 (<0.1)
脂漏性角化症	1 (0.2)	1 (0.2)	2 (0.2)
皮膚乳頭腫	8 (1.6)	5 (0.9)	13 (1.2)
口腔内扁平上皮癌	1 (0.2)	0	1 (<0.1)
子宮平滑筋腫	1 (0.2)	1 (0.2)	2 (0.2)
神経系障害	67 (13.1)	73 (13.7)	140 (13.4)
手根管症候群	1 (0.2)	0	1 (<0.1)
馬尾症候群	0	1 (0.2)	1 (<0.1)
脳血管発作	0	1 (0.2)	1 (<0.1)
浮動性めまい	10 (2.0)	9 (1.7)	19 (1.8)
味覚不全	0	2 (0.4)	2 (0.2)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
神経系障害 (Cont.)			
てんかん	0	1 (0.2)	1 (<0.1)
労作性頭痛	1 (0.2)	0	1 (<0.1)
全身性強直性間代性発作	0	1 (0.2)	1 (<0.1)
頭部不快感	0	1 (0.2)	1 (<0.1)
頭痛	35 (6.8)	35 (6.6)	70 (6.7)
過眠症	0	1 (0.2)	1 (<0.1)
筋緊張亢進	0	1 (0.2)	1 (<0.1)
感覚鈍麻	2 (0.4)	1 (0.2)	3 (0.3)
嗜眠	0	1 (0.2)	1 (<0.1)
片頭痛	5 (1.0)	3 (0.6)	8 (0.8)
前兆を伴う片頭痛	1 (0.2)	0	1 (<0.1)
多発性硬化症	0	1 (0.2)	1 (<0.1)
多発性硬化症再発	0	1 (0.2)	1 (<0.1)
神経圧迫	0	1 (0.2)	1 (<0.1)
末梢性ニューロパチー	1 (0.2)	1 (0.2)	2 (0.2)
錯感覚	3 (0.6)	1 (0.2)	4 (0.4)
嗅覚錯誤	0	1 (0.2)	1 (<0.1)

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神経系障害 (Cont.)			
末梢神経不全麻痺	2 (0.4)	0	2 (0.2)
ヘルペス後神経痛	2 (0.4)	1 (0.2)	3 (0.3)
失神寸前の状態	1 (0.2)	1 (0.2)	2 (0.2)
坐骨神経痛	1 (0.2)	2 (0.4)	3 (0.3)
傾眠	0	1 (0.2)	1 (<0.1)
くも膜下出血	1 (0.2)	0	1 (<0.1)
失神	0	1 (0.2)	1 (<0.1)
足根管症候群	1 (0.2)	0	1 (<0.1)
緊張性頭痛	0	1 (0.2)	1 (<0.1)
三叉神経痛	0	1 (0.2)	1 (<0.1)
トンネル状視野	0	1 (0.2)	1 (<0.1)
妊娠、産褥および周産期の状態	0	1 (0.2)	1 (<0.1)
自然流産	0	1 (0.2)	1 (<0.1)
精神障害	30 (5.9)	33 (6.2)	63 (6.0)
感情不安定	3 (0.6)	0	3 (0.3)
アルコール使用障害	0	1 (0.2)	1 (<0.1)
不安	6 (1.2)	4 (0.8)	10 (1.0)

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精神障害 (Cont.)			
注意欠陥多動性障害	1 (0.2)	2 (0.4)	3 (0.3)
双極性障害	0	1 (0.2)	1 (<0.1)
抑うつ気分	4 (0.8)	3 (0.6)	7 (0.7)
うつ病	3 (0.6)	4 (0.8)	7 (0.7)
抑うつ症状	1 (0.2)	0	1 (<0.1)
全般性不安障害	1 (0.2)	0	1 (<0.1)
不眠症	4 (0.8)	6 (1.1)	10 (1.0)
易刺激性	1 (0.2)	0	1 (<0.1)
リビドー減退	0	1 (0.2)	1 (<0.1)
リビドー亢進	1 (0.2)	0	1 (<0.1)
精神障害	0	3 (0.6)	3 (0.3)
混合性不安抑うつ障害	0	1 (0.2)	1 (<0.1)
悪夢	1 (0.2)	0	1 (<0.1)
パニック発作	1 (0.2)	1 (0.2)	2 (0.2)
心的外傷後ストレス障害	0	1 (0.2)	1 (<0.1)
睡眠障害	0	2 (0.4)	2 (0.2)
ストレス	2 (0.4)	2 (0.4)	4 (0.4)

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精神障害 (Cont.)			
自殺念慮	0	1 (0.2)	1 (<0.1)
自殺企図	1 (0.2)	0	1 (<0.1)
腎および尿路障害	15 (2.9)	17 (3.2)	32 (3.1)
急性腎障害	1 (0.2)	0	1 (<0.1)
アルブミン尿	2 (0.4)	2 (0.4)	4 (0.4)
尿路結石	1 (0.2)	0	1 (<0.1)
出血性膀胱炎	0	1 (0.2)	1 (<0.1)
排尿困難	3 (0.6)	0	3 (0.3)
糖尿	1 (0.2)	0	1 (<0.1)
血尿	2 (0.4)	5 (0.9)	7 (0.7)
水腎症	1 (0.2)	0	1 (<0.1)
緊張性膀胱	0	1 (0.2)	1 (<0.1)
腎結石症	1 (0.2)	2 (0.4)	3 (0.3)
夜間頻尿	1 (0.2)	0	1 (<0.1)
頻尿	0	2 (0.4)	2 (0.2)
多尿	1 (0.2)	0	1 (<0.1)
蛋白尿	1 (0.2)	3 (0.6)	4 (0.4)

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腎および尿路障害 (Cont.)			
腎仙痛	0	1 (0.2)	1 (<0.1)
生殖系および乳房障害	17 (3.3)	23 (4.3)	40 (3.8)
無月経	1 (0.2)	1 (0.2)	2 (0.2)
萎縮性外陰腟炎	0	1 (0.2)	1 (<0.1)
乳房嚢胞	2 (0.4)	0	2 (0.2)
子宮頚部上皮異形成	2 (0.4)	2 (0.4)	4 (0.4)
月経困難症	1 (0.2)	0	1 (<0.1)
子宮内膜症	0	2 (0.4)	2 (0.2)
勃起不全	1 (0.2)	3 (0.6)	4 (0.4)
女性化乳房	0	1 (0.2)	1 (<0.1)
過少月経	1 (0.2)	0	1 (<0.1)
月経過多	1 (0.2)	0	1 (<0.1)
月経障害	1 (0.2)	0	1 (<0.1)
不規則月経	1 (0.2)	2 (0.4)	3 (0.3)
不正子宮出血	0	1 (0.2)	1 (<0.1)
骨盤痛	0	1 (0.2)	1 (<0.1)
多嚢胞性卵巣	0	1 (0.2)	1 (<0.1)

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生殖系および乳房障害 (Cont.)			
前立腺炎	1 (0.2)	0	1 (<0.1)
精巣障害	0	1 (0.2)	1 (<0.1)
精巣腫瘤	0	2 (0.4)	2 (0.2)
精巣痛	1 (0.2)	3 (0.6)	4 (0.4)
腟分泌物	2 (0.4)	0	2 (0.2)
腟出血	1 (0.2)	1 (0.2)	2 (0.2)
女性外陰部潰瘍	0	1 (0.2)	1 (<0.1)
外陰腟乾燥	1 (0.2)	0	1 (<0.1)
呼吸器、胸郭および縦隔障害	97 (18.9)	92 (17.3)	189 (18.1)
急性呼吸窮迫症候群	0	1 (0.2)	1 (<0.1)
アレルギー性気管支炎	1 (0.2)	0	1 (<0.1)
失声症	2 (0.4)	0	2 (0.2)
喘息	12 (2.3)	11 (2.1)	23 (2.2)
無気肺	1 (0.2)	0	1 (<0.1)
カタル	6 (1.2)	5 (0.9)	11 (1.1)
慢性閉塞性肺疾患	0	1 (0.2)	1 (<0.1)
咳嗽	25 (4.9)	27 (5.1)	52 (5.0)

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呼吸器、胸郭および縦隔障害 (Cont.)			
呼吸困難	5 (1.0)	5 (0.9)	10 (1.0)
鼻出血	7 (1.4)	6 (1.1)	13 (1.2)
喀血	2 (0.4)	0	2 (0.2)
しゃっくり	0	1 (0.2)	1 (<0.1)
肺浸潤	1 (0.2)	0	1 (<0.1)
縦隔血腫	1 (0.2)	0	1 (<0.1)
鼻閉	1 (0.2)	1 (0.2)	2 (0.2)
鼻茸	1 (0.2)	0	1 (<0.1)
鼻中隔弯曲	1 (0.2)	0	1 (<0.1)
口腔咽頭痛	13 (2.5)	14 (2.6)	27 (2.6)
咽頭腫脹	0	1 (0.2)	1 (<0.1)
胸水	1 (0.2)	0	1 (<0.1)
胸膜痛	0	1 (0.2)	1 (<0.1)
湿性咳嗽	2 (0.4)	0	2 (0.2)
肺塞栓症	1 (0.2)	0	1 (<0.1)
肺肉芽腫	0	1 (0.2)	1 (<0.1)
肺腫瘤	1 (0.2)	2 (0.4)	3 (0.3)

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呼吸器、胸郭および縦隔障害 (Cont.)			
気道うっ血	0	2 (0.4)	2 (0.2)
アレルギー性鼻炎	0	3 (0.6)	3 (0.3)
鼻漏	8 (1.6)	5 (0.9)	13 (1.2)
副鼻腔うっ血	1 (0.2)	2 (0.4)	3 (0.3)
睡眠時無呼吸症候群	1 (0.2)	0	1 (<0.1)
くしゃみ	0	1 (0.2)	1 (<0.1)
喘息発作重積	1 (0.2)	0	1 (<0.1)
咽喉刺激感	0	1 (0.2)	1 (<0.1)
上気道うっ血	1 (0.2)	0	1 (<0.1)
喘鳴	1 (0.2)	1 (0.2)	2 (0.2)
皮膚および皮下組織障害	244 (47.7)	257 (48.2)	501 (47.9)
ざ瘡	68 (13.3)	100 (18.8)	168 (16.1)
嚢胞性ざ瘡	0	1 (0.2)	1 (<0.1)
後天性ブラシュコ皮膚炎	1 (0.2)	0	1 (<0.1)
光線角化症	0	2 (0.4)	2 (0.2)
脱毛症	2 (0.4)	1 (0.2)	3 (0.3)
血管浮腫	0	3 (0.6)	3 (0.3)

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皮膚および皮下組織障害 (Cont.)			
水疱	2 (0.4)	2 (0.4)	4 (0.4)
冷汗	0	1 (0.2)	1 (<0.1)
皮膚嚢腫	2 (0.4)	1 (0.2)	3 (0.3)
皮膚炎	6 (1.2)	2 (0.4)	8 (0.8)
ざ瘡様皮膚炎	5 (1.0)	4 (0.8)	9 (0.9)
アレルギー性皮膚炎	2 (0.4)	2 (0.4)	4 (0.4)
アトピー性皮膚炎	53 (10.4)	36 (6.8)	89 (8.5)
接触皮膚炎	8 (1.6)	8 (1.5)	16 (1.5)
疱疹状皮膚炎	0	1 (0.2)	1 (<0.1)
乾癬様皮膚炎	1 (0.2)	0	1 (<0.1)
薬疹	1 (0.2)	0	1 (<0.1)
皮膚乾燥	0	1 (0.2)	1 (<0.1)
異汗性湿疹	4 (0.8)	0	4 (0.4)
斑状出血	0	3 (0.6)	3 (0.3)
湿疹	13 (2.5)	8 (1.5)	21 (2.0)
小水疱性湿疹	0	1 (0.2)	1 (<0.1)
紅斑	3 (0.6)	2 (0.4)	5 (0.5)

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皮膚および皮下組織障害 (Cont.)			
過剰肉芽組織	1 (0.2)	0	1 (<0.1)
毛髪成長異常	1 (0.2)	1 (0.2)	2 (0.2)
多汗症	3 (0.6)	1 (0.2)	4 (0.4)
過角化	3 (0.6)	1 (0.2)	4 (0.4)
多毛症	1 (0.2)	1 (0.2)	2 (0.2)
特発性蕁麻疹	0	1 (0.2)	1 (<0.1)
嵌入爪	0	2 (0.4)	2 (0.2)
間擦疹	0	1 (0.2)	1 (<0.1)
苔癬化	0	1 (0.2)	1 (<0.1)
網状皮斑	0	1 (0.2)	1 (<0.1)
稗粒腫	0	1 (0.2)	1 (<0.1)
汗疹	5 (1.0)	2 (0.4)	7 (0.7)
神経皮膚炎	0	1 (0.2)	1 (<0.1)
寝汗	1 (0.2)	1 (0.2)	2 (0.2)
爪破損	0	1 (0.2)	1 (<0.1)
皮膚疼痛	1 (0.2)	0	1 (<0.1)
丘疹	0	1 (0.2)	1 (<0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)			
丘疹膿疱性酒さ	0	1 (0.2)	1 (<0.1)
口囲皮膚炎	2 (0.4)	3 (0.6)	5 (0.5)
光線過敏性反応	0	2 (0.4)	2 (0.2)
白色粃糠疹	1 (0.2)	0	1 (<0.1)
進行性黄斑メラニン減少症	1 (0.2)	0	1 (<0.1)
そう痒症	7 (1.4)	1 (0.2)	8 (0.8)
偽毛包炎	1 (0.2)	0	1 (<0.1)
紫斑	3 (0.6)	0	3 (0.3)
発疹	2 (0.4)	4 (0.8)	6 (0.6)
斑状丘疹状皮疹	0	1 (0.2)	1 (<0.1)
丘疹性皮疹	1 (0.2)	2 (0.4)	3 (0.3)
そう痒性皮疹	1 (0.2)	0	1 (<0.1)
小水疱性皮疹	1 (0.2)	1 (0.2)	2 (0.2)
酒さ	4 (0.8)	8 (1.5)	12 (1.1)
痂皮	0	3 (0.6)	3 (0.3)
脂漏	1 (0.2)	1 (0.2)	2 (0.2)
脂漏性皮膚炎	1 (0.2)	2 (0.4)	3 (0.3)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)			
敏感肌	1 (0.2)	0	1 (<0.1)
皮膚灼熱感	0	1 (0.2)	1 (<0.1)
皮膚変色	0	1 (0.2)	1 (<0.1)
皮膚障害	0	1 (0.2)	1 (<0.1)
皮膚剥脱	2 (0.4)	0	2 (0.2)
皮膚亀裂	1 (0.2)	5 (0.9)	6 (0.6)
皮膚刺激	2 (0.4)	1 (0.2)	3 (0.3)
皮膚腫瘤	3 (0.6)	2 (0.4)	5 (0.5)
皮膚線条	3 (0.6)	0	3 (0.3)
皮膚腫脹	0	1 (0.2)	1 (<0.1)
皮膚潰瘍	1 (0.2)	2 (0.4)	3 (0.3)
皮膚熱感	1 (0.2)	0	1 (<0.1)
日光黒子	1 (0.2)	0	1 (<0.1)
蕁麻疹	16 (3.1)	17 (3.2)	33 (3.2)
圧迫性蕁麻疹	0	1 (0.2)	1 (<0.1)
社会環境	1 (0.2)	0	1 (<0.1)
歯科補てつ物使用者	1 (0.2)	0	1 (<0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
外科および内科処置	1 (0.2)	4 (0.8)	5 (0.5)
人工流産	0	1 (0.2)	1 (<0.1)
子宮頚部円錐切除	1 (0.2)	0	1 (<0.1)
避妊用インプラント	0	1 (0.2)	1 (<0.1)
歯科手術	0	1 (0.2)	1 (<0.1)
ポリープ切除	0	1 (0.2)	1 (<0.1)
血管障害	13 (2.5)	14 (2.6)	27 (2.6)
大動脈瘤	0	1 (0.2)	1 (<0.1)
大動脈解離	0	1 (0.2)	1 (<0.1)
血腫	1 (0.2)	1 (0.2)	2 (0.2)
ほてり	0	1 (0.2)	1 (<0.1)
高血圧	10 (2.0)	9 (1.7)	19 (1.8)
起立性低血圧	1 (0.2)	0	1 (<0.1)
レイノー現象	0	1 (0.2)	1 (<0.1)
四肢静脈血栓症	1 (0.2)	0	1 (<0.1)

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Program Source Code: [redacted]

相互参照：M16-047 試験 CSR W52 Table 14.3__1.5.2.1

表 5. ウパダシチニブ投与期間中の有害事象の 100 人年あたりの発現率：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団，青少年）

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) (PYS=70.5) Events (E/100PY)	UPA 30 mg QD + TCS (N=54) (PYS=70.3) Events (E/100PY)	Total (N=112) (PYS=140.8) Events (E/100PY)
Any adverse event	229 (324.8)	218 (310.0)	447 (317.4)
血液およびリンパ系障害	6 (8.5)	7 (10.0)	13 (9.2)
貧血	3 (4.3)	0	3 (2.1)
好酸球増加症	0	1 (1.4)	1 (0.7)
白血球減少症	0	2 (2.8)	2 (1.4)
リンパ節症	2 (2.8)	1 (1.4)	3 (2.1)
大赤血球症	1 (1.4)	0	1 (0.7)
単球減少症	0	1 (1.4)	1 (0.7)
好中球減少症	0	2 (2.8)	2 (1.4)
耳および迷路障害	2 (2.8)	2 (2.8)	4 (2.8)
難聴	0	1 (1.4)	1 (0.7)
耳痛	2 (2.8)	0	2 (1.4)
耳鳴	0	1 (1.4)	1 (0.7)
内分泌障害	0	1 (1.4)	1 (0.7)
甲状腺機能正常症候群	0	1 (1.4)	1 (0.7)
眼障害	1 (1.4)	3 (4.3)	4 (2.8)
眼瞼炎	0	1 (1.4)	1 (0.7)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) (PYS=70.5) Events (E/100PY)	UPA 30 mg QD + TCS (N=54) (PYS=70.3) Events (E/100PY)	Total (N=112) (PYS=140.8) Events (E/100PY)
眼障害 (Cont.)			
霰粒腫	1 (1.4)	0	1 (0.7)
眼痛	0	1 (1.4)	1 (0.7)
春季カタル	0	1 (1.4)	1 (0.7)
胃腸障害	18 (25.5)	29 (41.2)	47 (33.4)
腹痛	2 (2.8)	6 (8.5)	8 (5.7)
上腹部痛	2 (2.8)	3 (4.3)	5 (3.6)
便秘	0	1 (1.4)	1 (0.7)
下痢	2 (2.8)	7 (10.0)	9 (6.4)
消化不良	2 (2.8)	1 (1.4)	3 (2.1)
変色便	1 (1.4)	0	1 (0.7)
胃食道逆流性疾患	0	2 (2.8)	2 (1.4)
腸閉塞	1 (1.4)	0	1 (0.7)
悪心	5 (7.1)	5 (7.1)	10 (7.1)
歯の障害	1 (1.4)	0	1 (0.7)
嘔吐	2 (2.8)	4 (5.7)	6 (4.3)
一般・全身障害および投与部位の状態	6 (8.5)	11 (15.6)	17 (12.1)
顔面痛	2 (2.8)	0	2 (1.4)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) (PYS=70.5) Events (E/100PY)	UPA 30 mg QD + TCS (N=54) (PYS=70.3) Events (E/100PY)	Total (N=112) (PYS=140.8) Events (E/100PY)
一般・全身障害および投与部位の状態 (Cont.)			
疲労	1 (1.4)	1 (1.4)	2 (1.4)
インフルエンザ様疾患	1 (1.4)	5 (7.1)	6 (4.3)
発熱	1 (1.4)	4 (5.7)	5 (3.6)
腫脹	1 (1.4)	0	1 (0.7)
顔面腫脹	0	1 (1.4)	1 (0.7)
肝胆道系障害	2 (2.8)	0	2 (1.4)
肝機能異常	2 (2.8)	0	2 (1.4)
免疫系障害	2 (2.8)	2 (2.8)	4 (2.8)
食物アレルギー	1 (1.4)	1 (1.4)	2 (1.4)
過敏症	1 (1.4)	1 (1.4)	2 (1.4)
感染症および寄生虫症	74 (105.0)	70 (99.5)	144 (102.3)
膿疱性ざ瘡	1 (1.4)	2 (2.8)	3 (2.1)
細菌性疾患キャリアー	1 (1.4)	0	1 (0.7)
細菌感染	1 (1.4)	1 (1.4)	2 (1.4)
バルトネラ症	1 (1.4)	0	1 (0.7)
気管支炎	1 (1.4)	0	1 (0.7)
結膜炎	2 (2.8)	2 (2.8)	4 (2.8)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) (PYS=70.5) Events (E/100PY)	UPA 30 mg QD + TCS (N=54) (PYS=70.3) Events (E/100PY)	Total (N=112) (PYS=140.8) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
コロナウイルス感染	2 (2.8)	1 (1.4)	3 (2.1)
赤痢	1 (1.4)	0	1 (0.7)
耳感染	2 (2.8)	0	2 (1.4)
感染性湿疹	0	1 (1.4)	1 (0.7)
エンテロバクター感染	1 (1.4)	0	1 (0.7)
毛包炎	3 (4.3)	2 (2.8)	5 (3.6)
真菌感染	1 (1.4)	0	1 (0.7)
せつ	2 (2.8)	1 (1.4)	3 (2.1)
胃腸炎	1 (1.4)	1 (1.4)	2 (1.4)
ウイルス性胃腸炎	0	1 (1.4)	1 (0.7)
単純ヘルペス	7 (9.9)	2 (2.8)	9 (6.4)
帯状疱疹	0	2 (2.8)	2 (1.4)
膿痂疹	5 (7.1)	2 (2.8)	7 (5.0)
インフルエンザ	1 (1.4)	2 (2.8)	3 (2.1)
シラミ寄生	0	1 (1.4)	1 (0.7)
伝染性軟属腫	1 (1.4)	2 (2.8)	3 (2.1)
鼻ヘルペス	1 (1.4)	0	1 (0.7)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

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感染症および寄生虫症 (Cont.)			
上咽頭炎	15 (21.3)	7 (10.0)	22 (15.6)
爪真菌症	1 (1.4)	0	1 (0.7)
眼部単純ヘルペス	1 (1.4)	0	1 (0.7)
口腔ヘルペス	1 (1.4)	1 (1.4)	2 (1.4)
爪囲炎	1 (1.4)	0	1 (0.7)
咽頭炎	3 (4.3)	4 (5.7)	7 (5.0)
レンサ球菌性咽頭炎	0	2 (2.8)	2 (1.4)
肺炎	0	1 (1.4)	1 (0.7)
ウイルス性気道感染	1 (1.4)	0	1 (0.7)
副鼻腔炎	0	1 (1.4)	1 (0.7)
皮膚感染	3 (4.3)	1 (1.4)	4 (2.8)
ブドウ球菌性膿瘍	1 (1.4)	0	1 (0.7)
ブドウ球菌性膿痂疹	1 (1.4)	0	1 (0.7)
ブドウ球菌感染	2 (2.8)	0	2 (1.4)
ブドウ球菌皮膚感染	1 (1.4)	5 (7.1)	6 (4.3)
白癬感染	0	1 (1.4)	1 (0.7)
足部白癬	1 (1.4)	0	1 (0.7)

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E/100PY = Events per 100 patient-years.

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感染症および寄生虫症 (Cont.)			
癜風	0	1 (1.4)	1 (0.7)
扁桃炎	0	2 (2.8)	2 (1.4)
上気道感染	4 (5.7)	14 (19.9)	18 (12.8)
尿路感染	1 (1.4)	3 (4.3)	4 (2.8)
ウイルス性咽頭炎	1 (1.4)	0	1 (0.7)
ウイルス性上気道感染	0	4 (5.7)	4 (2.8)
外陰部腟カンジダ症	1 (1.4)	0	1 (0.7)
傷害、中毒および処置合併症	6 (8.5)	8 (11.4)	14 (9.9)
事故	0	2 (2.8)	2 (1.4)
挫傷	1 (1.4)	0	1 (0.7)
足骨折	0	1 (1.4)	1 (0.7)
損傷	0	1 (1.4)	1 (0.7)
靭帯断裂	0	1 (1.4)	1 (0.7)
四肢損傷	1 (1.4)	0	1 (0.7)
橈骨骨折	0	1 (1.4)	1 (0.7)
交通事故	0	1 (1.4)	1 (0.7)
瘢痕	1 (1.4)	0	1 (0.7)

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傷害、中毒および処置合併症 (Cont.)			
スポーツ損傷	1 (1.4)	0	1 (0.7)
サンバーン	1 (1.4)	1 (1.4)	2 (1.4)
熱傷	1 (1.4)	0	1 (0.7)
臨床検査	27 (38.3)	24 (34.1)	51 (36.2)
アラニンアミノトランスフェラーゼ増加	2 (2.8)	0	2 (1.4)
アスパラギン酸アミノトランスフェラーゼ増加	2 (2.8)	0	2 (1.4)
血中アルカリホスファターゼ増加	1 (1.4)	0	1 (0.7)
血中コレステロール増加	1 (1.4)	0	1 (0.7)
血中クレアチンホスホキナーゼ増加	4 (5.7)	8 (11.4)	12 (8.5)
血中クレアチニン増加	0	1 (1.4)	1 (0.7)
血中葉酸減少	1 (1.4)	0	1 (0.7)
血中トリグリセリド増加	1 (1.4)	1 (1.4)	2 (1.4)
血中尿酸増加	3 (4.3)	0	3 (2.1)
心電図 QT 間隔異常	1 (1.4)	0	1 (0.7)
好酸球数増加	1 (1.4)	0	1 (0.7)
好酸球百分率増加	1 (1.4)	0	1 (0.7)
ヘモグロビン減少	0	1 (1.4)	1 (0.7)

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臨床検査 (Cont.)			
平均赤血球容積増加	1 (1.4)	0	1 (0.7)
結核菌群検査陽性	1 (1.4)	0	1 (0.7)
好中球数減少	2 (2.8)	5 (7.1)	7 (5.0)
好中球百分率減少	1 (1.4)	0	1 (0.7)
尿中蛋白陽性	1 (1.4)	0	1 (0.7)
ブドウ球菌検査陽性	1 (1.4)	0	1 (0.7)
体重増加	0	5 (7.1)	5 (3.6)
白血球数減少	1 (1.4)	2 (2.8)	3 (2.1)
尿中白血球陽性	1 (1.4)	1 (1.4)	2 (1.4)
代謝および栄養障害	7 (9.9)	1 (1.4)	8 (5.7)
食欲減退	2 (2.8)	0	2 (1.4)
食物不耐性	1 (1.4)	0	1 (0.7)
高コレステロール血症	1 (1.4)	0	1 (0.7)
高トリグリセリド血症	2 (2.8)	0	2 (1.4)
鉄欠乏	0	1 (1.4)	1 (0.7)
肥満	1 (1.4)	0	1 (0.7)

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筋骨格系および結合組織障害	2 (2.8)	3 (4.3)	5 (3.6)
背部痛	0	1 (1.4)	1 (0.7)
筋骨格系胸痛	0	1 (1.4)	1 (0.7)
頚部痛	1 (1.4)	0	1 (0.7)
四肢痛	0	1 (1.4)	1 (0.7)
顎関節症候群	1 (1.4)	0	1 (0.7)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2 (2.8)	0	2 (1.4)
異形成母斑	1 (1.4)	0	1 (0.7)
皮膚乳頭腫	1 (1.4)	0	1 (0.7)
神経系障害	8 (11.3)	9 (12.8)	17 (12.1)
浮動性めまい	1 (1.4)	1 (1.4)	2 (1.4)
頭痛	7 (9.9)	5 (7.1)	12 (8.5)
片頭痛	0	2 (2.8)	2 (1.4)
失神寸前の状態	0	1 (1.4)	1 (0.7)
精神障害	3 (4.3)	3 (4.3)	6 (4.3)
不安	1 (1.4)	0	1 (0.7)
注意欠陥多動性障害	0	1 (1.4)	1 (0.7)
抑うつ気分	0	1 (1.4)	1 (0.7)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) (PYS=70.5) Events (E/100PY)	UPA 30 mg QD + TCS (N=54) (PYS=70.3) Events (E/100PY)	Total (N=112) (PYS=140.8) Events (E/100PY)
精神障害 (Cont.)			
うつ病	1 (1.4)	1 (1.4)	2 (1.4)
悪夢	1 (1.4)	0	1 (0.7)
腎および尿路障害	1 (1.4)	0	1 (0.7)
蛋白尿	1 (1.4)	0	1 (0.7)
呼吸器、胸郭および縦隔障害	22 (31.2)	14 (19.9)	36 (25.6)
アレルギー性気管支炎	1 (1.4)	0	1 (0.7)
喘息	3 (4.3)	2 (2.8)	5 (3.6)
カタル	4 (5.7)	5 (7.1)	9 (6.4)
咳嗽	5 (7.1)	2 (2.8)	7 (5.0)
呼吸困難	1 (1.4)	0	1 (0.7)
鼻出血	1 (1.4)	0	1 (0.7)
しゃっくり	0	1 (1.4)	1 (0.7)
口腔咽頭痛	3 (4.3)	1 (1.4)	4 (2.8)
アレルギー性鼻炎	0	1 (1.4)	1 (0.7)
鼻漏	3 (4.3)	2 (2.8)	5 (3.6)
副鼻腔うっ血	1 (1.4)	0	1 (0.7)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) (PYS=70.5) Events (E/100PY)	UPA 30 mg QD + TCS (N=54) (PYS=70.3) Events (E/100PY)	Total (N=112) (PYS=140.8) Events (E/100PY)
皮膚および皮下組織障害	40 (56.7)	30 (42.7)	70 (49.7)
ざ瘡	12 (17.0)	15 (21.3)	27 (19.2)
脱毛症	1 (1.4)	0	1 (0.7)
皮膚炎	1 (1.4)	1 (1.4)	2 (1.4)
ざ瘡様皮膚炎	1 (1.4)	1 (1.4)	2 (1.4)
アトピー性皮膚炎	9 (12.8)	4 (5.7)	13 (9.2)
接触皮膚炎	1 (1.4)	1 (1.4)	2 (1.4)
乾癬様皮膚炎	1 (1.4)	0	1 (0.7)
異汗性湿疹	3 (4.3)	0	3 (2.1)
湿疹	1 (1.4)	0	1 (0.7)
紅斑	1 (1.4)	1 (1.4)	2 (1.4)
過角化	1 (1.4)	0	1 (0.7)
間擦疹	0	1 (1.4)	1 (0.7)
丘疹	0	1 (1.4)	1 (0.7)
白色粃糠疹	1 (1.4)	0	1 (0.7)
そう痒症	3 (4.3)	1 (1.4)	4 (2.8)
発疹	0	1 (1.4)	1 (0.7)
丘疹性皮疹	1 (1.4)	0	1 (0.7)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=58) (PYS=70.5) Events (E/100PY)	UPA 30 mg QD + TCS (N=54) (PYS=70.3) Events (E/100PY)	Total (N=112) (PYS=140.8) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)			
皮膚変色	0	1 (1.4)	1 (0.7)
皮膚剥脱	1 (1.4)	0	1 (0.7)
皮膚線条	1 (1.4)	0	1 (0.7)
蕁麻疹	1 (1.4)	2 (2.8)	3 (2.1)
血管障害	0	1 (1.4)	1 (0.7)
高血圧	0	1 (1.4)	1 (0.7)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

相互参照：M16-047 試験 CSR W52 Table 14.3__1.5.2.2

表 6. ウパダシチニブ投与期間中の有害事象の 100 人年あたりの発現率：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団, 成人）

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
Any adverse event	1501 (340.0)	1630 (352.2)	3131 (346.3)
*** Not coded ***	1 (0.2)	0	1 (0.1)
*** Not coded ***	1 (0.2)	0	1 (0.1)
血液およびリンパ系障害	11 (2.5)	26 (5.6)	37 (4.1)
貧血	2 (0.5)	5 (1.1)	7 (0.8)
大球性貧血	0	1 (0.2)	1 (0.1)
皮膚病性リンパ節症	1 (0.2)	0	1 (0.1)
好酸球増加症	1 (0.2)	0	1 (0.1)
赤血球減少症	0	1 (0.2)	1 (0.1)
内出血発生の増加傾向	0	2 (0.4)	2 (0.2)
鉄欠乏性貧血	0	1 (0.2)	1 (0.1)
白血球増加症	2 (0.5)	0	2 (0.2)
白血球減少症	0	2 (0.4)	2 (0.2)
リンパ節石灰化	1 (0.2)	0	1 (0.1)
リンパ節症	2 (0.5)	2 (0.4)	4 (0.4)
リンパ球増加症	0	1 (0.2)	1 (0.1)
リンパ組織過形成	0	1 (0.2)	1 (0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
血液およびリンパ系障害 (Cont.)			
リンパ球減少症	1 (0.2)	1 (0.2)	2 (0.2)
好中球減少症	1 (0.2)	6 (1.3)	7 (0.8)
汎血球減少症	0	1 (0.2)	1 (0.1)
血小板減少症	0	1 (0.2)	1 (0.1)
血小板増加症	0	1 (0.2)	1 (0.1)
心臓障害	7 (1.6)	11 (2.4)	18 (2.0)
急性冠動脈症候群	0	1 (0.2)	1 (0.1)
心房細動	0	1 (0.2)	1 (0.1)
第一度房室ブロック	1 (0.2)	0	1 (0.1)
徐脈	0	1 (0.2)	1 (0.1)
うっ血性心不全	0	1 (0.2)	1 (0.1)
左室肥大	1 (0.2)	0	1 (0.1)
僧帽弁閉鎖不全症	0	1 (0.2)	1 (0.1)
動悸	1 (0.2)	4 (0.9)	5 (0.6)
洞性徐脈	2 (0.5)	1 (0.2)	3 (0.3)
頻脈	2 (0.5)	0	2 (0.2)
心室性頻脈	0	1 (0.2)	1 (0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
先天性、家族性および遺伝性障害	3 (0.7)	2 (0.4)	5 (0.6)
先天性メラノサイト性母斑	0	1 (0.2)	1 (0.1)
表皮母斑	1 (0.2)	0	1 (0.1)
ジルベール症候群	0	1 (0.2)	1 (0.1)
色素性網膜炎	1 (0.2)	0	1 (0.1)
2a 型高脂血症	1 (0.2)	0	1 (0.1)
耳および迷路障害	7 (1.6)	6 (1.3)	13 (1.4)
耳の障害	1 (0.2)	0	1 (0.1)
耳痛	2 (0.5)	2 (0.4)	4 (0.4)
耳垢分泌過多	1 (0.2)	0	1 (0.1)
聴力低下	0	1 (0.2)	1 (0.1)
耳鳴	0	1 (0.2)	1 (0.1)
回転性めまい	2 (0.5)	2 (0.4)	4 (0.4)
頭位性回転性めまい	1 (0.2)	0	1 (0.1)
内分泌障害	2 (0.5)	2 (0.4)	4 (0.4)
甲状腺機能低下症	1 (0.2)	1 (0.2)	2 (0.2)
甲状腺腫瘤	1 (0.2)	1 (0.2)	2 (0.2)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
眼障害	28 (6.3)	35 (7.6)	63 (7.0)
眼瞼炎	4 (0.9)	3 (0.6)	7 (0.8)
白内障	0	4 (0.9)	4 (0.4)
霰粒腫	0	3 (0.6)	3 (0.3)
結膜沈着物	0	1 (0.2)	1 (0.1)
結膜充血	0	1 (0.2)	1 (0.1)
結膜刺激	0	1 (0.2)	1 (0.1)
アレルギー性結膜炎	2 (0.5)	3 (0.6)	5 (0.6)
角膜浮腫	1 (0.2)	0	1 (0.1)
ドライアイ	3 (0.7)	2 (0.4)	5 (0.6)
眼瞼紅斑	1 (0.2)	0	1 (0.1)
眼刺激	1 (0.2)	0	1 (0.1)
眼痛	1 (0.2)	0	1 (0.1)
眼の異常感覚	0	1 (0.2)	1 (0.1)
眼そう痒症	0	1 (0.2)	1 (0.1)
眼部腫脹	0	2 (0.4)	2 (0.2)
眼瞼障害	0	1 (0.2)	1 (0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
眼障害 (Cont.)			
緑内障	1 (0.2)	0	1 (0.1)
流涙増加	4 (0.9)	0	4 (0.4)
黄斑症	0	1 (0.2)	1 (0.1)
近視	0	1 (0.2)	1 (0.1)
視神経乳頭浮腫	0	1 (0.2)	1 (0.1)
眼窩周囲浮腫	1 (0.2)	0	1 (0.1)
羞明	0	1 (0.2)	1 (0.1)
屈折障害	1 (0.2)	0	1 (0.1)
網膜剥離	1 (0.2)	1 (0.2)	2 (0.2)
裂孔原性網膜剥離	0	2 (0.4)	2 (0.2)
眼瞼腫脹	2 (0.5)	1 (0.2)	3 (0.3)
潰瘍性角膜炎	1 (0.2)	1 (0.2)	2 (0.2)
霧視	3 (0.7)	1 (0.2)	4 (0.4)
視力低下	0	1 (0.2)	1 (0.1)
硝子体剥離	0	1 (0.2)	1 (0.1)
眼球乾燥症	1 (0.2)	0	1 (0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
胃腸障害	121 (27.4)	129 (27.9)	250 (27.6)
腹部不快感	3 (0.7)	2 (0.4)	5 (0.6)
腹部膨満	2 (0.5)	2 (0.4)	4 (0.4)
腹痛	14 (3.2)	9 (1.9)	23 (2.5)
下腹部痛	1 (0.2)	0	1 (0.1)
上腹部痛	16 (3.6)	3 (0.6)	19 (2.1)
腹部圧痛	0	1 (0.2)	1 (0.1)
肛門そう痒症	1 (0.2)	0	1 (0.1)
口角口唇炎	0	2 (0.4)	2 (0.2)
肛門直腸不快感	0	1 (0.2)	1 (0.1)
アフタ性潰瘍	2 (0.5)	2 (0.4)	4 (0.4)
便習慣変化	0	2 (0.4)	2 (0.2)
口唇のひび割れ	1 (0.2)	0	1 (0.1)
慢性胃炎	2 (0.5)	0	2 (0.2)
便秘	7 (1.6)	7 (1.5)	14 (1.5)
齲歯	5 (1.1)	6 (1.3)	11 (1.2)
下痢	15 (3.4)	29 (6.3)	44 (4.9)
口内乾燥	0	2 (0.4)	2 (0.2)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
胃腸障害 (Cont.)			
出血性十二指腸潰瘍	1 (0.2)	0	1 (0.1)
消化不良	8 (1.8)	4 (0.9)	12 (1.3)
嚥下障害	0	2 (0.4)	2 (0.2)
白色便	1 (0.2)	0	1 (0.1)
鼓腸	2 (0.5)	1 (0.2)	3 (0.3)
食中毒	0	1 (0.2)	1 (0.1)
排便回数増加	0	1 (0.2)	1 (0.1)
胃炎	2 (0.5)	3 (0.6)	5 (0.6)
胃腸障害	1 (0.2)	0	1 (0.1)
胃腸粘膜障害	1 (0.2)	0	1 (0.1)
胃食道逆流性疾患	3 (0.7)	8 (1.7)	11 (1.2)
舌炎	1 (0.2)	0	1 (0.1)
舌痛	0	1 (0.2)	1 (0.1)
痔核	1 (0.2)	1 (0.2)	2 (0.2)
裂孔ヘルニア	0	1 (0.2)	1 (0.1)
胃酸過多	0	1 (0.2)	1 (0.1)
過敏性腸症候群	0	2 (0.4)	2 (0.2)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
胃腸障害 (Cont.)			
口唇水疱	1 (0.2)	0	1 (0.1)
口腔内出血	0	1 (0.2)	1 (0.1)
口腔内潰瘍形成	2 (0.5)	1 (0.2)	3 (0.3)
悪心	12 (2.7)	13 (2.8)	25 (2.8)
嚥下痛	2 (0.5)	0	2 (0.2)
口腔瘻	1 (0.2)	0	1 (0.1)
口腔そう痒症	0	1 (0.2)	1 (0.1)
膵炎	2 (0.5)	0	2 (0.2)
歯周病	1 (0.2)	0	1 (0.1)
無髄歯	0	1 (0.2)	1 (0.1)
レッチング	0	1 (0.2)	1 (0.1)
口内炎	1 (0.2)	0	1 (0.1)
生歯	1 (0.2)	0	1 (0.1)
歯の障害	0	1 (0.2)	1 (0.1)
埋伏歯	2 (0.5)	3 (0.6)	5 (0.6)
歯痛	3 (0.7)	9 (1.9)	12 (1.3)
嘔吐	3 (0.7)	4 (0.9)	7 (0.8)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
一般・全身障害および投与部位の状態	74 (16.8)	64 (13.8)	138 (15.3)
胸部不快感	2 (0.5)	1 (0.2)	3 (0.3)
胸痛	5 (1.1)	4 (0.9)	9 (1.0)
悪寒	3 (0.7)	0	3 (0.3)
嚢胞	1 (0.2)	1 (0.2)	2 (0.2)
顔面浮腫	1 (0.2)	0	1 (0.1)
顔面痛	2 (0.5)	0	2 (0.2)
疲労	9 (2.0)	5 (1.1)	14 (1.5)
熱感	1 (0.2)	0	1 (0.1)
肉芽腫	0	1 (0.2)	1 (0.1)
ヘルニア	0	1 (0.2)	1 (0.1)
低体温	0	1 (0.2)	1 (0.1)
治癒不良	0	1 (0.2)	1 (0.1)
炎症	0	1 (0.2)	1 (0.1)
インフルエンザ様疾患	14 (3.2)	18 (3.9)	32 (3.5)
倦怠感	2 (0.5)	1 (0.2)	3 (0.3)
小結節	0	2 (0.4)	2 (0.2)

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E/100PY = Events per 100 patient-years.

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
一般・全身障害および投与部位の状態 (Cont.)			
非心臓性胸痛	0	1 (0.2)	1 (0.1)
末梢性浮腫	3 (0.7)	0	3 (0.3)
疼痛	5 (1.1)	2 (0.4)	7 (0.8)
末梢腫脹	1 (0.2)	1 (0.2)	2 (0.2)
発熱	20 (4.5)	18 (3.9)	38 (4.2)
腫脹	2 (0.5)	1 (0.2)	3 (0.3)
顔面腫脹	3 (0.7)	0	3 (0.3)
血管穿刺部位内出血	0	4 (0.9)	4 (0.4)
肝胆道系障害	8 (1.8)	7 (1.5)	15 (1.7)
肝機能異常	4 (0.9)	3 (0.6)	7 (0.8)
脂肪肝	3 (0.7)	1 (0.2)	4 (0.4)
肝細胞損傷	0	1 (0.2)	1 (0.1)
肝腫大	0	1 (0.2)	1 (0.1)
高ビリルビン血症	1 (0.2)	0	1 (0.1)
非アルコール性脂肪性肝炎	0	1 (0.2)	1 (0.1)
免疫系障害	7 (1.6)	12 (2.6)	19 (2.1)
アレルギー性浮腫	0	1 (0.2)	1 (0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
免疫系障害 (Cont.)			
動物アレルギー	0	1 (0.2)	1 (0.1)
アナフィラキシー反応	0	1 (0.2)	1 (0.1)
薬物過敏症	1 (0.2)	0	1 (0.1)
食物アレルギー	0	2 (0.4)	2 (0.2)
過敏症	2 (0.5)	3 (0.6)	5 (0.6)
季節性アレルギー	4 (0.9)	3 (0.6)	7 (0.8)
血清病	0	1 (0.2)	1 (0.1)
感染症および寄生虫症	564 (127.8)	576 (124.5)	1140 (126.1)
四肢膿瘍	0	1 (0.2)	1 (0.1)
口腔膿瘍	0	1 (0.2)	1 (0.1)
ダニ皮膚炎	1 (0.2)	1 (0.2)	2 (0.2)
急性副鼻腔炎	1 (0.2)	0	1 (0.1)
肛門膿瘍	1 (0.2)	0	1 (0.1)
虫垂炎	1 (0.2)	0	1 (0.1)
細菌感染	2 (0.5)	1 (0.2)	3 (0.3)
細菌性膣症	2 (0.5)	0	2 (0.2)
細菌尿	0	1 (0.2)	1 (0.1)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
体部白癬	2 (0.5)	6 (1.3)	8 (0.9)
気管支炎	9 (2.0)	15 (3.2)	24 (2.7)
ウイルス性気管支炎	0	1 (0.2)	1 (0.1)
水疱性膿痂疹	2 (0.5)	0	2 (0.2)
感染性滑液包炎	0	1 (0.2)	1 (0.1)
カンジダ感染	0	1 (0.2)	1 (0.1)
蜂巣炎	3 (0.7)	5 (1.1)	8 (0.9)
条虫感染	1 (0.2)	0	1 (0.1)
クラミジア感染	0	1 (0.2)	1 (0.1)
慢性副鼻腔炎	1 (0.2)	0	1 (0.1)
結膜炎	11 (2.5)	8 (1.7)	19 (2.1)
細菌性結膜炎	2 (0.5)	1 (0.2)	3 (0.3)
ウイルス性結膜炎	1 (0.2)	1 (0.2)	2 (0.2)
コロナウイルス感染	8 (1.8)	10 (2.2)	18 (2.0)
膀胱炎	6 (1.4)	2 (0.4)	8 (0.9)
涙嚢炎	1 (0.2)	0	1 (0.1)
医療機器関連感染	2 (0.5)	0	2 (0.2)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
感染性下痢	0	1 (0.2)	1 (0.1)
耳感染	1 (0.2)	1 (0.2)	2 (0.2)
ブドウ球菌性耳感染	0	1 (0.2)	1 (0.1)
ヘルペス性状湿疹	6 (1.4)	12 (2.6)	18 (2.0)
膿痂疹性湿疹	3 (0.7)	2 (0.4)	5 (0.6)
蟯虫症	1 (0.2)	0	1 (0.1)
丹毒	1 (0.2)	0	1 (0.1)
眼感染	1 (0.2)	0	1 (0.1)
ブドウ球菌性眼感染	1 (0.2)	1 (0.2)	2 (0.2)
ウイルス性眼感染	1 (0.2)	0	1 (0.1)
眼瞼感染	2 (0.5)	0	2 (0.2)
糸状虫症	0	1 (0.2)	1 (0.1)
毛包炎	19 (4.3)	21 (4.5)	40 (4.4)
真菌感染	2 (0.5)	0	2 (0.2)
皮膚真菌感染	4 (0.9)	5 (1.1)	9 (1.0)
せつ	2 (0.5)	8 (1.7)	10 (1.1)
ウイルス性胃炎	1 (0.2)	0	1 (0.1)

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感染症および寄生虫症 (Cont.)			
胃腸炎	12 (2.7)	15 (3.2)	27 (3.0)
ウイルス性胃腸炎	0	5 (1.1)	5 (0.6)
消化管感染	1 (0.2)	0	1 (0.1)
陰部ヘルペス	0	3 (0.6)	3 (0.3)
陰部単純ヘルペス	0	3 (0.6)	3 (0.3)
ジアルジア症	1 (0.2)	0	1 (0.1)
歯肉炎	1 (0.2)	1 (0.2)	2 (0.2)
ヘルペス眼感染	1 (0.2)	3 (0.6)	4 (0.4)
単純ヘルペス	35 (7.9)	29 (6.3)	64 (7.1)
帯状疱疹	18 (4.1)	26 (5.6)	44 (4.9)
皮膚播種性帯状疱疹	1 (0.2)	0	1 (0.1)
播種性帯状疱疹	0	1 (0.2)	1 (0.1)
耳帯状疱疹	0	2 (0.4)	2 (0.2)
麦粒腫	6 (1.4)	5 (1.1)	11 (1.2)
膿痂疹	11 (2.5)	9 (1.9)	20 (2.2)
切開部位蜂巣炎	1 (0.2)	0	1 (0.1)
感染性嚢腫	1 (0.2)	0	1 (0.1)

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感染症および寄生虫症 (Cont.)			
感染性皮膚嚢腫	0	1 (0.2)	1 (0.1)
感染	1 (0.2)	1 (0.2)	2 (0.2)
寄生虫感染	1 (0.2)	0	1 (0.1)
インフルエンザ	15 (3.4)	9 (1.9)	24 (2.7)
関節膿瘍	0	1 (0.2)	1 (0.1)
カポジ水痘様発疹	1 (0.2)	6 (1.3)	7 (0.8)
ウイルス性角膜炎	1 (0.2)	0	1 (0.1)
腎感染	1 (0.2)	0	1 (0.1)
大腸感染	1 (0.2)	0	1 (0.1)
喉頭炎	1 (0.2)	0	1 (0.1)
潜伏結核	1 (0.2)	3 (0.6)	4 (0.4)
マラセチア感染	1 (0.2)	1 (0.2)	2 (0.2)
細菌性乳腺炎	1 (0.2)	0	1 (0.1)
ウイルス性髄膜炎	1 (0.2)	0	1 (0.1)
メタニューモウイルス感染	1 (0.2)	0	1 (0.1)
伝染性軟属腫	4 (0.9)	2 (0.4)	6 (0.7)
鼻ヘルペス	0	3 (0.6)	3 (0.3)

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感染症および寄生虫症 (Cont.)			
上咽頭炎	113 (25.6)	83 (17.9)	196 (21.7)
爪真菌症	1 (0.2)	3 (0.6)	4 (0.4)
眼部単純ヘルペス	8 (1.8)	11 (2.4)	19 (2.1)
眼帯状疱疹	0	1 (0.2)	1 (0.1)
口腔カンジダ症	1 (0.2)	3 (0.6)	4 (0.4)
口腔ヘルペス	41 (9.3)	65 (14.0)	106 (11.7)
外耳炎	4 (0.9)	4 (0.9)	8 (0.9)
中耳炎	3 (0.7)	2 (0.4)	5 (0.6)
急性中耳炎	1 (0.2)	1 (0.2)	2 (0.2)
爪囲炎	2 (0.5)	2 (0.4)	4 (0.4)
インプラント周囲炎	1 (0.2)	0	1 (0.1)
軟骨膜炎	1 (0.2)	0	1 (0.1)
歯周炎	1 (0.2)	0	1 (0.1)
眼窩周囲蜂巣炎	2 (0.5)	0	2 (0.2)
扁桃周囲膿瘍	1 (0.2)	0	1 (0.1)
咽頭炎	9 (2.0)	9 (1.9)	18 (2.0)
レンサ球菌性咽頭炎	2 (0.5)	0	2 (0.2)

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感染症および寄生虫症 (Cont.)			
肺炎	4 (0.9)	4 (0.9)	8 (0.9)
マイコプラズマ性肺炎	0	2 (0.4)	2 (0.2)
ウイルス感染後疲労症候群	0	1 (0.2)	1 (0.1)
術後創感染	0	2 (0.4)	2 (0.2)
歯髄炎	0	1 (0.2)	1 (0.1)
化膿性分泌物	1 (0.2)	0	1 (0.1)
膿疱	1 (0.2)	3 (0.6)	4 (0.4)
腎盂腎炎	1 (0.2)	1 (0.2)	2 (0.2)
膿疱性皮疹	0	2 (0.4)	2 (0.2)
気道感染	4 (0.9)	1 (0.2)	5 (0.6)
ウイルス性気道感染	1 (0.2)	1 (0.2)	2 (0.2)
鼻炎	4 (0.9)	1 (0.2)	5 (0.6)
鼻喉頭炎	0	1 (0.2)	1 (0.1)
ライノウイルス感染	0	1 (0.2)	1 (0.1)
副鼻腔炎	5 (1.1)	7 (1.5)	12 (1.3)
皮膚細菌感染	3 (0.7)	1 (0.2)	4 (0.4)
皮膚感染	6 (1.4)	4 (0.9)	10 (1.1)

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感染症および寄生虫症 (Cont.)			
膿性痰	1 (0.2)	0	1 (0.1)
ブドウ球菌感染	3 (0.7)	3 (0.6)	6 (0.7)
ブドウ球菌皮膚感染	4 (0.9)	5 (1.1)	9 (1.0)
細菌重複感染	0	1 (0.2)	1 (0.1)
真菌重複感染	1 (0.2)	0	1 (0.1)
股部白癬	0	3 (0.6)	3 (0.3)
白癬感染	1 (0.2)	1 (0.2)	2 (0.2)
足部白癬	6 (1.4)	10 (2.2)	16 (1.8)
癜風	1 (0.2)	3 (0.6)	4 (0.4)
扁桃炎	5 (1.1)	4 (0.9)	9 (1.0)
歯感染	5 (1.1)	5 (1.1)	10 (1.1)
気管炎	2 (0.5)	2 (0.4)	4 (0.4)
気管気管支炎	1 (0.2)	0	1 (0.1)
トリコモナス症	0	1 (0.2)	1 (0.1)
トリコフィトン感染症	1 (0.2)	0	1 (0.1)
上気道感染	54 (12.2)	44 (9.5)	98 (10.8)
ウレアプラズマ感染	1 (0.2)	0	1 (0.1)

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感染症および寄生虫症 (Cont.)			
尿道炎	1 (0.2)	0	1 (0.1)
尿路感染	18 (4.1)	20 (4.3)	38 (4.2)
細菌性尿路感染	0	1 (0.2)	1 (0.1)
腟感染	2 (0.5)	1 (0.2)	3 (0.3)
ウイルス感染	1 (0.2)	3 (0.6)	4 (0.4)
ウイルス性咽頭炎	1 (0.2)	2 (0.4)	3 (0.3)
ウイルス性上気道感染	8 (1.8)	8 (1.7)	16 (1.8)
外陰部腟カンジダ症	2 (0.5)	1 (0.2)	3 (0.3)
外陰腟真菌感染	1 (0.2)	2 (0.4)	3 (0.3)
トリコモナス外陰腟炎	1 (0.2)	0	1 (0.1)
傷害、中毒および処置合併症	46 (10.4)	55 (11.9)	101 (11.2)
事故	1 (0.2)	0	1 (0.1)
動物咬傷	1 (0.2)	0	1 (0.1)
足関節部骨折	0	1 (0.2)	1 (0.1)
節足動物咬傷	0	2 (0.4)	2 (0.2)
節足動物刺傷	2 (0.5)	0	2 (0.2)
骨挫傷	0	1 (0.2)	1 (0.1)

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傷害、中毒および処置合併症 (Cont.)			
軟骨損傷	1 (0.2)	1 (0.2)	2 (0.2)
胸部損傷	0	1 (0.2)	1 (0.1)
鎖骨骨折	0	1 (0.2)	1 (0.1)
挫傷	1 (0.2)	4 (0.9)	5 (0.6)
角膜擦過傷	0	1 (0.2)	1 (0.1)
頭蓋脳損傷	1 (0.2)	1 (0.2)	2 (0.2)
胸骨脱臼	0	1 (0.2)	1 (0.1)
上顆炎	0	1 (0.2)	1 (0.1)
眼挫傷	0	1 (0.2)	1 (0.1)
眼外傷	0	1 (0.2)	1 (0.1)
転倒	2 (0.5)	5 (1.1)	7 (0.8)
大腿骨骨折	0	1 (0.2)	1 (0.1)
足骨折	3 (0.7)	0	3 (0.3)
尾骨骨折	1 (0.2)	0	1 (0.1)
頭部損傷	1 (0.2)	0	1 (0.1)
熱疲労	0	1 (0.2)	1 (0.1)
上腕骨骨折	0	1 (0.2)	1 (0.1)

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傷害、中毒および処置合併症 (Cont.)			
腸骨骨折	1 (0.2)	0	1 (0.1)
損傷	3 (0.7)	0	3 (0.3)
関節脱臼	0	1 (0.2)	1 (0.1)
関節損傷	1 (0.2)	5 (1.1)	6 (0.7)
靱帯損傷	2 (0.5)	0	2 (0.2)
靱帯捻挫	1 (0.2)	1 (0.2)	2 (0.2)
四肢損傷	3 (0.7)	1 (0.2)	4 (0.4)
半月板損傷	1 (0.2)	0	1 (0.1)
筋損傷	0	1 (0.2)	1 (0.1)
肉離れ	3 (0.7)	5 (1.1)	8 (0.9)
開放骨折	0	1 (0.2)	1 (0.1)
処置による疼痛	1 (0.2)	2 (0.4)	3 (0.3)
橈骨骨折	0	2 (0.4)	2 (0.2)
肋骨骨折	3 (0.7)	1 (0.2)	4 (0.4)
交通事故	0	2 (0.4)	2 (0.2)
皮膚擦過傷	2 (0.5)	1 (0.2)	3 (0.3)
皮膚裂傷	3 (0.7)	1 (0.2)	4 (0.4)

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傷害、中毒および処置合併症 (Cont.)			
脊椎骨折	1 (0.2)	0	1 (0.1)
胸骨骨折	1 (0.2)	0	1 (0.1)
腱損傷	0	1 (0.2)	1 (0.1)
腱断裂	1 (0.2)	0	1 (0.1)
歯牙破折	3 (0.7)	2 (0.4)	5 (0.6)
外傷性血腫	1 (0.2)	0	1 (0.1)
上肢骨折	0	1 (0.2)	1 (0.1)
創傷	0	1 (0.2)	1 (0.1)
創部分泌	0	1 (0.2)	1 (0.1)
手首関節骨折	1 (0.2)	0	1 (0.1)
臨床検査	124 (28.1)	114 (24.6)	238 (26.3)
アラニンアミノトランスフェラーゼ増加	15 (3.4)	8 (1.7)	23 (2.5)
アスパラギン酸アミノトランスフェラーゼ異常	1 (0.2)	0	1 (0.1)
アスパラギン酸アミノトランスフェラーゼ増加	7 (1.6)	7 (1.5)	14 (1.5)
血中重炭酸塩減少	0	1 (0.2)	1 (0.1)
血中ビリルビン増加	2 (0.5)	1 (0.2)	3 (0.3)
血中コレステロール	1 (0.2)	0	1 (0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
臨床検査 (Cont.)			
血中コレステロール増加	3 (0.7)	3 (0.6)	6 (0.7)
血中クレアチンホスホキナーゼ増加	41 (9.3)	46 (9.9)	87 (9.6)
血中クレアチニン増加	1 (0.2)	1 (0.2)	2 (0.2)
血中ブドウ糖増加	1 (0.2)	1 (0.2)	2 (0.2)
血中免疫グロブリン E 増加	1 (0.2)	0	1 (0.1)
血中鉄減少	0	1 (0.2)	1 (0.1)
血中リン減少	1 (0.2)	0	1 (0.1)
血中カリウム減少	0	1 (0.2)	1 (0.1)
血圧上昇	5 (1.1)	2 (0.4)	7 (0.8)
血中遊離テストステロン減少	1 (0.2)	0	1 (0.1)
血中トリグリセリド増加	1 (0.2)	3 (0.6)	4 (0.4)
血中尿素増加	0	1 (0.2)	1 (0.1)
血中尿酸増加	1 (0.2)	0	1 (0.1)
尿中血陽性	0	1 (0.2)	1 (0.1)
体温上昇	0	1 (0.2)	1 (0.1)
好酸球数増加	2 (0.5)	1 (0.2)	3 (0.3)
便量増加	0	1 (0.2)	1 (0.1)

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臨床検査 (Cont.)			
真菌検査陽性	1 (0.2)	0	1 (0.1)
ヘモグロビン減少	1 (0.2)	5 (1.1)	6 (0.7)
ヘリコバクター検査陽性	1 (0.2)	0	1 (0.1)
肝酵素上昇	1 (0.2)	0	1 (0.1)
肝機能検査異常	1 (0.2)	1 (0.2)	2 (0.2)
低比重リポ蛋白増加	1 (0.2)	3 (0.6)	4 (0.4)
リンパ球数減少	1 (0.2)	0	1 (0.1)
リンパ球数増加	1 (0.2)	0	1 (0.1)
単球数増加	0	1 (0.2)	1 (0.1)
結核菌群検査陽性	1 (0.2)	0	1 (0.1)
好中球数減少	6 (1.4)	2 (0.4)	8 (0.9)
好中球数増加	1 (0.2)	0	1 (0.1)
好中球百分率増加	1 (0.2)	0	1 (0.1)
ポリオーマウイルス検査陽性	1 (0.2)	0	1 (0.1)
尿中蛋白陽性	4 (0.9)	1 (0.2)	5 (0.6)
赤血球数減少	1 (0.2)	1 (0.2)	2 (0.2)
ブドウ球菌検査陽性	3 (0.7)	0	3 (0.3)

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臨床検査 (Cont.)			
トランスアミナーゼ上昇	0	2 (0.4)	2 (0.2)
トロポニン増加	0	1 (0.2)	1 (0.1)
ビタミン B12 減少	1 (0.2)	0	1 (0.1)
ビタミン D 減少	0	1 (0.2)	1 (0.1)
体重減少	2 (0.5)	0	2 (0.2)
体重増加	9 (2.0)	11 (2.4)	20 (2.2)
白血球数減少	2 (0.5)	2 (0.4)	4 (0.4)
白血球数増加	0	1 (0.2)	1 (0.1)
尿中白血球陽性	0	2 (0.4)	2 (0.2)
代謝および栄養障害	23 (5.2)	37 (8.0)	60 (6.6)
脱水	0	2 (0.4)	2 (0.2)
糖尿病	0	2 (0.4)	2 (0.2)
脂質異常症	0	2 (0.4)	2 (0.2)
水分過負荷	0	1 (0.2)	1 (0.1)
耐糖能障害	1 (0.2)	0	1 (0.1)
グルテン過敏症	0	1 (0.2)	1 (0.1)
痛風	1 (0.2)	1 (0.2)	2 (0.2)

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代謝および栄養障害 (Cont.)			
高コレステロール血症	3 (0.7)	6 (1.3)	9 (1.0)
高血糖	3 (0.7)	2 (0.4)	5 (0.6)
高ホモシステイン血症	1 (0.2)	0	1 (0.1)
高カリウム血症	1 (0.2)	0	1 (0.1)
高脂血症	1 (0.2)	6 (1.3)	7 (0.8)
高ナトリウム血症	2 (0.5)	0	2 (0.2)
高トリグリセリド血症	0	5 (1.1)	5 (0.6)
高尿酸血症	6 (1.4)	3 (0.6)	9 (1.0)
低カリウム血症	0	1 (0.2)	1 (0.1)
低マグネシウム血症	1 (0.2)	0	1 (0.1)
低ナトリウム血症	1 (0.2)	1 (0.2)	2 (0.2)
食欲亢進	0	2 (0.4)	2 (0.2)
ビタミン B12 欠乏	1 (0.2)	0	1 (0.1)
ビタミン D 欠乏	1 (0.2)	2 (0.4)	3 (0.3)
筋骨格系および結合組織障害	51 (11.6)	81 (17.5)	132 (14.6)
関節痛	10 (2.3)	12 (2.6)	22 (2.4)
関節炎	2 (0.5)	4 (0.9)	6 (0.7)

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筋骨格系および結合組織障害 (Cont.)			
背部痛	9 (2.0)	11 (2.4)	20 (2.2)
骨痛	0	1 (0.2)	1 (0.1)
滑液包炎	2 (0.5)	5 (1.1)	7 (0.8)
尾骨痛	0	1 (0.2)	1 (0.1)
外骨腫	1 (0.2)	0	1 (0.1)
出血性関節症	0	1 (0.2)	1 (0.1)
椎間板突出	0	4 (0.9)	4 (0.4)
関節ロック	0	1 (0.2)	1 (0.1)
関節腫脹	0	1 (0.2)	1 (0.1)
四肢不快感	1 (0.2)	0	1 (0.1)
筋痙縮	2 (0.5)	7 (1.5)	9 (1.0)
筋攣縮	0	1 (0.2)	1 (0.1)
筋骨格系胸痛	2 (0.5)	2 (0.4)	4 (0.4)
筋骨格痛	1 (0.2)	3 (0.6)	4 (0.4)
筋骨格硬直	0	1 (0.2)	1 (0.1)
筋肉痛	7 (1.6)	4 (0.9)	11 (1.2)
頚部腫瘤	0	1 (0.2)	1 (0.1)

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筋骨格系および結合組織障害 (Cont.)			
頚部痛	4 (0.9)	2 (0.4)	6 (0.7)
骨減少症	0	1 (0.2)	1 (0.1)
骨粗鬆症	0	1 (0.2)	1 (0.1)
四肢痛	5 (1.1)	7 (1.5)	12 (1.3)
顎痛	0	1 (0.2)	1 (0.1)
膝蓋大腿関節痛症候群	1 (0.2)	0	1 (0.1)
足底筋膜炎	1 (0.2)	0	1 (0.1)
脊柱管狭窄症	0	1 (0.2)	1 (0.1)
脊椎すべり症	0	1 (0.2)	1 (0.1)
軟骨下脆弱性骨折	0	1 (0.2)	1 (0.1)
滑液嚢腫	0	1 (0.2)	1 (0.1)
顎関節症候群	0	2 (0.4)	2 (0.2)
腱炎	1 (0.2)	2 (0.4)	3 (0.3)
腱鞘炎	0	1 (0.2)	1 (0.1)
斜頚	2 (0.5)	0	2 (0.2)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	13 (2.9)	16 (3.5)	29 (3.2)
結腸腺癌	0	1 (0.2)	1 (0.1)

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良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） (Cont.)			
肛門性器疣贅	0	2 (0.4)	2 (0.2)
良性新生物	0	1 (0.2)	1 (0.1)
精巣の良性新生物	0	1 (0.2)	1 (0.1)
血管腫	1 (0.2)	1 (0.2)	2 (0.2)
ケラトアカントーマ	0	1 (0.2)	1 (0.1)
表皮内悪性黒色腫	0	1 (0.2)	1 (0.1)
メラノサイト性母斑	1 (0.2)	0	1 (0.1)
結節性筋膜炎	1 (0.2)	0	1 (0.1)
化膿性肉芽腫	0	1 (0.2)	1 (0.1)
脂漏性角化症	1 (0.2)	1 (0.2)	2 (0.2)
皮膚乳頭腫	7 (1.6)	5 (1.1)	12 (1.3)
口腔内扁平上皮癌	1 (0.2)	0	1 (0.1)
子宮平滑筋腫	1 (0.2)	1 (0.2)	2 (0.2)
神経系障害	59 (13.4)	64 (13.8)	123 (13.6)
手根管症候群	1 (0.2)	0	1 (0.1)
馬尾症候群	0	1 (0.2)	1 (0.1)
脳血管発作	0	1 (0.2)	1 (0.1)

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神経系障害 (Cont.)			
浮動性めまい	9 (2.0)	8 (1.7)	17 (1.9)
味覚不全	0	2 (0.4)	2 (0.2)
てんかん	0	1 (0.2)	1 (0.1)
労作性頭痛	1 (0.2)	0	1 (0.1)
全身性強直性間代性発作	0	1 (0.2)	1 (0.1)
頭部不快感	0	1 (0.2)	1 (0.1)
頭痛	28 (6.3)	30 (6.5)	58 (6.4)
過眠症	0	1 (0.2)	1 (0.1)
筋緊張亢進	0	1 (0.2)	1 (0.1)
感覚鈍麻	2 (0.5)	1 (0.2)	3 (0.3)
嗜眠	0	1 (0.2)	1 (0.1)
片頭痛	5 (1.1)	1 (0.2)	6 (0.7)
前兆を伴う片頭痛	1 (0.2)	0	1 (0.1)
多発性硬化症	0	1 (0.2)	1 (0.1)
多発性硬化症再発	0	1 (0.2)	1 (0.1)
神経圧迫	0	1 (0.2)	1 (0.1)
末梢性ニューロパチー	1 (0.2)	1 (0.2)	2 (0.2)

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神経系障害 (Cont.)			
錯感覚	3 (0.7)	1 (0.2)	4 (0.4)
嗅覚錯誤	0	1 (0.2)	1 (0.1)
末梢神経不全麻痺	2 (0.5)	0	2 (0.2)
ヘルペス後神経痛	2 (0.5)	1 (0.2)	3 (0.3)
失神寸前の状態	1 (0.2)	0	1 (0.1)
坐骨神経痛	1 (0.2)	2 (0.4)	3 (0.3)
傾眠	0	1 (0.2)	1 (0.1)
くも膜下出血	1 (0.2)	0	1 (0.1)
失神	0	1 (0.2)	1 (0.1)
足根管症候群	1 (0.2)	0	1 (0.1)
緊張性頭痛	0	1 (0.2)	1 (0.1)
三叉神経痛	0	1 (0.2)	1 (0.1)
トンネル状視野	0	1 (0.2)	1 (0.1)
妊娠、産褥および周産期の状態	0	1 (0.2)	1 (0.1)
自然流産	0	1 (0.2)	1 (0.1)
精神障害	27 (6.1)	30 (6.5)	57 (6.3)
感情不安定	3 (0.7)	0	3 (0.3)

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精神障害 (Cont.)			
アルコール使用障害	0	1 (0.2)	1 (0.1)
不安	5 (1.1)	4 (0.9)	9 (1.0)
注意欠陥多動性障害	1 (0.2)	1 (0.2)	2 (0.2)
双極性障害	0	1 (0.2)	1 (0.1)
抑うつ気分	4 (0.9)	2 (0.4)	6 (0.7)
うつ病	2 (0.5)	3 (0.6)	5 (0.6)
抑うつ症状	1 (0.2)	0	1 (0.1)
全般性不安障害	1 (0.2)	0	1 (0.1)
不眠症	4 (0.9)	6 (1.3)	10 (1.1)
易刺激性	1 (0.2)	0	1 (0.1)
リビドー減退	0	1 (0.2)	1 (0.1)
リビドー亢進	1 (0.2)	0	1 (0.1)
精神障害	0	3 (0.6)	3 (0.3)
混合性不安抑うつ障害	0	1 (0.2)	1 (0.1)
パニック発作	1 (0.2)	1 (0.2)	2 (0.2)
心的外傷後ストレス障害	0	1 (0.2)	1 (0.1)
睡眠障害	0	2 (0.4)	2 (0.2)

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精神障害 (Cont.)			
ストレス	2 (0.5)	2 (0.4)	4 (0.4)
自殺念慮	0	1 (0.2)	1 (0.1)
自殺企図	1 (0.2)	0	1 (0.1)
腎および尿路障害	14 (3.2)	17 (3.7)	31 (3.4)
急性腎障害	1 (0.2)	0	1 (0.1)
アルブミン尿	2 (0.5)	2 (0.4)	4 (0.4)
尿路結石	1 (0.2)	0	1 (0.1)
出血性膀胱炎	0	1 (0.2)	1 (0.1)
排尿困難	3 (0.7)	0	3 (0.3)
糖尿	1 (0.2)	0	1 (0.1)
血尿	2 (0.5)	5 (1.1)	7 (0.8)
水腎症	1 (0.2)	0	1 (0.1)
緊張性膀胱	0	1 (0.2)	1 (0.1)
腎結石症	1 (0.2)	2 (0.4)	3 (0.3)
夜間頻尿	1 (0.2)	0	1 (0.1)
頻尿	0	2 (0.4)	2 (0.2)
多尿	1 (0.2)	0	1 (0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
腎および尿路障害 (Cont.)			
蛋白尿	0	3 (0.6)	3 (0.3)
腎仙痛	0	1 (0.2)	1 (0.1)
生殖系および乳房障害	17 (3.9)	23 (5.0)	40 (4.4)
無月経	1 (0.2)	1 (0.2)	2 (0.2)
萎縮性外陰腟炎	0	1 (0.2)	1 (0.1)
乳房嚢胞	2 (0.5)	0	2 (0.2)
子宮頚部上皮異形成	2 (0.5)	2 (0.4)	4 (0.4)
月経困難症	1 (0.2)	0	1 (0.1)
子宮内膜症	0	2 (0.4)	2 (0.2)
勃起不全	1 (0.2)	3 (0.6)	4 (0.4)
女性化乳房	0	1 (0.2)	1 (0.1)
過少月経	1 (0.2)	0	1 (0.1)
月経過多	1 (0.2)	0	1 (0.1)
月経障害	1 (0.2)	0	1 (0.1)
不規則月経	1 (0.2)	2 (0.4)	3 (0.3)
不正子宮出血	0	1 (0.2)	1 (0.1)
骨盤痛	0	1 (0.2)	1 (0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
生殖系および乳房障害 (Cont.)			
多嚢胞性卵巣	0	1 (0.2)	1 (0.1)
前立腺炎	1 (0.2)	0	1 (0.1)
精巣障害	0	1 (0.2)	1 (0.1)
精巣腫瘤	0	2 (0.4)	2 (0.2)
精巣痛	1 (0.2)	3 (0.6)	4 (0.4)
腟分泌物	2 (0.5)	0	2 (0.2)
腟出血	1 (0.2)	1 (0.2)	2 (0.2)
女性外陰部潰瘍	0	1 (0.2)	1 (0.1)
外陰腟乾燥	1 (0.2)	0	1 (0.1)
呼吸器、胸郭および縦隔障害	75 (17.0)	78 (16.9)	153 (16.9)
急性呼吸窮迫症候群	0	1 (0.2)	1 (0.1)
失声症	2 (0.5)	0	2 (0.2)
喘息	9 (2.0)	9 (1.9)	18 (2.0)
無気肺	1 (0.2)	0	1 (0.1)
カタル	2 (0.5)	0	2 (0.2)
慢性閉塞性肺疾患	0	1 (0.2)	1 (0.1)
咳嗽	20 (4.5)	25 (5.4)	45 (5.0)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
呼吸器、胸郭および縦隔障害 (Cont.)			
呼吸困難	4 (0.9)	5 (1.1)	9 (1.0)
鼻出血	6 (1.4)	6 (1.3)	12 (1.3)
喀血	2 (0.5)	0	2 (0.2)
肺浸潤	1 (0.2)	0	1 (0.1)
縦隔血腫	1 (0.2)	0	1 (0.1)
鼻閉	1 (0.2)	1 (0.2)	2 (0.2)
鼻茸	1 (0.2)	0	1 (0.1)
鼻中隔彎曲	1 (0.2)	0	1 (0.1)
口腔咽頭痛	10 (2.3)	13 (2.8)	23 (2.5)
咽頭腫脹	0	1 (0.2)	1 (0.1)
胸水	1 (0.2)	0	1 (0.1)
胸膜痛	0	1 (0.2)	1 (0.1)
湿性咳嗽	2 (0.5)	0	2 (0.2)
肺塞栓症	1 (0.2)	0	1 (0.1)
肺肉芽腫	0	1 (0.2)	1 (0.1)
肺腫瘤	1 (0.2)	2 (0.4)	3 (0.3)
気道うっ血	0	2 (0.4)	2 (0.2)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
呼吸器、胸郭および縦隔障害 (Cont.)			
アレルギー性鼻炎	0	2 (0.4)	2 (0.2)
鼻漏	5 (1.1)	3 (0.6)	8 (0.9)
副鼻腔うっ血	0	2 (0.4)	2 (0.2)
睡眠時無呼吸症候群	1 (0.2)	0	1 (0.1)
くしゃみ	0	1 (0.2)	1 (0.1)
喘息発作重積	1 (0.2)	0	1 (0.1)
咽喉刺激感	0	1 (0.2)	1 (0.1)
上気道うっ血	1 (0.2)	0	1 (0.1)
喘鳴	1 (0.2)	1 (0.2)	2 (0.2)
皮膚および皮下組織障害	204 (46.2)	227 (49.0)	431 (47.7)
ざ瘡	56 (12.7)	85 (18.4)	141 (15.6)
嚢胞性ざ瘡	0	1 (0.2)	1 (0.1)
後天性ブラシュコ皮膚炎	1 (0.2)	0	1 (0.1)
光線角化症	0	2 (0.4)	2 (0.2)
脱毛症	1 (0.2)	1 (0.2)	2 (0.2)
血管浮腫	0	3 (0.6)	3 (0.3)
水疱	2 (0.5)	2 (0.4)	4 (0.4)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)			
冷汗	0	1 (0.2)	1 (0.1)
皮膚嚢腫	2 (0.5)	1 (0.2)	3 (0.3)
皮膚炎	5 (1.1)	1 (0.2)	6 (0.7)
ざ瘡様皮膚炎	4 (0.9)	3 (0.6)	7 (0.8)
アレルギー性皮膚炎	2 (0.5)	2 (0.4)	4 (0.4)
アトピー性皮膚炎	44 (10.0)	32 (6.9)	76 (8.4)
接触皮膚炎	7 (1.6)	7 (1.5)	14 (1.5)
疱疹状皮膚炎	0	1 (0.2)	1 (0.1)
薬疹	1 (0.2)	0	1 (0.1)
皮膚乾燥	0	1 (0.2)	1 (0.1)
異汗性湿疹	1 (0.2)	0	1 (0.1)
斑状出血	0	3 (0.6)	3 (0.3)
湿疹	12 (2.7)	8 (1.7)	20 (2.2)
小水疱性湿疹	0	1 (0.2)	1 (0.1)
紅斑	2 (0.5)	1 (0.2)	3 (0.3)
過剰肉芽組織	1 (0.2)	0	1 (0.1)
毛髪成長異常	1 (0.2)	1 (0.2)	2 (0.2)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)			
多汗症	3 (0.7)	1 (0.2)	4 (0.4)
過角化	2 (0.5)	1 (0.2)	3 (0.3)
多毛症	1 (0.2)	1 (0.2)	2 (0.2)
特発性蕁麻疹	0	1 (0.2)	1 (0.1)
嵌入爪	0	2 (0.4)	2 (0.2)
苔癬化	0	1 (0.2)	1 (0.1)
網状皮斑	0	1 (0.2)	1 (0.1)
稗粒腫	0	1 (0.2)	1 (0.1)
汗疹	5 (1.1)	2 (0.4)	7 (0.8)
神経皮膚炎	0	1 (0.2)	1 (0.1)
寝汗	1 (0.2)	1 (0.2)	2 (0.2)
爪破損	0	1 (0.2)	1 (0.1)
皮膚疼痛	1 (0.2)	0	1 (0.1)
丘疹膿疱性酒さ	0	1 (0.2)	1 (0.1)
口囲皮膚炎	2 (0.5)	3 (0.6)	5 (0.6)
光線過敏性反応	0	2 (0.4)	2 (0.2)
進行性黄斑メラニン減少症	1 (0.2)	0	1 (0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)			
そう痒症	4 (0.9)	0	4 (0.4)
偽毛包炎	1 (0.2)	0	1 (0.1)
紫斑	3 (0.7)	0	3 (0.3)
発疹	2 (0.5)	3 (0.6)	5 (0.6)
斑状丘疹状皮疹	0	1 (0.2)	1 (0.1)
丘疹性皮疹	0	2 (0.4)	2 (0.2)
そう痒性皮疹	1 (0.2)	0	1 (0.1)
小水疱性皮疹	1 (0.2)	1 (0.2)	2 (0.2)
酒さ	4 (0.9)	8 (1.7)	12 (1.3)
痂皮	0	3 (0.6)	3 (0.3)
脂漏	1 (0.2)	1 (0.2)	2 (0.2)
脂漏性皮膚炎	1 (0.2)	2 (0.4)	3 (0.3)
敏感肌	1 (0.2)	0	1 (0.1)
皮膚灼熱感	0	1 (0.2)	1 (0.1)
皮膚障害	0	1 (0.2)	1 (0.1)
皮膚剥脱	1 (0.2)	0	1 (0.1)
皮膚亀裂	1 (0.2)	5 (1.1)	6 (0.7)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)			
皮膚刺激	2 (0.5)	1 (0.2)	3 (0.3)
皮膚腫瘤	3 (0.7)	2 (0.4)	5 (0.6)
皮膚線条	2 (0.5)	0	2 (0.2)
皮膚腫脹	0	1 (0.2)	1 (0.1)
皮膚潰瘍	1 (0.2)	2 (0.4)	3 (0.3)
皮膚熱感	1 (0.2)	0	1 (0.1)
日光黒子	1 (0.2)	0	1 (0.1)
蕁麻疹	15 (3.4)	15 (3.2)	30 (3.3)
圧迫性蕁麻疹	0	1 (0.2)	1 (0.1)
社会環境	1 (0.2)	0	1 (0.1)
歯科補てつ物使用者	1 (0.2)	0	1 (0.1)
外科および内科処置	1 (0.2)	4 (0.9)	5 (0.6)
人工流産	0	1 (0.2)	1 (0.1)
子宮頚部円錐切除	1 (0.2)	0	1 (0.1)
避妊用インプラント	0	1 (0.2)	1 (0.1)
歯科手術	0	1 (0.2)	1 (0.1)
ポリープ切除	0	1 (0.2)	1 (0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=385) (PYS=441.4) Events (E/100PY)	UPA 30 mg QD + TCS (N=382) (PYS=462.8) Events (E/100PY)	Total (N=767) (PYS=904.2) Events (E/100PY)
血管障害	13 (2.9)	13 (2.8)	26 (2.9)
大動脈瘤	0	1 (0.2)	1 (0.1)
大動脈解離	0	1 (0.2)	1 (0.1)
血腫	1 (0.2)	1 (0.2)	2 (0.2)
ほてり	0	1 (0.2)	1 (0.1)
高血圧	10 (2.3)	8 (1.7)	18 (2.0)
起立性低血圧	1 (0.2)	0	1 (0.1)
レイノー現象	0	1 (0.2)	1 (0.1)
四肢静脈血栓症	1 (0.2)	0	1 (0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

相互参照：M16-047 試験 CSR W52 Table 14.3__1.5.2.3

表 7. ウパダシチニブ投与期間中に治験薬と関連ありの有害事象を発現した被験者数及び発現割合：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団）

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
Any adverse event	207 (46.7)	239 (54.8)	446 (50.7)
血液およびリンパ系障害	6 (1.4)	14 (3.2)	20 (2.3)
貧血	1 (0.2)	1 (0.2)	2 (0.2)
大球性貧血	0	1 (0.2)	1 (0.1)
赤血球減少症	0	1 (0.2)	1 (0.1)
内出血発生の増加傾向	0	2 (0.5)	2 (0.2)
白血球増加症	1 (0.2)	0	1 (0.1)
白血球減少症	0	3 (0.7)	3 (0.3)
リンパ節石灰化	1 (0.2)	0	1 (0.1)
リンパ節症	1 (0.2)	2 (0.5)	3 (0.3)
リンパ球減少症	0	1 (0.2)	1 (0.1)
大赤血球症	1 (0.2)	0	1 (0.1)
単球減少症	0	1 (0.2)	1 (0.1)
好中球減少症	1 (0.2)	4 (0.9)	5 (0.6)
血小板減少症	0	1 (0.2)	1 (0.1)
血小板増加症	0	1 (0.2)	1 (0.1)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
心臓障害	1 (0.2)	3 (0.7)	4 (0.5)
徐脈	0	1 (0.2)	1 (0.1)
動悸	0	2 (0.5)	2 (0.2)
洞性徐脈	1 (0.2)	0	1 (0.1)
先天性、家族性および遺伝性障害	1 (0.2)	0	1 (0.1)
表皮母斑	1 (0.2)	0	1 (0.1)
耳および迷路障害	0	2 (0.5)	2 (0.2)
難聴	0	1 (0.2)	1 (0.1)
耳鳴	0	2 (0.5)	2 (0.2)
眼障害	5 (1.1)	13 (3.0)	18 (2.0)
眼瞼炎	0	2 (0.5)	2 (0.2)
白内障	0	1 (0.2)	1 (0.1)
結膜沈着物	0	1 (0.2)	1 (0.1)
結膜充血	0	1 (0.2)	1 (0.1)
アレルギー性結膜炎	0	1 (0.2)	1 (0.1)
眼痛	1 (0.2)	0	1 (0.1)
眼の異常感覚	0	1 (0.2)	1 (0.1)
眼そう痒症	0	1 (0.2)	1 (0.1)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
眼障害 (Cont.)			
眼瞼障害	0	1 (0.2)	1 (0.1)
流涙増加	3 (0.7)	0	3 (0.3)
近視	0	1 (0.2)	1 (0.1)
視神経乳頭浮腫	0	1 (0.2)	1 (0.1)
羞明	0	1 (0.2)	1 (0.1)
網膜剥離	1 (0.2)	1 (0.2)	2 (0.2)
裂孔原性網膜剥離	0	1 (0.2)	1 (0.1)
眼瞼腫脹	0	1 (0.2)	1 (0.1)
潰瘍性角膜炎	0	1 (0.2)	1 (0.1)
硝子体剥離	0	1 (0.2)	1 (0.1)
眼球乾燥症	1 (0.2)	0	1 (0.1)
胃腸障害	27 (6.1)	33 (7.6)	60 (6.8)
腹部不快感	1 (0.2)	1 (0.2)	2 (0.2)
腹部膨満	1 (0.2)	1 (0.2)	2 (0.2)
腹痛	5 (1.1)	4 (0.9)	9 (1.0)
上腹部痛	7 (1.6)	1 (0.2)	8 (0.9)
口角口唇炎	0	1 (0.2)	1 (0.1)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
胃腸障害 (Cont.)			
肛門直腸不快感	0	1 (0.2)	1 (0.1)
アフタ性潰瘍	1 (0.2)	1 (0.2)	2 (0.2)
便習慣変化	0	1 (0.2)	1 (0.1)
便秘	3 (0.7)	2 (0.5)	5 (0.6)
下痢	7 (1.6)	9 (2.1)	16 (1.8)
口内乾燥	0	1 (0.2)	1 (0.1)
出血性十二指腸潰瘍	1 (0.2)	0	1 (0.1)
消化不良	2 (0.5)	3 (0.7)	5 (0.6)
嚥下障害	0	1 (0.2)	1 (0.1)
白色便	1 (0.2)	0	1 (0.1)
鼓腸	1 (0.2)	1 (0.2)	2 (0.2)
排便回数増加	0	1 (0.2)	1 (0.1)
胃炎	2 (0.5)	1 (0.2)	3 (0.3)
胃腸障害	1 (0.2)	0	1 (0.1)
胃食道逆流性疾患	0	3 (0.7)	3 (0.3)
舌炎	1 (0.2)	0	1 (0.1)
胃酸過多	0	1 (0.2)	1 (0.1)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
胃腸障害 (Cont.)			
過敏性腸症候群	0	1 (0.2)	1 (0.1)
口腔内出血	0	1 (0.2)	1 (0.1)
口腔内潰瘍形成	2 (0.5)	0	2 (0.2)
悪心	7 (1.6)	6 (1.4)	13 (1.5)
嘔吐	1 (0.2)	3 (0.7)	4 (0.5)
一般・全身障害および投与部位の状態	18 (4.1)	17 (3.9)	35 (4.0)
胸部不快感	1 (0.2)	0	1 (0.1)
顔面浮腫	1 (0.2)	0	1 (0.1)
顔面痛	1 (0.2)	0	1 (0.1)
疲労	7 (1.6)	5 (1.1)	12 (1.4)
インフルエンザ様疾患	5 (1.1)	5 (1.1)	10 (1.1)
倦怠感	1 (0.2)	1 (0.2)	2 (0.2)
小結節	0	1 (0.2)	1 (0.1)
疼痛	1 (0.2)	0	1 (0.1)
発熱	4 (0.9)	5 (1.1)	9 (1.0)
腫脹	2 (0.5)	0	2 (0.2)
顔面腫脹	2 (0.5)	0	2 (0.2)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
肝胆道系障害	2 (0.5)	3 (0.7)	5 (0.6)
肝機能異常	2 (0.5)	1 (0.2)	3 (0.3)
肝細胞損傷	0	1 (0.2)	1 (0.1)
肝腫大	0	1 (0.2)	1 (0.1)
感染症および寄生虫症	131 (29.6)	136 (31.2)	267 (30.4)
四肢膿瘍	0	1 (0.2)	1 (0.1)
虫垂炎	1 (0.2)	0	1 (0.1)
細菌感染	0	1 (0.2)	1 (0.1)
バルトネラ症	1 (0.2)	0	1 (0.1)
体部白癬	1 (0.2)	3 (0.7)	4 (0.5)
気管支炎	2 (0.5)	3 (0.7)	5 (0.6)
条虫感染	1 (0.2)	0	1 (0.1)
慢性副鼻腔炎	1 (0.2)	0	1 (0.1)
結膜炎	5 (1.1)	4 (0.9)	9 (1.0)
ウイルス性結膜炎	0	1 (0.2)	1 (0.1)
コロナウイルス感染	0	1 (0.2)	1 (0.1)
膀胱炎	1 (0.2)	0	1 (0.1)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
感染症および寄生虫症 (Cont.)			
医療機器関連感染	1 (0.2)	0	1 (0.1)
耳感染	1 (0.2)	0	1 (0.1)
ヘルペス性状湿疹	4 (0.9)	4 (0.9)	8 (0.9)
膿痂疹性湿疹	1 (0.2)	0	1 (0.1)
感染性湿疹	0	1 (0.2)	1 (0.1)
エンテロバクター感染	1 (0.2)	0	1 (0.1)
ブドウ球菌性眼感染	1 (0.2)	0	1 (0.1)
糸状虫症	0	1 (0.2)	1 (0.1)
毛包炎	8 (1.8)	13 (3.0)	21 (2.4)
せつ	3 (0.7)	4 (0.9)	7 (0.8)
ウイルス性胃炎	1 (0.2)	0	1 (0.1)
胃腸炎	2 (0.5)	4 (0.9)	6 (0.7)
陰部ヘルペス	0	2 (0.5)	2 (0.2)
陰部単純ヘルペス	0	1 (0.2)	1 (0.1)
歯肉炎	0	1 (0.2)	1 (0.1)
ヘルペス眼感染	1 (0.2)	3 (0.7)	4 (0.5)
単純ヘルペス	19 (4.3)	13 (3.0)	32 (3.6)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
感染症および寄生虫症 (Cont.)			
帯状疱疹	14 (3.2)	20 (4.6)	34 (3.9)
皮膚播種性帯状疱疹	1 (0.2)	0	1 (0.1)
播種性帯状疱疹	0	1 (0.2)	1 (0.1)
耳帯状疱疹	0	2 (0.5)	2 (0.2)
麦粒腫	0	1 (0.2)	1 (0.1)
膿痂疹	6 (1.4)	3 (0.7)	9 (1.0)
インフルエンザ	4 (0.9)	4 (0.9)	8 (0.9)
カポジ水痘様発疹	1 (0.2)	4 (0.9)	5 (0.6)
腎感染	1 (0.2)	0	1 (0.1)
大腸感染	1 (0.2)	0	1 (0.1)
喉頭炎	1 (0.2)	0	1 (0.1)
潜伏結核	0	2 (0.5)	2 (0.2)
マラセチア感染	1 (0.2)	1 (0.2)	2 (0.2)
伝染性軟属腫	1 (0.2)	3 (0.7)	4 (0.5)
鼻ヘルペス	0	2 (0.5)	2 (0.2)
上咽頭炎	29 (6.5)	23 (5.3)	52 (5.9)
爪真菌症	1 (0.2)	0	1 (0.1)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
感染症および寄生虫症 (Cont.)			
眼部単純ヘルペス	4 (0.9)	6 (1.4)	10 (1.1)
眼帯状疱疹	0	1 (0.2)	1 (0.1)
口腔カンジダ症	1 (0.2)	1 (0.2)	2 (0.2)
口腔ヘルペス	16 (3.6)	25 (5.7)	41 (4.7)
外耳炎	1 (0.2)	1 (0.2)	2 (0.2)
インプラント周囲炎	1 (0.2)	0	1 (0.1)
眼窩周囲蜂巣炎	1 (0.2)	0	1 (0.1)
咽頭炎	5 (1.1)	4 (0.9)	9 (1.0)
レンサ球菌性咽頭炎	0	2 (0.5)	2 (0.2)
肺炎	4 (0.9)	1 (0.2)	5 (0.6)
マイコプラズマ性肺炎	0	1 (0.2)	1 (0.1)
膿疱	1 (0.2)	1 (0.2)	2 (0.2)
膿疱性皮疹	0	1 (0.2)	1 (0.1)
ウイルス性気道感染	2 (0.5)	1 (0.2)	3 (0.3)
鼻炎	1 (0.2)	1 (0.2)	2 (0.2)
鼻喉頭炎	0	1 (0.2)	1 (0.1)
副鼻腔炎	2 (0.5)	2 (0.5)	4 (0.5)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
感染症および寄生虫症 (Cont.)			
皮膚細菌感染	1 (0.2)	0	1 (0.1)
皮膚感染	4 (0.9)	2 (0.5)	6 (0.7)
膿性痰	1 (0.2)	0	1 (0.1)
ブドウ球菌性膿瘍	1 (0.2)	0	1 (0.1)
ブドウ球菌感染	0	3 (0.7)	3 (0.3)
ブドウ球菌皮膚感染	3 (0.7)	3 (0.7)	6 (0.7)
股部白癬	0	1 (0.2)	1 (0.1)
白癬感染	1 (0.2)	0	1 (0.1)
足部白癬	2 (0.5)	2 (0.5)	4 (0.5)
癜風	0	1 (0.2)	1 (0.1)
扁桃炎	1 (0.2)	1 (0.2)	2 (0.2)
歯感染	1 (0.2)	2 (0.5)	3 (0.3)
気管気管支炎	1 (0.2)	0	1 (0.1)
上気道感染	18 (4.1)	16 (3.7)	34 (3.9)
尿路感染	3 (0.7)	8 (1.8)	11 (1.3)
細菌性尿路感染	0	1 (0.2)	1 (0.1)
ウイルス感染	0	1 (0.2)	1 (0.1)

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感染症および寄生虫症 (Cont.)			
ウイルス性咽頭炎	2 (0.5)	0	2 (0.2)
ウイルス性上気道感染	3 (0.7)	3 (0.7)	6 (0.7)
外陰部腟カンジダ症	1 (0.2)	0	1 (0.1)
外陰腟真菌感染	0	1 (0.2)	1 (0.1)
傷害、中毒および処置合併症	2 (0.5)	3 (0.7)	5 (0.6)
節足動物咬傷	0	1 (0.2)	1 (0.1)
挫傷	0	1 (0.2)	1 (0.1)
転倒	1 (0.2)	1 (0.2)	2 (0.2)
瘢痕	1 (0.2)	0	1 (0.1)
創部分泌	0	1 (0.2)	1 (0.1)
臨床検査	47 (10.6)	56 (12.8)	103 (11.7)
アラニンアミノトランスフェラーゼ増加	7 (1.6)	7 (1.6)	14 (1.6)
アスパラギン酸アミノトランスフェラーゼ増加	5 (1.1)	4 (0.9)	9 (1.0)
血中アルカリホスファターゼ増加	1 (0.2)	0	1 (0.1)
血中ビリルビン増加	1 (0.2)	1 (0.2)	2 (0.2)
血中コレステロール増加	2 (0.5)	2 (0.5)	4 (0.5)
血中クレアチンホスホキナーゼ増加	15 (3.4)	32 (7.3)	47 (5.3)

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臨床検査 (Cont.)			
血中クレアチニン増加	1 (0.2)	1 (0.2)	2 (0.2)
血中葉酸減少	1 (0.2)	0	1 (0.1)
血中ブドウ糖増加	1 (0.2)	0	1 (0.1)
血中鉄減少	0	1 (0.2)	1 (0.1)
血中リン減少	1 (0.2)	0	1 (0.1)
血圧上昇	1 (0.2)	0	1 (0.1)
血中トリグリセリド増加	2 (0.5)	2 (0.5)	4 (0.5)
血中尿酸増加	1 (0.2)	0	1 (0.1)
体温上昇	0	1 (0.2)	1 (0.1)
心電図 QT 間隔異常	1 (0.2)	0	1 (0.1)
好酸球数増加	2 (0.5)	0	2 (0.2)
ヘモグロビン減少	1 (0.2)	5 (1.1)	6 (0.7)
ヘリコバクター検査陽性	1 (0.2)	0	1 (0.1)
肝酵素上昇	1 (0.2)	0	1 (0.1)
肝機能検査異常	0	1 (0.2)	1 (0.1)
低比重リポ蛋白増加	1 (0.2)	2 (0.5)	3 (0.3)
リンパ球数減少	1 (0.2)	0	1 (0.1)

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臨床検査 (Cont.)			
リンパ球数増加	1 (0.2)	0	1 (0.1)
平均赤血球容積増加	1 (0.2)	0	1 (0.1)
単球数増加	0	1 (0.2)	1 (0.1)
好中球数減少	8 (1.8)	4 (0.9)	12 (1.4)
好中球数増加	1 (0.2)	0	1 (0.1)
好中球百分率減少	1 (0.2)	0	1 (0.1)
好中球百分率増加	1 (0.2)	0	1 (0.1)
尿中蛋白陽性	2 (0.5)	0	2 (0.2)
赤血球数減少	1 (0.2)	1 (0.2)	2 (0.2)
体重減少	1 (0.2)	0	1 (0.1)
体重増加	7 (1.6)	7 (1.6)	14 (1.6)
白血球数減少	2 (0.5)	2 (0.5)	4 (0.5)
白血球数増加	0	1 (0.2)	1 (0.1)
尿中白血球陽性	1 (0.2)	0	1 (0.1)
代謝および栄養障害	8 (1.8)	13 (3.0)	21 (2.4)
食欲減退	1 (0.2)	0	1 (0.1)
高コレステロール血症	2 (0.5)	3 (0.7)	5 (0.6)

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代謝および栄養障害 (Cont.)			
高カリウム血症	1 (0.2)	0	1 (0.1)
高脂血症	1 (0.2)	5 (1.1)	6 (0.7)
高ナトリウム血症	1 (0.2)	0	1 (0.1)
高トリグリセリド血症	1 (0.2)	2 (0.5)	3 (0.3)
高尿酸血症	2 (0.5)	2 (0.5)	4 (0.5)
食欲亢進	0	2 (0.5)	2 (0.2)
鉄欠乏	0	1 (0.2)	1 (0.1)
肥満	1 (0.2)	0	1 (0.1)
ビタミンＤ欠乏	0	1 (0.2)	1 (0.1)
筋骨格系および結合組織障害	6 (1.4)	11 (2.5)	17 (1.9)
関節痛	0	1 (0.2)	1 (0.1)
背部痛	1 (0.2)	0	1 (0.1)
滑液包炎	0	1 (0.2)	1 (0.1)
椎間板突出	0	1 (0.2)	1 (0.1)
関節ロック	0	1 (0.2)	1 (0.1)
筋痙縮	0	3 (0.7)	3 (0.3)
筋骨格系胸痛	0	1 (0.2)	1 (0.1)

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筋骨格系および結合組織障害 (Cont.)			
筋肉痛	4 (0.9)	3 (0.7)	7 (0.8)
頚部腫瘤	0	1 (0.2)	1 (0.1)
頚部痛	1 (0.2)	0	1 (0.1)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	4 (0.9)	6 (1.4)	10 (1.1)
肛門性器疣贅	0	2 (0.5)	2 (0.2)
異形成母斑	1 (0.2)	0	1 (0.1)
ケラトアカントーマ	0	1 (0.2)	1 (0.1)
脂漏性角化症	1 (0.2)	0	1 (0.1)
皮膚乳頭腫	2 (0.5)	3 (0.7)	5 (0.6)
神経系障害	12 (2.7)	17 (3.9)	29 (3.3)
浮動性めまい	3 (0.7)	5 (1.1)	8 (0.9)
味覚不全	0	1 (0.2)	1 (0.1)
頭痛	7 (1.6)	8 (1.8)	15 (1.7)
過眠症	0	1 (0.2)	1 (0.1)
嗜眠	0	1 (0.2)	1 (0.1)
多発性硬化症再発	0	1 (0.2)	1 (0.1)
末梢性ニューロパチー	1 (0.2)	1 (0.2)	2 (0.2)

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神経系障害 (Cont.)			
錯感覚	1 (0.2)	1 (0.2)	2 (0.2)
失神寸前の状態	1 (0.2)	0	1 (0.1)
傾眠	0	1 (0.2)	1 (0.1)
失神	0	1 (0.2)	1 (0.1)
精神障害	7 (1.6)	10 (2.3)	17 (1.9)
感情不安定	2 (0.5)	0	2 (0.2)
不安	1 (0.2)	0	1 (0.1)
注意欠陥多動性障害	0	1 (0.2)	1 (0.1)
抑うつ気分	0	2 (0.5)	2 (0.2)
うつ病	0	1 (0.2)	1 (0.1)
不眠症	0	2 (0.5)	2 (0.2)
リビドー減退	0	1 (0.2)	1 (0.1)
リビドー亢進	1 (0.2)	0	1 (0.1)
精神障害	0	1 (0.2)	1 (0.1)
混合性不安抑うつ障害	0	1 (0.2)	1 (0.1)
悪夢	1 (0.2)	0	1 (0.1)
パニック発作	0	1 (0.2)	1 (0.1)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
精神障害 (Cont.)			
睡眠障害	0	1 (0.2)	1 (0.1)
ストレス	1 (0.2)	0	1 (0.1)
自殺企図	1 (0.2)	0	1 (0.1)
腎および尿路障害	7 (1.6)	6 (1.4)	13 (1.5)
アルブミン尿	2 (0.5)	1 (0.2)	3 (0.3)
排尿困難	1 (0.2)	0	1 (0.1)
血尿	1 (0.2)	2 (0.5)	3 (0.3)
夜間頻尿	1 (0.2)	0	1 (0.1)
頻尿	0	1 (0.2)	1 (0.1)
多尿	1 (0.2)	0	1 (0.1)
蛋白尿	1 (0.2)	2 (0.5)	3 (0.3)
生殖系および乳房障害	4 (0.9)	3 (0.7)	7 (0.8)
子宮頚部上皮異形成	1 (0.2)	0	1 (0.1)
勃起不全	0	2 (0.5)	2 (0.2)
月経過多	1 (0.2)	0	1 (0.1)
不規則月経	1 (0.2)	0	1 (0.1)
前立腺炎	1 (0.2)	0	1 (0.1)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
生殖系および乳房障害 (Cont.)			
精巣痛	1 (0.2)	1 (0.2)	2 (0.2)
呼吸器、胸郭および縦隔障害	22 (5.0)	20 (4.6)	42 (4.8)
失声症	1 (0.2)	0	1 (0.1)
喘息	2 (0.5)	3 (0.7)	5 (0.6)
カタル	0	1 (0.2)	1 (0.1)
咳嗽	8 (1.8)	9 (2.1)	17 (1.9)
呼吸困難	3 (0.7)	2 (0.5)	5 (0.6)
鼻出血	3 (0.7)	1 (0.2)	4 (0.5)
肺浸潤	1 (0.2)	0	1 (0.1)
鼻閉	0	1 (0.2)	1 (0.1)
口腔咽頭痛	1 (0.2)	5 (1.1)	6 (0.7)
咽頭腫脹	0	1 (0.2)	1 (0.1)
胸水	1 (0.2)	0	1 (0.1)
湿性咳嗽	1 (0.2)	0	1 (0.1)
肺塞栓症	1 (0.2)	0	1 (0.1)
肺腫瘤	1 (0.2)	0	1 (0.1)
鼻漏	3 (0.7)	0	3 (0.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)			
副鼻腔うっ血	1 (0.2)	1 (0.2)	2 (0.2)
皮膚および皮下組織障害	80 (18.1)	98 (22.5)	178 (20.3)
ざ瘡	52 (11.7)	67 (15.4)	119 (13.5)
後天性ブラシュコ皮膚炎	1 (0.2)	0	1 (0.1)
光線角化症	0	1 (0.2)	1 (0.1)
脱毛症	1 (0.2)	0	1 (0.1)
水疱	0	2 (0.5)	2 (0.2)
ざ瘡様皮膚炎	5 (1.1)	4 (0.9)	9 (1.0)
アレルギー性皮膚炎	0	1 (0.2)	1 (0.1)
アトピー性皮膚炎	6 (1.4)	7 (1.6)	13 (1.5)
接触皮膚炎	0	1 (0.2)	1 (0.1)
乾癬様皮膚炎	1 (0.2)	0	1 (0.1)
異汗性湿疹	1 (0.2)	0	1 (0.1)
湿疹	2 (0.5)	2 (0.5)	4 (0.5)
紅斑	1 (0.2)	0	1 (0.1)
過剰肉芽組織	1 (0.2)	0	1 (0.1)
毛髪成長異常	1 (0.2)	1 (0.2)	2 (0.2)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
皮膚および皮下組織障害 (Cont.)			
多汗症	2 (0.5)	0	2 (0.2)
多毛症	1 (0.2)	1 (0.2)	2 (0.2)
苔癬化	0	1 (0.2)	1 (0.1)
稗粒腫	0	1 (0.2)	1 (0.1)
寝汗	1 (0.2)	0	1 (0.1)
丘疹	0	1 (0.2)	1 (0.1)
口囲皮膚炎	0	2 (0.5)	2 (0.2)
光線過敏性反応	0	1 (0.2)	1 (0.1)
そう痒症	1 (0.2)	1 (0.2)	2 (0.2)
偽毛包炎	1 (0.2)	0	1 (0.1)
紫斑	1 (0.2)	0	1 (0.1)
発疹	1 (0.2)	1 (0.2)	2 (0.2)
丘疹性皮疹	1 (0.2)	1 (0.2)	2 (0.2)
そう痒性皮疹	1 (0.2)	0	1 (0.1)
小水疱性皮疹	0	1 (0.2)	1 (0.1)
酒さ	1 (0.2)	3 (0.7)	4 (0.5)
痂皮	0	2 (0.5)	2 (0.2)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) n (%)	UPA 30 mg QD + TCS (N=436) n (%)	Total (N=879) n (%)
皮膚および皮下組織障害 (Cont.)			
脂漏	1 (0.2)	1 (0.2)	2 (0.2)
脂漏性皮膚炎	0	1 (0.2)	1 (0.1)
皮膚障害	0	1 (0.2)	1 (0.1)
皮膚剥脱	1 (0.2)	0	1 (0.1)
皮膚亀裂	0	2 (0.5)	2 (0.2)
皮膚腫瘤	1 (0.2)	1 (0.2)	2 (0.2)
皮膚線条	2 (0.5)	0	2 (0.2)
皮膚腫脹	0	1 (0.2)	1 (0.1)
日光黒子	1 (0.2)	0	1 (0.1)
蕁麻疹	2 (0.5)	3 (0.7)	5 (0.6)
血管障害	2 (0.5)	2 (0.5)	4 (0.5)
高血圧	2 (0.5)	1 (0.2)	3 (0.3)
レイノー現象	0	1 (0.2)	1 (0.1)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

相互参照：M16-047 試験 CSR W52 Table 14.3__1.8.1

表 8. ウパダシチニブ投与期間中の治験薬と関連ありの有害事象の 100 人年あたりの発現率：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団）

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
Any adverse event	635 (124.0)	722 (135.4)	1357 (129.9)
血液およびリンパ系障害	7 (1.4)	19 (3.6)	26 (2.5)
貧血	2 (0.4)	1 (0.2)	3 (0.3)
大球性貧血	0	1 (0.2)	1 (<0.1)
赤血球減少症	0	1 (0.2)	1 (<0.1)
内出血発生の増加傾向	0	2 (0.4)	2 (0.2)
白血球増加症	1 (0.2)	0	1 (<0.1)
白血球減少症	0	3 (0.6)	3 (0.3)
リンパ節石灰化	1 (0.2)	0	1 (<0.1)
リンパ節症	1 (0.2)	2 (0.4)	3 (0.3)
リンパ球減少症	0	1 (0.2)	1 (<0.1)
大赤血球症	1 (0.2)	0	1 (<0.1)
単球減少症	0	1 (0.2)	1 (<0.1)
好中球減少症	1 (0.2)	5 (0.9)	6 (0.6)
血小板減少症	0	1 (0.2)	1 (<0.1)
血小板増加症	0	1 (0.2)	1 (<0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
心臓障害	1 (0.2)	3 (0.6)	4 (0.4)
徐脈	0	1 (0.2)	1 (<0.1)
動悸	0	2 (0.4)	2 (0.2)
洞性徐脈	1 (0.2)	0	1 (<0.1)
先天性、家族性および遺伝性障害	1 (0.2)	0	1 (<0.1)
表皮母斑	1 (0.2)	0	1 (<0.1)
耳および迷路障害	0	3 (0.6)	3 (0.3)
難聴	0	1 (0.2)	1 (<0.1)
耳鳴	0	2 (0.4)	2 (0.2)
眼障害	6 (1.2)	18 (3.4)	24 (2.3)
眼瞼炎	0	2 (0.4)	2 (0.2)
白内障	0	1 (0.2)	1 (<0.1)
結膜沈着物	0	1 (0.2)	1 (<0.1)
結膜充血	0	1 (0.2)	1 (<0.1)
アレルギー性結膜炎	0	1 (0.2)	1 (<0.1)
眼痛	1 (0.2)	0	1 (<0.1)
眼の異常感覚	0	1 (0.2)	1 (<0.1)
眼そう痒症	0	1 (0.2)	1 (<0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
眼障害 (Cont.)			
眼瞼障害	0	1 (0.2)	1 (<0.1)
流涙増加	3 (0.6)	0	3 (0.3)
近視	0	1 (0.2)	1 (<0.1)
視神経乳頭浮腫	0	1 (0.2)	1 (<0.1)
羞明	0	1 (0.2)	1 (<0.1)
網膜剥離	1 (0.2)	1 (0.2)	2 (0.2)
裂孔原性網膜剥離	0	2 (0.4)	2 (0.2)
眼瞼腫脹	0	1 (0.2)	1 (<0.1)
潰瘍性角膜炎	0	1 (0.2)	1 (<0.1)
硝子体剥離	0	1 (0.2)	1 (<0.1)
眼球乾燥症	1 (0.2)	0	1 (<0.1)
胃腸障害	49 (9.6)	59 (11.1)	108 (10.3)
腹部不快感	1 (0.2)	1 (0.2)	2 (0.2)
腹部膨満	1 (0.2)	1 (0.2)	2 (0.2)
腹痛	5 (1.0)	6 (1.1)	11 (1.1)
上腹部痛	7 (1.4)	1 (0.2)	8 (0.8)
口角口唇炎	0	1 (0.2)	1 (<0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
胃腸障害 (Cont.)			
肛門直腸不快感	0	1 (0.2)	1 (<0.1)
アフタ性潰瘍	2 (0.4)	2 (0.4)	4 (0.4)
便習慣変化	0	1 (0.2)	1 (<0.1)
便秘	3 (0.6)	2 (0.4)	5 (0.5)
下痢	9 (1.8)	20 (3.8)	29 (2.8)
口内乾燥	0	1 (0.2)	1 (<0.1)
出血性十二指腸潰瘍	1 (0.2)	0	1 (<0.1)
消化不良	2 (0.4)	3 (0.6)	5 (0.5)
嚥下障害	0	1 (0.2)	1 (<0.1)
白色便	1 (0.2)	0	1 (<0.1)
鼓腸	1 (0.2)	1 (0.2)	2 (0.2)
排便回数増加	0	1 (0.2)	1 (<0.1)
胃炎	2 (0.4)	1 (0.2)	3 (0.3)
胃腸障害	1 (0.2)	0	1 (<0.1)
胃食道逆流性疾患	0	3 (0.6)	3 (0.3)
舌炎	1 (0.2)	0	1 (<0.1)
胃酸過多	0	1 (0.2)	1 (<0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
胃腸障害 (Cont.)			
過敏性腸症候群	0	1 (0.2)	1 (<0.1)
口腔内出血	0	1 (0.2)	1 (<0.1)
口腔内潰瘍形成	2 (0.4)	0	2 (0.2)
悪心	9 (1.8)	6 (1.1)	15 (1.4)
嘔吐	1 (0.2)	3 (0.6)	4 (0.4)
一般・全身障害および投与部位の状態	27 (5.3)	20 (3.8)	47 (4.5)
胸部不快感	1 (0.2)	0	1 (<0.1)
顔面浮腫	1 (0.2)	0	1 (<0.1)
顔面痛	1 (0.2)	0	1 (<0.1)
疲労	7 (1.4)	5 (0.9)	12 (1.1)
インフルエンザ様疾患	5 (1.0)	7 (1.3)	12 (1.1)
倦怠感	1 (0.2)	1 (0.2)	2 (0.2)
小結節	0	2 (0.4)	2 (0.2)
疼痛	2 (0.4)	0	2 (0.2)
発熱	5 (1.0)	5 (0.9)	10 (1.0)
腫脹	2 (0.4)	0	2 (0.2)
顔面腫脹	2 (0.4)	0	2 (0.2)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
肝胆道系障害	2 (0.4)	4 (0.8)	6 (0.6)
肝機能異常	2 (0.4)	2 (0.4)	4 (0.4)
肝細胞損傷	0	1 (0.2)	1 (<0.1)
肝腫大	0	1 (0.2)	1 (<0.1)
感染症および寄生虫症	268 (52.4)	267 (50.1)	535 (51.2)
四肢膿瘍	0	1 (0.2)	1 (<0.1)
虫垂炎	1 (0.2)	0	1 (<0.1)
細菌感染	0	1 (0.2)	1 (<0.1)
バルトネラ症	1 (0.2)	0	1 (<0.1)
体部白癬	1 (0.2)	3 (0.6)	4 (0.4)
気管支炎	2 (0.4)	3 (0.6)	5 (0.5)
条虫感染	1 (0.2)	0	1 (<0.1)
慢性副鼻腔炎	1 (0.2)	0	1 (<0.1)
結膜炎	5 (1.0)	4 (0.8)	9 (0.9)
ウイルス性結膜炎	0	1 (0.2)	1 (<0.1)
コロナウイルス感染	0	1 (0.2)	1 (<0.1)
膀胱炎	5 (1.0)	0	5 (0.5)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
医療機器関連感染	2 (0.4)	0	2 (0.2)
耳感染	1 (0.2)	0	1 (<0.1)
ヘルペス性状湿疹	5 (1.0)	4 (0.8)	9 (0.9)
膿痂疹性湿疹	2 (0.4)	0	2 (0.2)
感染性湿疹	0	1 (0.2)	1 (<0.1)
エンテロバクター感染	1 (0.2)	0	1 (<0.1)
ブドウ球菌性眼感染	1 (0.2)	0	1 (<0.1)
糸状虫症	0	1 (0.2)	1 (<0.1)
毛包炎	9 (1.8)	14 (2.6)	23 (2.2)
せつ	3 (0.6)	8 (1.5)	11 (1.1)
ウイルス性胃炎	1 (0.2)	0	1 (<0.1)
胃腸炎	3 (0.6)	6 (1.1)	9 (0.9)
陰部ヘルペス	0	3 (0.6)	3 (0.3)
陰部単純ヘルペス	0	1 (0.2)	1 (<0.1)
歯肉炎	0	1 (0.2)	1 (<0.1)
ヘルペス眼感染	1 (0.2)	3 (0.6)	4 (0.4)
単純ヘルペス	37 (7.2)	19 (3.6)	56 (5.4)

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MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
帯状疱疹	14 (2.7)	20 (3.8)	34 (3.3)
皮膚播種性帯状疱疹	1 (0.2)	0	1 (<0.1)
播種性帯状疱疹	0	1 (0.2)	1 (<0.1)
耳帯状疱疹	0	2 (0.4)	2 (0.2)
麦粒腫	0	1 (0.2)	1 (<0.1)
膿痂疹	7 (1.4)	3 (0.6)	10 (1.0)
インフルエンザ	4 (0.8)	4 (0.8)	8 (0.8)
カポジ水痘様発疹	1 (0.2)	6 (1.1)	7 (0.7)
腎感染	1 (0.2)	0	1 (<0.1)
大腸感染	1 (0.2)	0	1 (<0.1)
喉頭炎	1 (0.2)	0	1 (<0.1)
潜伏結核	0	2 (0.4)	2 (0.2)
マラセチア感染	1 (0.2)	1 (0.2)	2 (0.2)
伝染性軟属腫	1 (0.2)	3 (0.6)	4 (0.4)
鼻ヘルペス	0	2 (0.4)	2 (0.2)
上咽頭炎	41 (8.0)	25 (4.7)	66 (6.3)
爪真菌症	1 (0.2)	0	1 (<0.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
眼部単純ヘルペス	7 (1.4)	8 (1.5)	15 (1.4)
眼帯状疱疹	0	1 (0.2)	1 (<0.1)
口腔カンジダ症	1 (0.2)	1 (0.2)	2 (0.2)
口腔ヘルペス	35 (6.8)	45 (8.4)	80 (7.7)
外耳炎	1 (0.2)	1 (0.2)	2 (0.2)
インプラント周囲炎	1 (0.2)	0	1 (<0.1)
眼窩周囲蜂巣炎	2 (0.4)	0	2 (0.2)
咽頭炎	7 (1.4)	4 (0.8)	11 (1.1)
レンサ球菌性咽頭炎	0	2 (0.4)	2 (0.2)
肺炎	4 (0.8)	1 (0.2)	5 (0.5)
マイコプラズマ性肺炎	0	1 (0.2)	1 (<0.1)
膿疱	1 (0.2)	1 (0.2)	2 (0.2)
膿疱性皮疹	0	1 (0.2)	1 (<0.1)
ウイルス性気道感染	2 (0.4)	1 (0.2)	3 (0.3)
鼻炎	1 (0.2)	1 (0.2)	2 (0.2)
鼻喉頭炎	0	1 (0.2)	1 (<0.1)
副鼻腔炎	2 (0.4)	2 (0.4)	4 (0.4)

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感染症および寄生虫症 (Cont.)			
皮膚細菌感染	1 (0.2)	0	1 (<0.1)
皮膚感染	5 (1.0)	2 (0.4)	7 (0.7)
膿性痰	1 (0.2)	0	1 (<0.1)
ブドウ球菌性膿瘍	1 (0.2)	0	1 (<0.1)
ブドウ球菌感染	0	3 (0.6)	3 (0.3)
ブドウ球菌皮膚感染	3 (0.6)	3 (0.6)	6 (0.6)
股部白癬	0	1 (0.2)	1 (<0.1)
白癬感染	1 (0.2)	0	1 (<0.1)
足部白癬	2 (0.4)	2 (0.4)	4 (0.4)
癜風	0	1 (0.2)	1 (<0.1)
扁桃炎	1 (0.2)	1 (0.2)	2 (0.2)
歯感染	2 (0.4)	2 (0.4)	4 (0.4)
気管気管支炎	1 (0.2)	0	1 (<0.1)
上気道感染	20 (3.9)	20 (3.8)	40 (3.8)
尿路感染	3 (0.6)	9 (1.7)	12 (1.1)
細菌性尿路感染	0	1 (0.2)	1 (<0.1)
ウイルス感染	0	1 (0.2)	1 (<0.1)

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感染症および寄生虫症 (Cont.)			
ウイルス性咽頭炎	2 (0.4)	0	2 (0.2)
ウイルス性上気道感染	3 (0.6)	4 (0.8)	7 (0.7)
外陰部腟カンジダ症	1 (0.2)	0	1 (<0.1)
外陰腟真菌感染	0	1 (0.2)	1 (<0.1)
傷害、中毒および処置合併症	2 (0.4)	4 (0.8)	6 (0.6)
節足動物咬傷	0	1 (0.2)	1 (<0.1)
挫傷	0	1 (0.2)	1 (<0.1)
転倒	1 (0.2)	1 (0.2)	2 (0.2)
瘢痕	1 (0.2)	0	1 (<0.1)
創部分泌	0	1 (0.2)	1 (<0.1)
臨床検査	84 (16.4)	84 (15.8)	168 (16.1)
アラニンアミノトランスフェラーゼ増加	10 (2.0)	7 (1.3)	17 (1.6)
アスパラギン酸アミノトランスフェラーゼ増加	5 (1.0)	4 (0.8)	9 (0.9)
血中アルカリホスファターゼ増加	1 (0.2)	0	1 (<0.1)
血中ビリルビン増加	2 (0.4)	1 (0.2)	3 (0.3)
血中コレステロール増加	2 (0.4)	3 (0.6)	5 (0.5)
血中クレアチンホスホキナーゼ増加	19 (3.7)	35 (6.6)	54 (5.2)

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臨床検査 (Cont.)			
血中クレアチニン増加	1 (0.2)	1 (0.2)	2 (0.2)
血中葉酸減少	1 (0.2)	0	1 (<0.1)
血中ブドウ糖増加	1 (0.2)	0	1 (<0.1)
血中鉄減少	0	1 (0.2)	1 (<0.1)
血中リン減少	1 (0.2)	0	1 (<0.1)
血圧上昇	1 (0.2)	0	1 (<0.1)
血中トリグリセリド増加	2 (0.4)	3 (0.6)	5 (0.5)
血中尿酸増加	1 (0.2)	0	1 (<0.1)
体温上昇	0	1 (0.2)	1 (<0.1)
心電図 QT 間隔異常	1 (0.2)	0	1 (<0.1)
好酸球数増加	2 (0.4)	0	2 (0.2)
ヘモグロビン減少	1 (0.2)	5 (0.9)	6 (0.6)
ヘリコバクター検査陽性	1 (0.2)	0	1 (<0.1)
肝酵素上昇	1 (0.2)	0	1 (<0.1)
肝機能検査異常	0	1 (0.2)	1 (<0.1)
低比重リポ蛋白増加	1 (0.2)	2 (0.4)	3 (0.3)
リンパ球数減少	1 (0.2)	0	1 (<0.1)

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臨床検査 (Cont.)			
リンパ球数増加	1 (0.2)	0	1 (<0.1)
平均赤血球容積増加	1 (0.2)	0	1 (<0.1)
単球数増加	0	1 (0.2)	1 (<0.1)
好中球数減少	8 (1.6)	6 (1.1)	14 (1.3)
好中球数増加	1 (0.2)	0	1 (<0.1)
好中球百分率減少	1 (0.2)	0	1 (<0.1)
好中球百分率増加	1 (0.2)	0	1 (<0.1)
尿中蛋白陽性	4 (0.8)	0	4 (0.4)
赤血球数減少	1 (0.2)	1 (0.2)	2 (0.2)
体重減少	1 (0.2)	0	1 (<0.1)
体重増加	7 (1.4)	9 (1.7)	16 (1.5)
白血球数減少	2 (0.4)	2 (0.4)	4 (0.4)
白血球数増加	0	1 (0.2)	1 (<0.1)
尿中白血球陽性	1 (0.2)	0	1 (<0.1)
代謝および栄養障害	13 (2.5)	18 (3.4)	31 (3.0)
食欲減退	1 (0.2)	0	1 (<0.1)
高コレステロール血症	3 (0.6)	3 (0.6)	6 (0.6)

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代謝および栄養障害 (Cont.)			
高カリウム血症	1 (0.2)	0	1 (<0.1)
高脂血症	1 (0.2)	5 (0.9)	6 (0.6)
高ナトリウム血症	2 (0.4)	0	2 (0.2)
高トリグリセリド血症	2 (0.4)	3 (0.6)	5 (0.5)
高尿酸血症	2 (0.4)	3 (0.6)	5 (0.5)
食欲亢進	0	2 (0.4)	2 (0.2)
鉄欠乏	0	1 (0.2)	1 (<0.1)
肥満	1 (0.2)	0	1 (<0.1)
ビタミン D 欠乏	0	1 (0.2)	1 (<0.1)
筋骨格系および結合組織障害	6 (1.2)	13 (2.4)	19 (1.8)
関節痛	0	1 (0.2)	1 (<0.1)
背部痛	1 (0.2)	0	1 (<0.1)
滑液包炎	0	1 (0.2)	1 (<0.1)
椎間板突出	0	1 (0.2)	1 (<0.1)
関節ロック	0	1 (0.2)	1 (<0.1)
筋痙縮	0	4 (0.8)	4 (0.4)
筋骨格系胸痛	0	1 (0.2)	1 (<0.1)

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筋骨格系および結合組織障害 (Cont.)			
筋肉痛	4 (0.8)	3 (0.6)	7 (0.7)
頚部腫瘤	0	1 (0.2)	1 (<0.1)
頚部痛	1 (0.2)	0	1 (<0.1)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	4 (0.8)	6 (1.1)	10 (1.0)
肛門性器疣贅	0	2 (0.4)	2 (0.2)
異形成母斑	1 (0.2)	0	1 (<0.1)
ケラトアカントーマ	0	1 (0.2)	1 (<0.1)
脂漏性角化症	1 (0.2)	0	1 (<0.1)
皮膚乳頭腫	2 (0.4)	3 (0.6)	5 (0.5)
神経系障害	17 (3.3)	23 (4.3)	40 (3.8)
浮動性めまい	5 (1.0)	7 (1.3)	12 (1.1)
味覚不全	0	1 (0.2)	1 (<0.1)
頭痛	8 (1.6)	8 (1.5)	16 (1.5)
過眠症	0	1 (0.2)	1 (<0.1)
嗜眠	0	1 (0.2)	1 (<0.1)
多発性硬化症再発	0	1 (0.2)	1 (<0.1)
末梢性ニューロパチー	1 (0.2)	1 (0.2)	2 (0.2)

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神経系障害 (Cont.)			
錯感覚	2 (0.4)	1 (0.2)	3 (0.3)
失神寸前の状態	1 (0.2)	0	1 (<0.1)
傾眠	0	1 (0.2)	1 (<0.1)
失神	0	1 (0.2)	1 (<0.1)
精神障害	7 (1.4)	13 (2.4)	20 (1.9)
感情不安定	2 (0.4)	0	2 (0.2)
不安	1 (0.2)	0	1 (<0.1)
注意欠陥多動性障害	0	1 (0.2)	1 (<0.1)
抑うつ気分	0	2 (0.4)	2 (0.2)
うつ病	0	1 (0.2)	1 (<0.1)
不眠症	0	2 (0.4)	2 (0.2)
リビドー減退	0	1 (0.2)	1 (<0.1)
リビドー亢進	1 (0.2)	0	1 (<0.1)
精神障害	0	3 (0.6)	3 (0.3)
混合性不安抑うつ障害	0	1 (0.2)	1 (<0.1)
悪夢	1 (0.2)	0	1 (<0.1)
パニック発作	0	1 (0.2)	1 (<0.1)

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精神障害 (Cont.)			
睡眠障害	0	1 (0.2)	1 (<0.1)
ストレス	1 (0.2)	0	1 (<0.1)
自殺企図	1 (0.2)	0	1 (<0.1)
腎および尿路障害	7 (1.4)	7 (1.3)	14 (1.3)
アルブミン尿	2 (0.4)	2 (0.4)	4 (0.4)
排尿困難	1 (0.2)	0	1 (<0.1)
血尿	1 (0.2)	2 (0.4)	3 (0.3)
夜間頻尿	1 (0.2)	0	1 (<0.1)
頻尿	0	1 (0.2)	1 (<0.1)
多尿	1 (0.2)	0	1 (<0.1)
蛋白尿	1 (0.2)	2 (0.4)	3 (0.3)
生殖系および乳房障害	5 (1.0)	3 (0.6)	8 (0.8)
子宮頚部上皮異形成	1 (0.2)	0	1 (<0.1)
勃起不全	0	2 (0.4)	2 (0.2)
月経過多	1 (0.2)	0	1 (<0.1)
不規則月経	1 (0.2)	0	1 (<0.1)
前立腺炎	1 (0.2)	0	1 (<0.1)

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生殖系および乳房障害 (Cont.)			
精巣痛	1 (0.2)	1 (0.2)	2 (0.2)
呼吸器、胸郭および縦隔障害	30 (5.9)	25 (4.7)	55 (5.3)
失声症	2 (0.4)	0	2 (0.2)
喘息	2 (0.4)	3 (0.6)	5 (0.5)
カタル	0	1 (0.2)	1 (<0.1)
咳嗽	9 (1.8)	9 (1.7)	18 (1.7)
呼吸困難	3 (0.6)	2 (0.4)	5 (0.5)
鼻出血	3 (0.6)	1 (0.2)	4 (0.4)
肺浸潤	1 (0.2)	0	1 (<0.1)
鼻閉	0	1 (0.2)	1 (<0.1)
口腔咽頭痛	1 (0.2)	6 (1.1)	7 (0.7)
咽頭腫脹	0	1 (0.2)	1 (<0.1)
胸水	1 (0.2)	0	1 (<0.1)
湿性咳嗽	2 (0.4)	0	2 (0.2)
肺塞栓症	1 (0.2)	0	1 (<0.1)
肺腫瘤	1 (0.2)	0	1 (<0.1)
鼻漏	3 (0.6)	0	3 (0.3)

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呼吸器、胸郭および縦隔障害 (Cont.)			
副鼻腔うっ血	1 (0.2)	1 (0.2)	2 (0.2)
皮膚および皮下組織障害	97 (18.9)	131 (24.6)	228 (21.8)
ざ瘡	57 (11.1)	83 (15.6)	140 (13.4)
後天性ブラシュコ皮膚炎	1 (0.2)	0	1 (<0.1)
光線角化症	0	1 (0.2)	1 (<0.1)
脱毛症	1 (0.2)	0	1 (<0.1)
水疱	0	2 (0.4)	2 (0.2)
ざ瘡様皮膚炎	5 (1.0)	4 (0.8)	9 (0.9)
アレルギー性皮膚炎	0	1 (0.2)	1 (<0.1)
アトピー性皮膚炎	7 (1.4)	8 (1.5)	15 (1.4)
接触皮膚炎	0	1 (0.2)	1 (<0.1)
乾癬様皮膚炎	1 (0.2)	0	1 (<0.1)
異汗性湿疹	1 (0.2)	0	1 (<0.1)
湿疹	2 (0.4)	2 (0.4)	4 (0.4)
紅斑	1 (0.2)	0	1 (<0.1)
過剰肉芽組織	1 (0.2)	0	1 (<0.1)
毛髪成長異常	1 (0.2)	1 (0.2)	2 (0.2)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)			
多汗症	2 (0.4)	0	2 (0.2)
多毛症	1 (0.2)	1 (0.2)	2 (0.2)
苔癬化	0	1 (0.2)	1 (<0.1)
稗粒腫	0	1 (0.2)	1 (<0.1)
寝汗	1 (0.2)	0	1 (<0.1)
丘疹	0	1 (0.2)	1 (<0.1)
口囲皮膚炎	0	2 (0.4)	2 (0.2)
光線過敏性反応	0	1 (0.2)	1 (<0.1)
そう痒症	1 (0.2)	1 (0.2)	2 (0.2)
偽毛包炎	1 (0.2)	0	1 (<0.1)
紫斑	1 (0.2)	0	1 (<0.1)
発疹	1 (0.2)	1 (0.2)	2 (0.2)
丘疹性皮疹	1 (0.2)	2 (0.4)	3 (0.3)
そう痒性皮疹	1 (0.2)	0	1 (<0.1)
小水疱性皮疹	0	1 (0.2)	1 (<0.1)
酒さ	1 (0.2)	3 (0.6)	4 (0.4)
痂皮	0	2 (0.4)	2 (0.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=443) (PYS=511.9) Events (E/100PY)	UPA 30 mg QD + TCS (N=436) (PYS=533.1) Events (E/100PY)	Total (N=879) (PYS=1045.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)			
脂漏	1 (0.2)	1 (0.2)	2 (0.2)
脂漏性皮膚炎	0	1 (0.2)	1 (<0.1)
皮膚障害	0	1 (0.2)	1 (<0.1)
皮膚剥脱	1 (0.2)	0	1 (<0.1)
皮膚亀裂	0	3 (0.6)	3 (0.3)
皮膚腫瘤	1 (0.2)	1 (0.2)	2 (0.2)
皮膚線条	2 (0.4)	0	2 (0.2)
皮膚腫脹	0	1 (0.2)	1 (<0.1)
日光黒子	1 (0.2)	0	1 (<0.1)
蕁麻疹	2 (0.4)	3 (0.6)	5 (0.5)
血管障害	2 (0.4)	2 (0.4)	4 (0.4)
高血圧	2 (0.4)	1 (0.2)	3 (0.3)
レイノー現象	0	1 (0.2)	1 (<0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

相互参照：M16-047 試験 CSR W52 Table 14.3__1.8.2

重篤な有害事象の叙述

Subject [redacted] ([redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
急性呼吸不全	X	X		
肺炎	X	X		X
ブドウ球菌性敗血症	X	X		X

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

Medical History	Onset Year
ASTHMA	19[redacted]
SEASONAL ALLERGIES	19[redacted]
CHRONIC OBSTRUCTIVE PULMONARY DISEASE	20[redacted]
ATOPIC DERMATITIS	20[redacted]
HYPERTENSION	20[redacted]
HYPERCHOLESTEROLEMIA	20[redacted]
HEPATITIS B VACCINATION	20[redacted]
SEBORRHEIC DERMATITIS - GROIN	20[redacted]
ALLERGIC RHINITIS	NOT REPORTED
ASTHMA	NOT REPORTED

Prior Procedures	Procedure Year
Not reported.	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	CURRENT	10 CIGARETTE	40	
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
PLACEBO		ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 71	71

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BUDESONIDE W/FORMOTEROL FUMARATE	2 OTHER: PUFFS	BID	Y: 20[redacted]
TIOTROPIUM	18 ug	QD	Y: 20[redacted]
AMLODIPINE	10 mg	QD	Y: 20[redacted]
PRAVASTATIN	40 mg	QD	Y: 20[redacted]
PREDNISONE	20 mg	QD	Y: 20[redacted]
PREDNISONE	60 mg	QD	Y: 20[redacted]
HEPATITIS B IMMUNIZATION	NOT REPORTED	NOT REPORTED	Y-M: 20[redacted]
METHOTREXATE	15 mg	1 TIME PER WEEK	Y-M: 20[redacted]
METHOTREXATE	20 mg	1 TIME PER WEEK	Y-M: 20[redacted]
PREDNISONE	30 mg	QD	Y-M: 20[redacted]
TRIAMCINOLONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -76
NIVEA	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -30

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
BUDESONIDE W/FORMOTEROL FUMARATE	2 OTHER: PUFFS	BID	Y: 20[redacted]	ONGOING
TIOTROPIUM	18 ug	QD	Y: 20[redacted]	ONGOING
AMLODIPINE	10 mg	QD	Y: 20[redacted]	ONGOING
PRAVASTATIN	40 mg	QD	Y: 20[redacted]	Y-M: 20[redacted] / 81
NIVEA	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -30	ONGOING
FLUTICASONE	2 OTHER: PUFFS	QD	Y-M: 20[redacted] / 82	ONGOING
OMEPRAZOLE	40 mg	QD	Y-M: 20[redacted] / 82	ONGOING
SALBUTAMOL	2 OTHER: PUFFS	OTHER: EVERY 6 HOURS	Y-M: 20[redacted] / 82	ONGOING
AZITHROMYCIN	500 mg	QD	Y-M: 20[redacted] / 82	Y-M: 20[redacted] / 86
ATORVASTATIN	10 mg	QD	Y-M: 20[redacted] / 82	Y-M: 20[redacted] / 89
BUDESONIDE	0.5 mg	QD	Y-M: 20[redacted] / 82	Y-M: 20[redacted] / 89

COMBIVENT	0.5-2.5/3 OTHER: MG/ML	OTHER: EVERY 4 HOURS	Y-M: 20[redacted] / 82	Y-M: 20[redacted] / 89
FLUTICASONE FUROATE W/VILANTEROL	100-25 ug	QD	Y-M: 20[redacted] / 82	Y-M: 20[redacted] / 89
FORMOTEROL	20 ug	BID	Y-M: 20[redacted] / 82	Y-M: 20[redacted] / 89
METHYLPREDNISOLONE	40 mg	OTHER: EVERY 8 HOURS	Y-M: 20[redacted] / 82	Y-M: 20[redacted] / 89
NICOTINE	21 mg	QD	Y-M: 20[redacted] / 82	Y-M: 20[redacted] / 89
ONDANSETRON	4 mg	OTHER: EVERY 6 HOURS	Y-M: 20[redacted] / 82	Y-M: 20[redacted] / 89
SODIUM CHLORIDE	75 OTHER: ML/HOUR	OTHER: CONTINUOUS	Y-M: 20[redacted] / 82	Y-M: 20[redacted] / 89
UMECLIDINIUM	62.5 ug	QD	Y-M: 20[redacted] / 82	Y-M: 20[redacted] / 89
CEFTRIAXONE	1 g	QD	Y-M: 20[redacted] / 82	Y-M: 20[redacted] / 100
INFLUENZA VACCINE	0.5 mL	OTHER: ONCE	Y-M: 20[redacted] / 83	Y-M: 20[redacted] / 83
GUAIFENESIN	400 mg	OTHER: EVERY 4 HOURS	Y-M: 20[redacted] / 83	Y-M: 20[redacted] / 89
PARACETAMOL	650 mg	OTHER: EVERY 6 HOURS	Y-M: 20[redacted] / 84	Y-M: 20[redacted] / 89
VANCOMYCIN	1.5 g	QD	Y-M: 20[redacted] / 85	ONGOING
HYDRALAZINE	10 mg	OTHER: EVERY 2 HOURS	Y-M: 20[redacted] / 87	Y-M: 20[redacted] / 89
AZITHROMYCIN	250 mg	QD	Y-M: 20[redacted] / 87	Y-M: 20[redacted] / 92
PRAVASTATIN	40 mg	QD	Y-M: 20[redacted] / 90	ONGOING
PREDNISONE	10 mg	QD	Y-M: 20[redacted] / 90	Y-M: 20[redacted] / 94
PREDNISONE	5 mg	QD	Y-M: 20[redacted] / 95	Y-M: 20[redacted] / 99

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

Event Description	PNEUMONIA
Preferred term	肺炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 69
Age at AE Onset	6[redacted]
Laboratory Testing	[redacted]20[redacted] (RX DAY 81): Eosinophils/Leukocytes: 1.2 [0.3 - 6.2] %; Leukocytes: 8.9 [4 - 11] 10^9/L; Lymphocytes: 1.2 [1.1 - 3.3] 10^9/L; Lymphocytes/Leukocytes: 13.1 [15.2 - 43.3] %; Monocytes: 0.7 [0.3 - 1.1] 10^9/L; Monocytes/Leukocytes: 8.1 [5.5 - 13.7] %; Neutrophils: 6.9 [2 - 6.7] 10^9/L; Neutrophils/Leukocytes: 77.4 [39.6 - 74.7] %; [redacted]20[redacted] (RX DAY 83): Eosinophils/Leukocytes: 0 [0.3 - 6.2] %; Leukocytes: 12.4 [4 - 11] 10^9/L; Lymphocytes: 0.6 [1.1 - 3.3] 10^9/L; Lymphocytes/Leukocytes: 5.1 [15.2 - 43.3] %; Monocytes: 0.2 [0.3 - 1.1] 10^9/L; Monocytes/Leukocytes: 1.8 [5.5 - 13.7] %; Neutrophils: 11.6 [2 - 6.7] 10^9/L; Neutrophils/Leukocytes: 93 [39.6 - 74.7] %; [redacted]20[redacted] (RX DAY 88): Leukocytes: 16.1 [4 - 11] 10^9/L

Microbiology	[redacted]20[redacted] (RX DAY 82): BLOOD NPTST021-BLOOD CULTURE: Positive-DIPHTHEROID BACILLI; BLOOD NPTST021-BLOOD CULTURE: Positive-METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 81): 2-VIEW CHEST X-RAY: 1. PATCHY PERIHILAR GROUND-GLASS AIR SPACE DISEASE WITH BRONCHIAL WALL THICKENING MAY REFLECT MILD BRONCHITIS/PNEUMONITIS. 2. QUESTION BACKGROUND OF MILD COPD/EMPHYSEMA; [redacted]20[redacted] (RX DAY 84): SINGLE-VIEW CHEST X-RAY: VASCULAR PROMINENCE AND INTERSTITIAL THICKENING WHICH IS SLIGHTLY WORSENED.; [redacted]20[redacted] (RX DAY 86): SINGLE-VIEW CHEST X-RAY: RIGHT UPPER EXTREMITY PICC TERMINATES OVER THE CAVOATRIAL JUNCTION. NO PNEUMOTHORAX IS SEEN. NO ACUTE CARDIOPULMONARY ABNORMALITY IS APPRECIATED. THE HEART IS NOT ENLARGED.; [redacted]20[redacted] (RX DAY 88): SINGLE-VIEW CHEST X-RAY: 1. NO ACUTE CARDIOPULMONARY PROCESS IDENTIFIED 2. STABLE RIGHT UPPER EXTREMITY PICC.
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Toxicity Grade	2
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	COPD AND CIGARETTE USE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #2: Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Event Description	ACUTE RESPIRATORY FAILURE
Preferred term	急性呼吸不全
AE Onset Date / Rx Day	[redacted]20[redacted] / 81 (10 DAYS AFTER LAST TREATMENT)
Age at AE Onset	6[redacted]
Laboratory Testing	[redacted]20[redacted] (RX DAY 81): Eosinophils/Leukocytes: 1.2 [0.3 - 6.2] %; Leukocytes: 8.9 [4 - 11] 10^9/L; Lymphocytes: 1.2 [1.1 - 3.3] 10^9/L; Lymphocytes/Leukocytes: 13.1 [15.2 - 43.3] %; Monocytes: 0.7 [0.3 - 1.1] 10^9/L; Monocytes/Leukocytes: 8.1 [5.5 - 13.7] %; Neutrophils: 6.9 [2 - 6.7] 10^9/L; Neutrophils/Leukocytes: 77.4 [39.6 - 74.7] %; [redacted]20[redacted] (RX DAY 83): Eosinophils/Leukocytes: 0 [0.3 - 6.2] %; Leukocytes: 12.4 [4 - 11] 10^9/L; Lymphocytes: 0.6 [1.1 - 3.3] 10^9/L; Lymphocytes/Leukocytes: 5.1 [15.2 - 43.3] %; Monocytes: 0.2 [0.3 - 1.1] 10^9/L; Monocytes/Leukocytes: 1.8 [5.5 - 13.7] %; Neutrophils: 11.6 [2 - 6.7] 10^9/L; Neutrophils/Leukocytes: 93 [39.6 - 74.7] %; [redacted]20[redacted] (RX DAY 88): Leukocytes: 16.1 [4 - 11] 10^9/L
Microbiology	[redacted]20[redacted] (RX DAY 82): BLOOD NPTST021-BLOOD CULTURE: Positive-DIPHTHEROID BACILLI; BLOOD NPTST021-BLOOD CULTURE: Positive-METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 81): 2-VIEW CHEST X-RAY: 1. PATCHY PERIHILAR GROUND-GLASS AIR SPACE DISEASE WITH BRONCHIAL WALL THICKENING MAY REFLECT MILD BRONCHITIS/PNEUMONITIS. 2. QUESTION BACKGROUND OF MILD COPD/EMPHYSEMA; [redacted]20[redacted] (RX DAY 84): SINGLE-VIEW CHEST X-RAY: VASCULAR PROMINENCE AND INTERSTITIAL THICKENING WHICH IS SLIGHTLY WORSENED.; [redacted]20[redacted] (RX DAY 86): SINGLE-VIEW CHEST X-RAY: RIGHT UPPER EXTREMITY PICC TERMINATES OVER THE CAVOATRIAL JUNCTION. NO PNEUMOTHORAX IS SEEN. NO ACUTE CARDIOPULMONARY ABNORMALITY IS APPRECIATED. THE HEART IS NOT

	ENLARGED.; [redacted]20[redacted] (RX DAY 88): SINGLE-VIEW CHEST X-RAY: 1. NO ACUTE CARDIOPULMONARY PROCESS IDENTIFIED 2. STABLE RIGHT UPPER EXTREMITY PICC.
AE Stopped Rx Day	89 (18 DAYS AFTER LAST TREATMENT)
Duration of AE	9 DAYS
Toxicity Grade	2
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	SECONDARY TO PNEUMONIA
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #3: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Event of Interest - Serious Infections

Event Description	SEPSIS WITH MRSA
Preferred term	ブドウ球菌性敗血症
AE Onset Date / Rx Day	[redacted]20[redacted] / 84 (13 DAYS AFTER LAST TREATMENT)
Age at AE Onset	6[redacted]
Laboratory Testing	[redacted]20[redacted] (RX DAY 81): Eosinophils/Leukocytes: 1.2 [0.3 - 6.2] %; Leukocytes: 8.9 [4 - 11] 10^9/L; Lymphocytes: 1.2 [1.1 - 3.3] 10^9/L; Lymphocytes/Leukocytes: 13.1 [15.2 - 43.3] %; Monocytes: 0.7 [0.3 - 1.1] 10^9/L; Monocytes/Leukocytes: 8.1 [5.5 - 13.7] %; Neutrophils: 6.9 [2 - 6.7] 10^9/L; Neutrophils/Leukocytes: 77.4 [39.6 - 74.7] %; [redacted]20[redacted] (RX DAY 83): Eosinophils/Leukocytes: 0 [0.3 - 6.2] %; Leukocytes: 12.4 [4 - 11] 10^9/L; Lymphocytes: 0.6 [1.1 - 3.3] 10^9/L; Lymphocytes/Leukocytes: 5.1 [15.2 - 43.3] %; Monocytes: 0.2 [0.3 - 1.1] 10^9/L; Monocytes/Leukocytes: 1.8 [5.5 - 13.7] %; Neutrophils: 11.6 [2 - 6.7] 10^9/L; Neutrophils/Leukocytes: 93 [39.6 - 74.7] %; [redacted]20[redacted] (RX DAY 88): Leukocytes: 16.1 [4 - 11] 10^9/L
Microbiology	[redacted]20[redacted] (RX DAY 82): BLOOD NPTST021-BLOOD CULTURE: Positive-DIPHTHEROID BACILLI; BLOOD NPTST021-BLOOD CULTURE: Positive-METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 81): 2-VIEW CHEST X-RAY: 1. PATCHY PERIHILAR GROUND-GLASS AIR SPACE DISEASE WITH BRONCHIAL WALL THICKENING MAY REFLECT MILD BRONCHITIS/PNEUMONITIS. 2. QUESTION BACKGROUND OF MILD COPD/EMPHYSEMA; [redacted]20[redacted] (RX DAY 84): SINGLE-VIEW CHEST X-RAY: VASCULAR PROMINENCE AND INTERSTITIAL THICKENING WHICH IS SLIGHTLY WORSENED.; [redacted]20[redacted] (RX DAY 86): SINGLE-VIEW CHEST X-RAY: RIGHT UPPER EXTREMITY PICC TERMINATES OVER THE CAVOATRIAL JUNCTION. NO PNEUMOTHORAX IS SEEN. NO ACUTE CARDIOPULMONARY ABNORMALITY IS APPRECIATED. THE HEART IS NOT ENLARGED.; [redacted]0[redacted] (RX DAY 88): SINGLE-VIEW CHEST X-RAY: 1. NO ACUTE CARDIOPULMONARY PROCESS IDENTIFIED 2. STABLE RIGHT UPPER EXTREMITY PICC.
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE

Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者は米国の 6[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，トリアムシノロンアセトニド及びヒドロコルチゾンを投与され，メチシリン耐性黄色ブドウ球菌（以下「MRSA」）性敗血症，肺炎及び急性呼吸不全を発現した。被験者は喫煙者（紙巻タバコ 10 本／日，40 年間）かつ非飲酒者であり，関連する病歴は喘息，季節性アレルギー，慢性閉塞性肺疾患，高血圧，高コレステロール血症，アトピー性皮膚炎，アレルギー性鼻炎であった。

20[redacted] 年[redacted] 月[redacted] 日，被験者は肺炎を発現した。20[redacted] 年[redacted] 月[redacted] 日，被験者は急性呼吸不全を発現した。20[redacted] 年[redacted] 月[redacted] 日，被験者は MRSA 性敗血症を発現した。20[redacted] 年[redacted] 月[redacted] 日，急性呼吸不全は消失した。

20[redacted] 年[redacted] 月[redacted] 日，被験者は入院した。入院当初の喀痰は緑色であったが，徐々に無色になった。被験者の訴えでは，喀痰を伴う咳嗽が 1 週間持続しており，胸痛，動悸及び失神する感覚はなかった。胸部 X 線像で肺門周囲の肺胞含気腔の斑状すりガラス病変及び気管支壁肥厚が認められ，軽度の気管支炎／肺臓炎が疑われた。血液培養の結果から敗血症と判断された。被験者は呼吸器科で併診され，内科治療を受けた。末梢挿入型中心静脈カテーテル（以下「PICC」）も留置された。PICC を介した抗生物質投与計画が立てられ，20[redacted] 年[redacted] 月[redacted] 日，被験者は退院した。

PULMICORT RESPULES，塩化ナトリウム，メチルプレドニゾロン，ZOFRAN，インフルエンザワクチン，グアイフェネシン，vancomycin，アセトアミノフェン，フルチカゾンフランカルボン酸エステル/vilanterol，albuterol，prednisone，INCRUSE ELLIPTA，formoterol，fluticasone，azithromycin，DUONEB 及び ROCEPHIN が投与された。

The patient's past medications include:

PREDNISONE for ATOPIC DERMATITIS (20[redacted] - 20[redacted], 20[redacted] - 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

METHOTREXATE for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

TRIAMCINOLONE for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABT-494 (Blinded)

---

1) Sepsis MRSA (10049253) (Staphylococcal sepsis (10056430)) [v.22.1] [10049253]

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

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

Dechallenge: Not Applicable

2) Pneumonia (10035664) (Pneumonia (10035664)) [v.22.1] [10035664]

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

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

Dechallenge: No

3) Acute respiratory failure (10001053) (Acute respiratory failure (10001053)) [v.22.1] [10001053]

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

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

Dechallenge: Not Applicable

Causality for TRIAMCINOLONE ACETONIDE (Open Label)

---

1) Sepsis MRSA (10049253) (Staphylococcal sepsis (10056430)) [v.22.1] [10049253]

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

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

Dechallenge: Not Applicable

2) Pneumonia (10035664) (Pneumonia (10035664)) [v.22.1] [10035664]

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

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

Dechallenge: Not Applicable

3) Acute respiratory failure (10001053) (Acute respiratory failure (10001053)) [v.22.1] [10001053]

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

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

Dechallenge: Not Applicable

Causality for HYDROCORTISONE (Open Label)

---

1) Sepsis MRSA (10049253) (Staphylococcal sepsis (10056430)) [v.22.1] [10049253]

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

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

Dechallenge: Not Applicable

2) Pneumonia (10035664) (Pneumonia (10035664)) [v.22.1] [10035664]

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

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

Dechallenge: Not Applicable

3) Acute respiratory failure (10001053) (Acute respiratory failure (10001053)) [v.22.1] [10001053]

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABT-494 (Blinded)

Event of SEPSIS WITH MRSA

- Investigator: NOT APPLICABLE

- AbbVie: EVENT IS MORE LIKELY A COMPLICATION FROM PRECEDING PNEUMONIA.

Event of PNEUMONIA

- Investigator: COPD and cigarette use

- AbbVie: RISK FACTORS INCLUDE CURRENT LONG TERM SMOKING HISTORY, PRE-EXISTING CHRONIC OBSTRUCTIVE PULMONARY DISEASE, AND PRE-EXISTING ASTHMA.

Event of ACUTE RESPIRATORY FAILURE

- Investigator: SECONDARY TO PNEUMONIA

- AbbVie: EVENT IS MORE LIKELY A COMPLICATION FROM PRECEDING PNEUMONIA.

Alternative Etiology for TRIAMCINOLONE ACETONIDE (Open Label)

Event of SEPSIS WITH MRSA

- Investigator: NOT REPORTED

- AbbVie: EVENT IS MORE LIKELY A COMPLICATION FROM PRECEDING PNEUMONIA.

Event of PNEUMONIA

- Investigator: LOCAL FACTORS RAIN AND COLD.

- AbbVie: RISK FACTORS INCLUDE CURRENT LONG TERM SMOKING HISTORY, PRE-EXISTING CHRONIC OBSTRUCTIVE PULMONARY DISEASE, AND PRE-EXISTING ASTHMA.

Event of ACUTE RESPIRATORY FAILURE

- Investigator: SECONDARY TO PNEUMONIA

- AbbVie: EVENT IS MORE LIKELY A COMPLICATION FROM PRECEDINGPNEUMONIA.

Alternative Etiology for HYDROCORTISONE (Open Label)

Event of SEPSIS WITH MRSA

- Investigator: NOT REPORTED

- AbbVie: EVENT IS MORE LIKELY A COMPLICATION FROM PRECEDING PNEUMONIA.

Event of PNEUMONIA

- Investigator: LOCAL FACTORS RAIN AND COLD.

- AbbVie: RISK FACTORS INCLUDE CURRENT LONG TERM SMOKING HISTORY, PRE-EXISTING CHRONIC OBSTRUCTIVE PULMONARY DISEASE, AND PRE-EXISTING ASTHMA.

Event of ACUTE RESPIRATORY FAILURE

- Investigator: SECONDARY TO PNEUMONIA

- AbbVie: EVENT IS MORE LIKELY A COMPLICATION FROM PRECEDING PNEUMONIA.

RISK/BENEFIT STATEMENT:

There is no change to the risk/benefit profile for this study/product as a result of this individual report/event(s).

Relevant Laboratory & Other Diagnostic Tests

[redacted] **2-VIEW CHEST X-RAY:** 1. PATCHY PERIHILAR GROUND-GLASS AIR SPACE DISEASE WITH BRONCHIAL WALL THICKENING MY REFLECT MILD BRONCHITIS/PNEUMONITIS.2. QUESTION BACKGROUND OF MILD COPD/EMPHYSEMA

[redacted] **BLOOD CULTURE:** METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS

[redacted] **CHEST X-RAY:** normal

[redacted] **20[redacted] EOSINOPHILS %:** 1.2 % (normal 0.3 to 6.2)

[redacted] **20[redacted] EOSINOPHILS %:** 0.0 % (normal 0.3 to 6.2)

[redacted] **20[redacted] LYMPHOCYTES %:** 13.1 % (normal 15.2 to 43.3)

[redacted] **20[redacted] LYMPHOCYTES %:** 5.1 % (normal 15.2 to 43.3)

[redacted] **20[redacted] LYMPHOCYTES ABS:** 1.2 10^3/uL (normal 1.1 to 3.3)

[redacted] **20[redacted] LYMPHOCYTES ABS:** 0.6 10^3/uL (normal 1.1 to 3.3)

[redacted] **20[redacted] MONOCYTES %:** 8.1 % (normal 5.5 to 13.7)

[redacted] **20[redacted] MONOCYTES %:** 1.8 % (normal 5.5 to 13.7)

[redacted] **20[redacted] MONOCYTES ABS:** 0.7 10^3/uL (normal 0.3 to 1.1)

[redacted] **20[redacted] MONOCYTES ABS:** 0.2 10^3/uL (normal 0.3 to 1.1)

[redacted] **20[redacted] NEUTROPHILS %:** 77.4 % (normal 39.6 to 74.7)

[redacted] **20[redacted] NEUTROPHILS %:** 93.0 % (normal 39.6 to 74.7)

[redacted] **20[redacted] NEUTROPHILS ABS:** 6.9 X10**3/MM**3 (normal 2.0 to 6.7)

[redacted] **20[redacted] NEUTROPHILS ABS:** 11.6 X10**3/MM**3 (normal 2.0 to 6.7)

[redacted] **20[redacted] SINGLE-VIEW CHEST X-RAY:** VASCULAR PROMINENCE AND INTERSTITIAL THICKENING, WHICH IS SLIGHTLY WORSENED.

[redacted] **20[redacted] SINGLE-VIEW CHEST X-RAY:** RIGHT UPPER EXTREMITY PICC TERMINATES OVER THE CAVOATRIAL JUNCTION. NO PNEUMOTHORAX IS SEEN. NO ACUTE CARDIOPULMONARY ABNORMALITY IS APPRECIATED. THE HEART IS NOT ENLARGED.

[redacted] **20[redacted] SINGLE-VIEW CHEST X-RAY:** 1. NO ACUTE CARDIOPULMONARY PROCESS IDENTIFIED 2. STABLE RIGHT UPPER EXTREMITY PICC.

[redacted] **20[redacted] BLOOD CULTURE:** Positive DIPHTHEROID BACILLI

[redacted] **20[redacted] WHITE BLOOD CELLS:** 8.9 10^3/uL (normal 4.0 to 11.0)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 12.4 10^3/uL (normal 4.0 to 11.0)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 16.1 10^3/uL (normal 4.0 to 11.0)

Subject [redacted] ([redacted])

Reason for Narrative

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

Treatment Group	Age at Study Start	Sex	Race
UPA 15 MG QD	6[redacted]	MALE	WHITE

Medical History	Onset Year
ATOPIC DERMATITIS	19[redacted]
PET DANDER ALLERGY	19
POLEN ALLERGY	19
CERVICAL SPINAL STENOSIS	20
ANXIETY	20
DEPRESSION	20
INTERMITTENT HYPERTENSION	20
HERNIA	20
SQUAMOUS CELL CARCINOMA (NMSC)	20
LEFT HIP PAIN	20

Prior Procedures	Procedure Year
PRIOR PROCEDURES: SURGICAL DECOMPRESSION	20[redacted]
PRIOR PROCEDURES: HERNIOPLASTY	20
PRIOR PROCEDURES: EXCISIONAL SURGERY	20

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	20 CIGARETTE	5	20[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	More than 4

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
UPA	15 MG	ORAL	QD	[redacted] / 1	[redacted] / 104	104

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
VITAMINS NOS	1 OTHER: CAP	QD	Y: 20[redacted]
ALL OTHER NON-THERAPEUTIC PRODUCTS	40 OTHER: SESSIONS	OTHER: 3 TIMES PER WEEK	Y: 20[redacted]
DOXEPIN	25 mg	QD	Y: 20[redacted]
PREDNISONE	10 mg	QD	Y: 20[redacted]
TRIAMCINOLONE	0.1 %	BID	Y: 20[redacted]
AQUAPHOR	1 OTHER: APPLICATION	BID	Y: 20[redacted]
BUPROPION	50 mg	QD	Y: 20[redacted]
IBUPROFEN	200 mg	QD	Y-M: 20[redacted] / -320

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
VITAMINS NOS	1 OTHER: CAP	QD	Y: 20[redacted]	ONGOING
DOXEPIN	25 mg	QD	Y: 20[redacted]	ONGOING
AQUAPHOR	1 OTHER: APPLICATION	BID	Y: 20[redacted]	ONGOING
BUPROPION	50 mg	QD	Y: 20[redacted]	ONGOING
IBUPROFEN	200 mg	QD	Y-M: 20[redacted] / -320	ONGOING
BISMUTH	30 mL	PRN	Y-M: 20[redacted] / 41	ONGOING
IBUPROFEN	600 mg	PRN	Y-M: 20[redacted] / 100	ONGOING
PARACETAMOL	650 mg	PRN	Y-M: 20[redacted] / 100	ONGOING
OXYCODONE	5 mg	PRN	Y-M: 20[redacted] / 100	Y-M: 20[redacted] / 102

Event #1: Serious Adverse Event

Event Description	PLEURAL EFFUSION
Preferred term	胸水
AE Onset Date / Rx Day	[redacted] / 100
Age at AE Onset	6[redacted]
Laboratory Testing	NOT REPORTED
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted] (RX DAY 100): CHEST X-RAY: PER SUBJECT REPORT, CXR SHOWED FLUID AROUND LUNGS
AE Stopped Rx Day	102
Duration of AE	3 DAYS
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE

Investigator Alternative Etiology NOT REPORTED
Discontinued Study Drug Due to the Event NO
SAE Criteria REQUIRES OR PROLONGS HOSPITALIZATION

Generated [redacted]
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者は米国の 6[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，トリアムシノロンアセトニド及びヒドロコルチゾンを投与され，胸水を発現した。被験者は元喫煙者（紙巻タバコ 20 本／日，5 年間）かつ飲酒者（4 杯超／日）であり，関連する病歴はアトピー性皮膚炎，間欠性高血圧，非黒色腫皮膚癌，扁平上皮癌であった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は胸水を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，胸水は消失した。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は息切れ及び胸部不快感の症状で入院した。被験者によれば，胸部 X 線検査を受けたところ肺周囲に胸水が認められ，その後胸水のドレナージ及び疼痛に対する治療を受けた。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

The patient's past medications include:

PREDNISONE for ATOPIC DERMATITIS (20[redacted] - 20[redacted])

TRIAMCINOLONE for ATOPIC DERMATITIS (20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Pleural effusion (10035598) (Pleural effusion (10035598)) [v.22.1] [10035598]

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

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

Dechallenge: Not Applicable

Causality for TRIAMCINOLONE ACETONIDE (Open Label)

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1) Pleural effusion (10035598) (Pleural effusion (10035598)) [v.22.1] [10035598]

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

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

Dechallenge: Not Applicable

Causality for HYDROCORTISONE (Open Label)

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1) Pleural effusion (10035598) (Pleural effusion (10035598)) [v.22.1] [10035598]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of PLEURAL EFFUSION

- Investigator: Not applicable.

- AbbVie: Event with multiple underlying etiologies.

Alternative Etiology for TRIAMCINOLONE ACETONIDE (Open Label)

Event of PLEURAL EFFUSION

- Investigator: More likely related to Upadacitinib/placebo.

- AbbVie: Lack of temporal association with last dose of study drug close to 10 weeks prior to onset of event .

Alternative Etiology for HYDROCORTISONE (Open Label)

Event of PLEURAL EFFUSION

- Investigator: More likely related to Upadacitinib/placebo.

- AbbVie: Lack of temporal association with last dose of study drug close to 9 weeks prior to onset of event .

RISK/BENEFIT STATEMENT:

There is no change to the risk/benefit profile for this study/product as a result of this individual report/event(s).

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CHEST XRAY:** Fluid around lungs

Subject [redacted] ([redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
急性腎障害				X
水腎症	X			
腎結石症	X			
肺炎	X			X
潰瘍性角膜炎	X			X

Treatment Group	Age at Study Start	Sex	Race
UPA 15 MG QD/UPA 15 MG QD	3[redacted]	MALE	WHITE

Medical History	Onset Year
ATOPIC DERMATITIS	19[redacted]
NECK PAIN	20[redacted]
CHOLECYSTITIS	20[redacted]
RUL PULMONARY NODULE	20[redacted]
HERPES SIMPLEX VIRUS INFECTION LEFT CORNEA	20[redacted]
LEFT CORNEAL ULCER	20[redacted]

Prior Procedures	Procedure Year
PRIOR PROCEDURES: CERVICAL FUSION	20[redacted]
PRIOR PROCEDURES: CHOLECYSTECTOMY	20[redacted]
PRIOR PROCEDURES: BRONCHOSCOPY	20[redacted]

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

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	2 - 4

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
UPA	15 MG	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 115	115
UPA	15 MG	ORAL	QD	[redacted]20[redacted] / 116		

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
METHOTREXATE	12.5 mg	1 TIME PER WEEK	Y-M: 20[redacted]
PIMECROLIMUS	1 OTHER: APPLICATION	BID	Y: 20[redacted]
TRIAMCINOLONE	1 OTHER: APPLICATION	BID	Y: 20[redacted]
MYCOPHENOLIC ACID	1000 mg	BID	Y-M: 20[redacted]
AZATHIOPRINE	100 mg	QD	Y-M: 20[redacted]
APREMILAST	30 mg	BID	Y-M: 20[redacted] / -158
OTHER EMOLLIENTS AND PROTECTIVES	N/A OTHER: N/A	BID	Y-M: 20[redacted] / -12

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
OTHER EMOLLIENTS AND PROTECTIVES	N/A OTHER: N/A	BID	Y-M: 20[redacted] / -12	NOT REPORTED
KETOROLAC	15 mg	OTHER: ONCE	Y-M: 20[redacted] / 93	Y-M: 20[redacted] / 93
METHYLPREDNISOLONE	125 mg	OTHER: ONCE	Y-M: 20[redacted] / 93	Y-M: 20[redacted] / 93
ONDANSETRON	4 mg	OTHER: ONCE	Y-M: 20[redacted] / 93	Y-M: 20[redacted] / 93
SODIUM CHLORIDE	1000 mL	OTHER: ONCE	Y-M: 20[redacted] / 93	Y-M: 20[redacted] / 93
PREDNISONE	20 mg	BID	Y-M: 20[redacted] / 93	Y-M: 20[redacted] / 95
HYDROMORPHONE	1 mg	OTHER: Q3H PRN	Y-M: 20[redacted] / 95	Y-M: 20[redacted] / 97

ENOXAPARIN	40 mg	QD	Y-M: 20[redacted]-[redacted] / 95	Y-M: 20[redacted]-[redacted] / 98
FLEBOBAG RING LACT	1000 mL	OTHER: NOT SPECIFIED	Y-M: 20[redacted]-[redacted] / 95	Y-M: 20[redacted]-[redacted] / 98
ONDANSETRON	4 mg	OTHER: Q4H, PRN	Y-M: 20[redacted]-[redacted] / 95	Y-M: 20[redacted]-[redacted] / 98
OXYCODONE	5 mg	OTHER: Q4H, PRN	Y-M: 20[redacted]-[redacted] / 95	Y-M: 20[redacted]-[redacted] / 98
PARACETAMOL	325 mg	OTHER: Q4H, PRN	Y-M: 20[redacted]-[redacted] / 95	Y-M: 20[redacted]-[redacted] / 98
LIDOCAINE	2 %	OTHER: ONE TIME	Y-M: 20[redacted]-[redacted] / 96	Y-M: 20[redacted]-[redacted] / 96
DOCUSATE	100 mg	QD	Y-M: 20[redacted]-[redacted] / 96	Y-M: 20[redacted]-[redacted] / 98
LEVOFLOXACIN	500 mg	QD	Y-M: 20[redacted]-[redacted] / 96	Y-M: 20[redacted]-[redacted] / 98
SODIUM CHLORIDE	1000 mL	OTHER: NOT SPECIFIED	Y-M: 20[redacted]-[redacted] / 96	Y-M: 20[redacted]-[redacted] / 98
MORPHINE	2 mg	OTHER: Q4H, PRN	Y-M: 20[redacted]-[redacted] / 97	Y-M: 20[redacted]-[redacted] / 98
OXYCOCET	5-325 mg	TID	Y-M: 20[redacted]-[redacted] / 98	Y-M: 20[redacted]-[redacted] / 105
EYE STREAM	15 mL	OTHER: ONE TIME	Y-M: 20[redacted]-[redacted] / 228	Y-M: 20[redacted]-[redacted] / 228
FLUORESCEIN	1 mg	OTHER: ONE TIME	Y-M: 20[redacted]-[redacted] / 228	Y-M: 20[redacted]-[redacted] / 228
TETRACAINE	0.5 %	OTHER: ONE TIME	Y-M: 20[redacted]-[redacted] / 228	Y-M: 20[redacted]-[redacted] / 228
PARACETAMOL	650 mg	OTHER: EVERY 4 HOURS AS NEEDED	Y-M: 20[redacted]-[redacted] / 229	Y-M: 20[redacted]-[redacted] / 229
TOBRAMYCIN	15 OTHER: MG/ML	OTHER: Q1H	Y-M: 20[redacted]-[redacted] / 229	Y-M: 20[redacted]-[redacted] / 230
VANCOMYCIN	50 OTHER: MG/ML	OTHER: Q1H	Y-M: 20[redacted]-[redacted] / 229	Y-M: 20[redacted]-[redacted] / 230
ENOXAPARIN	40 mg	QD	Y-M: 20[redacted]-[redacted] / 229	Y-M: 20[redacted]-[redacted] / 231

OXYCOCET	5-325 mg	OTHER: EVERY 6 HOURS AS NEEDED	Y-M: 20[redacted] / 229	Y-M: 20[redacted] / 231
ACICLOVIR	400 mg	OTHER: 5 TIMES DAILY	Y-M: 20[redacted] / 229	Y-M: 20[redacted] / 233
ATROPINE	1 %	BID	Y-M: 20[redacted] / 229	Y-M: 20[redacted] / 249
TOBRAMYCIN	15 OTHER: MG/ML	OTHER: Q1H WHILE AWAKE	Y-M: 20[redacted] / 230	Y-M: 20[redacted] / 231
VANCOMYCIN	50 OTHER: MG/ML	OTHER: Q1H WHILE AWAKE	Y-M: 20[redacted] / 230	Y-M: 20[redacted] / 231
PROCHLORPERAZINE	10 mg	OTHER: EVERY 6 HOURS AS NEEDED	Y-M: 20[redacted] / 231	Y-M: 20[redacted] / 231
TOBRAMYCIN	0.3 %	OTHER: EVERY 2 HOURS WHILE AWAKE	Y-M: 20[redacted] / 231	Y-M: 20[redacted] / 233
VANCOMYCIN	50 OTHER: MG/ML	OTHER: EVERY 2 HOURS WHILE AWAKE	Y-M: 20[redacted] / 231	Y-M: 20[redacted] / 233
OXYCOCET	5-325 mg	OTHER: EVERY 4 HOURS AS NEEDED	Y-M: 20[redacted] / 231	Y-M: 20[redacted] / 236
TOBRAMYCIN	0.3 %	OTHER: 6 TIMES PER DAY	Y-M: 20[redacted] / 233	Y-M: 20[redacted] / 240
VANCOMYCIN	50 OTHER: MG/ML	OTHER: 6 TIMES PER DAY	Y-M: 20[redacted] / 233	Y-M: 20[redacted] / 240
ACICLOVIR	400 mg	BID	Y-M: 20[redacted] / 233	Y-M: 20[redacted] / 400
OFLOXACIN	0.3 %	OTHER: 6 TIMES PER DAY	Y-M: 20[redacted] / 240	Y-M: 20[redacted] / 249
POLYMYXIN B W/TRIMETHOPRIM	10000 - 0.1 OTHER: UNIT/ML - %	OTHER: 6 TIMES PER DAY	Y-M: 20[redacted] / 240	Y-M: 20[redacted] / 249
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 240	Y-M: 20[redacted] / 281
OFLOXACIN	0.3 %	QID	Y-M: 20[redacted] / 249	Y-M: 20[redacted] / 263
POLYMYXIN B W/TRIMETHOPRIM	10000 - 0.1 OTHER: UNIT/ML - %	QID	Y-M: 20[redacted] / 249	Y-M: 20[redacted] / 263
OFLOXACIN	0.3 %	BID	Y-M: 20[redacted] / 263	Y-M: 20[redacted] / 400

POLYMYXIN B W/TRIMETHOPRIM	10000 - 0.1 OTHER: UNIT/ML - %	BID	Y-M: 20[redacted] / 263	Y-M: 20[redacted] / 400
CEFTRIAXONE	1000 mg	OTHER: UNK	Y-M: 20[redacted] / 365	Y-M: 20[redacted] / 365
IOPAMIDOL	75 mL	OTHER: ONCE	Y-M: 20[redacted] / 365	Y-M: 20[redacted] / 365
MAGNESIUM SULFATE	2 g	OTHER: UNK	Y-M: 20[redacted] / 365	Y-M: 20[redacted] / 365
COMBIVENT	0.5-2.5/3 OTHER: MG/ML	OTHER: Q4H WHILE AWAKE	Y-M: 20[redacted] / 365	Y-M: 20[redacted] / 368
METHYLPREDNISOLONE	125 mg	OTHER: UNK	Y-M: 20[redacted] / 365	Y-M: 20[redacted] / 368
ALUMINIUM W/MAGNESIUM HYDROXIDE/SIMETICONE	30 mL	OTHER: Q4H, PRN	Y-M: 20[redacted] / 366	Y-M: 20[redacted] / 368
AZITHROMYCIN	UNKNOWN OTHER: UNK	PRN	Y-M: 20[redacted] / 366	Y-M: 20[redacted] / 368
CEFTRIAXONE	2000/50 OTHER: MG/ML	OTHER: UNKNOWN	Y-M: 20[redacted] / 366	Y-M: 20[redacted] / 368
ENOXAPARIN	40 mg	QD	Y-M: 20[redacted] / 366	Y-M: 20[redacted] / 368
MAGNESIUM HYDROXIDE	30 mL	OTHER: QD, PRN	Y-M: 20[redacted] / 366	Y-M: 20[redacted] / 368
ONDANSETRON	4 mg	OTHER: Q4H, PRN	Y-M: 20[redacted] / 366	Y-M: 20[redacted] / 368
PARACETAMOL	650 mg	OTHER: Q4H, PRN	Y-M: 20[redacted] / 366	Y-M: 20[redacted] / 368
SALBUTAMOL	2.5/3 OTHER: MG/ML	OTHER: Q2H	Y-M: 20[redacted] / 366	Y-M: 20[redacted] / 368
BUDESONIDE	0.5/2 OTHER: MG/ML	BID	Y-M: 20[redacted] / 367	Y-M: 20[redacted] / 368
GUAIFENESIN	1200 MG mg	OTHER: Q12H	Y-M: 20[redacted] / 367	Y-M: 20[redacted] / 368
KETOROLAC	15/1 OTHER: MG/ML	OTHER: Q6H, PRN	Y-M: 20[redacted] / 367	Y-M: 20[redacted] / 368
FLUTICASONE	44 OTHER: MCG/INHALATION	BID	Y-M: 20[redacted] / 368	Y-M: 20[redacted] / 383

PREDNISONE	10 mg	QD	Y-M: 20[redacted] / 369 — Y-M: 20[redacted] / 374
LEVOFLOXACIN	750 mg	QD	Y-M: 20[redacted] / 369 — Y-M: 20[redacted] / 383
ACICLOVIR	400 mg	OTHER: 4 TIMES PER DAY	Y-M: 20[redacted] / 400 — Y-M: 20[redacted] / 442
OFLOXACIN	0.3 %	OTHER: 1 DROP IN LEFT EYE 6 TIMES PER DAY	Y-M: 20[redacted] / 400 — Y-M: 20[redacted] / 442
POLYMYXIN B W/TRIMETHOPRIM	10000 - 0.1 OTHER: UNIT/ML - %	OTHER: 1 DROP IN BOTH EYES 6 TIMES PER DAY	Y-M: 20[redacted] / 400 — Y-M: 20[redacted] / 442
ACICLOVIR	400 mg	BID	Y-M: 20[redacted] / 442 — NOT REPORTED
OFLOXACIN	0.3 %	BID	Y-M: 20[redacted] / 442 — NOT REPORTED
POLYMYXIN B W/TRIMETHOPRIM	10000 - 0.1 OTHER: UNIT/ML - %	BID	Y-M: 20[redacted] / 442 — NOT REPORTED

Event #1: Serious Adverse Event

Event Description	RENAL CALCULI W/ HYDRONEPHROSIS
Preferred term	水腎症
AE Onset Date / Rx Day	[redacted]20[redacted] / 93
Age at AE Onset	3[redacted]
Laboratory Testing	[redacted]20[redacted] (RX DAY 93): NPTST145-UA BLOOD: MODERATE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 96): Creatinine: 139 [53 - 115] UMOL/L; [redacted]20[redacted] (RX DAY 97): Creatinine: 78 [53 - 115] UMOL/L; [redacted]20[redacted] (RX DAY 98): Creatinine: 80 [53 - 115] UMOL/L
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 93): CT ABD/PEL W/ CONTRAST: NO ACUTE INTRA-ABDOMINAL ABNORMALITY; ECG: SINUS BRADYCARDIA WITH SINUS ARRHYTHMIA; [redacted]20[redacted] (RX DAY 95): CT ABD/PEL W/O CONTRAST: MODERATE TO SEVERE LEFT HYDRONEPHROSIS SECONDARY TO 4MM DISTAL LEFT URETERAL CALCULUS, JUST PROXIMAL TO THE LEFT URETEROVESICULAR JUNCTION. NON-OBSTRUCTING 1 MM LEFT INTRARENAL CALCULUS NO RIGHT-SIDED NEPHROLITHIASIS; [redacted]20[redacted] (RX DAY 96): CYSTOSCOPY/URETEROSCOPY WITH STONE REMOVAL AND STENT PLACEMENT: STENT PLACED; FLUOROSCOPY: CANNULATION OF THE LEFT URETER VIA RETROGRADE BLADDER ACCESS WITH INSTILLATION OF WATER SOLUBLE CONTRAST. A WIRE IS EXTENDED PROXIMAL TO THE OBSTRUCTING DISTAL CALCULUS WITH CONTRAST INSTALLATION DEMONSTRATING URETERAL DISTENTION AND HYDRONEPHROSIS WHICH APPEARS STABLE COMPARED TO THE PRIOR CT
AE Stopped Rx Day	98
Duration of AE	6 DAYS
Toxicity Grade	3

Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	UNKNOWN - PER SUB-I, EVENT COULD POSSIBLY HAVE BEEN CAUSED BY DEHYDRATION
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #2: Serious Adverse Event

Event Description	RENAL CALCULI W/ HYDRONEPHROSIS
Preferred term	腎結石症
AE Onset Date / Rx Day	[redacted]20[redacted] / 93
Age at AE Onset	3[redacted]
Laboratory Testing	[redacted]20[redacted] (RX DAY 93): NPTST145-UA BLOOD: MODERATE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 96): Creatinine: 139 [53 - 115] UMOL/L; [redacted]20[redacted] (RX DAY 97): Creatinine: 78 [53 - 115] UMOL/L; [redacted]20[redacted] (RX DAY 98): Creatinine: 80 [53 - 115] UMOL/L
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 93): CT ABD/PEL W/ CONTRAST: NO ACUTE INTRA-ABDOMINAL ABNORMALITY; ECG: SINUS BRADYCARDIA WITH SINUS ARRHYTHMIA; [redacted]20[redacted] (RX DAY 95): CT ABD/PEL W/O CONTRAST: MODERATE TO SEVERE LEFT HYDRONEPHROSIS SECONDARY TO 4MM DISTAL LEFT URETERAL CALCULUS, JUST PROXIMAL TO THE LEFT URETEROVESICULAR JUNCTION. NON-OBSTRUCTING 1 MM LEFT INTRARENAL CALCULUS NO RIGHT-SIDED NEPHROLITHIASIS; [redacted]20[redacted] (RX DAY 96): CYSTOSCOPY/URETEROSCOPY WITH STONE REMOVAL AND STENT PLACEMENT: STENT PLACED; FLUOROSCOPY: CANNULATION OF THE LEFT URETER VIA RETROGRADE BLADDER ACCESS WITH INSTILLATION OF WATER SOLUBLE CONTRAST. A WIRE IS EXTENDED PROXIMAL TO THE OBSTRUCTING DISTAL CALCULUS WITH CONTRAST INSTALLATION DEMONSTRATING URETERAL DISTENTION AND HYDRONEPHROSIS WHICH APPEARS STABLE COMPARED TO THE PRIOR CT
AE Stopped Rx Day	98
Duration of AE	6 DAYS
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	UNKNOWN - PER SUB-I, EVENT COULD POSSIBLY HAVE BEEN CAUSED BY DEHYDRATION
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #3: Event of Interest - Renal Dysfunction

Event Description	ACUTE KIDNEY INJURY
Preferred term	急性腎障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 96

Age at AE Onset	3[redacted]
Laboratory Testing	NOT APPLICABLE
Microbiology	NOT APPLICABLE
SAE Supplemental Procedure	NOT APPLICABLE
AE Stopped Rx Day	97
Duration of AE	2 DAYS
Toxicity Grade	1
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Serious Adverse Event, Event of Interest - Serious Infections

Event Description	CORNEAL ULCER - LEFT
Preferred term	潰瘍性角膜炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 222
Age at AE Onset	3[redacted]
Laboratory Testing	NOT REPORTED
Microbiology	[redacted]20[redacted] (RX DAY 228): OTHER EYE SMEAR NPTST018-BACTERIAL CULTURE: Positive-ONE COLONY CORYNEBACTERIUM STRIATUM; OTHER LEFT CORNEA SWAB NPTST068-HERPES SIMPLEX VIRUS PCR, VARIES: Positive-HSV POSITIVE
SAE Supplemental Procedure	NOT REPORTED
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Toxicity Grade	4
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #5: Serious Adverse Event, Event of Interest - Serious Infections

Event Description	RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS, OTHER, PNEUMONIA
Preferred term	肺炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 362
Age at AE Onset	3[redacted]
Laboratory Testing	NOT REPORTED
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 365): CHEST CT: HYPEREXPANDED LUNG VOLUME. MILD MEDIAL ANTERIOR RIGHT UPPER LOB PATCHY GROUND-GLASS OPACITIES.; CHEST X-RAY: NO ACUTE PULMONARY PROCESS; [redacted]20[redacted] (RX DAY 366): EKG: NORMAL ECG - OVERALL STABLE FROM PRIOR [redacted] 20[redacted]
AE Stopped Rx Day	383
Duration of AE	22 DAYS
Toxicity Grade	3

Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者は米国の 3[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬及びトリアムシノロンアセトニドを投与され，水腎症を伴う腎結石を発現した。被験者は元喫煙者（紙巻タバコ 10 本／日，10 年間），元噛みタバコ使用者かつ元飲酒者（2～4 杯／日）であり，関連する病歴はアトピー性皮膚炎であった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は水腎症を伴う腎結石を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，水腎症を伴う腎結石は消失した。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は救急治療室を受診し，左側の腹痛を訴えた。検尿で血尿が認められ，被験者は救急治療室でメチルプレドニゾロン，オンダンセトロン，Toradol 及び生理食塩液のボーラス投与を受けてから prednisone の処方を受けて帰宅した。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は左側の腹部痛及び潮紅の症状で入院した。静脈内輸液及び鎮痛薬の静脈内投与が行われた。コンピュータ断層撮影が行われ，4 mm 径の尿管結石とその続発症である中等度から重度の左側水腎症が認められた。20[redacted] 年 [redacted] 月 [redacted] 日，X 線透視撮影検査で左側の遠位尿管結石が認められた。同日，膀胱鏡検査，逆行性腎盂造影，尿管鏡検査，ホルミウムレーザー及びバスケットカテーテルによる結石除去操作並びにステント留置が行われた。被験者は急性腎障害（非重篤）も発現し，クレアチニン値は 1.57 mg/dL であった。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院し，泌尿器科及びかかり付け医の経過観察を受けた。

MORPHINE PRESERVATIVE FREE，TORADOL，DILAUDID，PERCOCET，LEVAQUIN，乳酸リンゲル液，メチルプレドニゾロン，PERCOCET，oxycodone，オンダンセトロン，アセトアミノフェン，morphine，DOCUSATE，enoxaparin，リドカイン及び prednisone が投与された。

The patient's past medications include:

METHOTREXATE for ATOPIC DERMATITIS ([redacted] [redacted] 20[redacted] - [redacted] 20[redacted])

ELIDEL for ATOPIC DERMATITIS (20[redacted] - [redacted] 20[redacted])

KENALOG for ATOPIC DERMATITIS (20[redacted] - [redacted] 20[redacted])

CELLCEPT for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

IMURAN for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

OTEZLA for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Renal calculi (10038385) (Nephrolithiasis (10029148)) [v.23.0] [10038385]

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

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

Dechallenge: Not Applicable

2) Hydronephrosis (10020524) (Hydronephrosis (10020524)) [v.23.0] [10020524]

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

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

Dechallenge: Not Applicable

Causality for TRIAMCINOLONE ACETONIDE (Open Label)

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1) Renal calculi (10038385) (Nephrolithiasis (10029148)) [v.23.0] [10038385]

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

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

Dechallenge: Not Applicable

2) Hydronephrosis (10020524) (Hydronephrosis (10020524)) [v.23.0] [10020524]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of RENAL CALCULI W/ HYDRONEPHROSIS

- Investigator: UNKNOWN - PER SUB-I, EVENT COULD POSSIBLY HAVE BEEN CAUSED BY DEHYDRATION

- AbbVie: Renal stone disease is a common event in the male population with an estimated 19 percent of men diagnosed with a kidney stone by the age of 70 years. Hydronephrosis is more likely related to left sided renal calculus.

Alternative Etiology for TRIAMCINOLONE ACETONIDE (Open Label)

Event of RENAL CALCULI W/ HYDRONEPHROSIS

- Investigator: UNKNOWN - PER SUB-I, EVENT COULD POSSIBLY HAVE BEEN CAUSED BY DEHYDRATION

- AbbVie: Renal stone disease is a common event in the male population with an estimated 19 percent of men diagnosed with a kidney stone by the age of 70 years. Hydronephrosis is more likely related to left sided renal calculus.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CBC:** No clinical significant.

[redacted] **20[redacted] CMP:** No clinical significant.

[redacted] **20[redacted] CREATININE:** 1.57 mg/dL (normal 0.60 to 1.30)

[redacted] **20[redacted] CREATININE:** 0.88 mg/dL (normal 0.60 to 1.30)

[redacted] **20[redacted] CREATININE:** 0.90 mg/dL (normal 0.60 to 1.30)

[redacted] **20[redacted] CT ABDOMEN AND PELVIS:** Moderate to severe left sided hydronephrosis secondary to a 4mm ureteral calculus, just proximal to the left ureterovesicular junction. Non-obstructing 1 mm left intrarenal

calculus No right-sided nephrolithiasis

[redacted] **20[redacted] CT ABDOMEN AND PELVIS WITH CONTRAST:** No acute intra-abdominal abnormality

[redacted] **20[redacted] ECG:** Sinus bradycardia with sinus arrhythmia.

[redacted] **20[redacted] FLUOROSCOPY:** Cannulation of the left ureter via retrograde bladder access with instillation of water soluble contrast. A wire is extended proximal to the obstructing distal calculus with contrast installation demonstrating ureteral distention and hydronephrosis which appears stable compared to the prior CT

[redacted] **20[redacted] UA BLOOD:** Negative

[redacted] **20[redacted] URINALYSIS:** Hematuria.

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者は米国の 3[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬及びトリアムシノロンアセトニドを投与され，角膜潰瘍（左眼）を発現した。被験者は元喫煙者（紙巻タバコ 0.5 箱／日，10 年間），元噛みタバコ使用者かつ元飲酒者（2～4 杯／日）であり，関連する病歴はアトピー性皮膚炎及び左眼の角膜潰瘍であった。

被験者は本試験開始時の 16 週間の二重盲検投与期に参加していた。20[redacted] 年[redacted] 月[redacted] 日，被験者は盲検継続投与期に移行し，盲検下でウパダシチニブ投与が開始された。

20[redacted] 年[redacted] 月[redacted] 日，被験者は角膜潰瘍（左眼）を発現した。

20[redacted] 年[redacted] 月[redacted] 日，被験者は左眼の眼痛，発赤，羞明及び霧視を発現した。詳しい診察のため，被験者は救急治療室に案内された。同日，被験者は帰宅した。治験責任医師の報告によれば，被験者は処方薬を何も使用せず，20[redacted] 年[redacted] 月[redacted] 日に救急治療室を再受診して同じ症状を訴えた。フルオレセイン及び tetracaine が投与され，眼洗浄が行われた。被験者は臨床検査を受け，角膜潰瘍と診断された。20[redacted] 年[redacted] 月[redacted] 日，被験者は入院し，抗生物質及び抗ウイルス治療を投与された。20[redacted] 年[redacted] 月[redacted] 日，視力検査が行われ，左眼視力は 20/200（0.1 相当）と判定された。20[redacted] 年[redacted] 月[redacted] 日，被験者は退院した。

被験者の申告では，20[redacted] 年に眼外傷を受傷した。また，20[redacted] 年に角膜潰瘍と診断され，単純ヘルペスウイルス（以下「HSV」）感染が疑われたが，その際は HSV 検査が行われなかった。20[redacted] 年[redacted] 月，被験者は黄色ブドウ球菌感染を発現しており，治療を受けた。

tetracaine，フルオレセイン，oxycodone 及びアセトアミノフェン，ATROPINE OPHTHALMIC，アシクロビル，アセトアミノフェン，プロクロルペラジン，VANCOMYCIN TOPICAL OPHTHALMIC SOLUTION，トブラマイシン，polymyxin B - トリメトプリム，オフロキサシン並びに doxycycline が投与された。

The patient's past medications include:

METHOTREXATE for ATOPIC DERMATITIS ([redacted])

ELIDEL for ATOPIC DERMATITIS ([redacted])

KENALOG for ATOPIC DERMATITIS ([redacted])

CELLCEPT for ATOPIC DERMATITIS ([redacted])

IMURAN for ATOPIC DERMATITIS ([redacted])

OTEZLA for ATOPIC DERMATITIS ([redacted])

Causality for UPADACITINIB (Blinded)

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1) Corneal ulcer (10048492) (Ulcerative keratitis (10064996)) [v.23.0] [10048492]

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

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

Dechallenge: Not Applicable

Causality for TRIAMCINOLONE ACETONIDE (Open Label)

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1) Corneal ulcer (10048492) (Ulcerative keratitis (10064996)) [v.23.0] [10048492]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of CORNEAL ULCER - LEFT

- Investigator: Not reported.

- AbbVie: Event is more likely related to pre-existing left corneal ulcer.

Alternative Etiology for TRIAMCINOLONE ACETONIDE (Open Label)

Event of CORNEAL ULCER - LEFT

- Investigator: Not reported

- AbbVie: Event is more likely related to pre-existing left corneal ulcer.

RISK/BENEFIT STATEMENT:

There is no change to the risk/benefit profile for this study/product as a result of this individual report/event(s).

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] **EYE SMEAR BACTERIAL CULTURE:** POSITIVE: ONE COLONY CORYNEBACTERIUM STRIATUM

[redacted] 20[redacted] **LEFT CORNEAL SWAB HERPES SIMPLEX VIRUS PCR, VARIES:** HSV POSITIVE

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者は米国の 3[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，トリアムシノロンアセトニド及びベタメタゾンジプロピオン酸エステルを投与され，肺炎（呼吸器，胸郭，縦隔のその他疾患）を発現した。被験者は元喫煙者（紙巻タバコ 10 本／日，10 年間）かつ元飲酒者（2～4 杯／日）であり，関連する病歴はアトピー性皮膚炎，右肺上葉の肺結節（影）であった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は肺炎（呼吸器，胸郭，縦隔のその他疾患）を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，肺炎（呼吸器，胸郭，縦隔のその他疾患）は消失した。

20[redacted] 年 [redacted] 月 [redacted] 日（第 52 週の規定来院日），被験者は上気道感染の症状（喘鳴，咳嗽及び息切れ）を訴え，これらは 3 日間持続した。被験者によれば，これらの症状は 20[redacted] 年 [redacted] 月 [redacted] 日の朝に始まったばかりであった。20[redacted] 年 [redacted] 月 [redacted] 日の夜に症状が悪化したため，20[redacted] 年 [redacted] 月 [redacted] 日の早朝に被験者は救急治療室を受診した。被験者は肺炎の診断で入院した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

被験者のコメント：被験者の記憶によれば，過去 2～3 年間に肺炎の診断を 2，3 回受けているが，詳細や具体的な診断時期（年月日）は思い出せなかった。

IPRATROPIUM/albuterol，ROCEPHIN，MUCINEX，PULMICORT，酸素，メチルプレドニゾロン，magnesium sulfate，ceftriaxone，アセトアミノフェン，aluminum hydroxide/水酸化マグネシウム/simethicone，albuterol，azithromycin，ketorolac，fluticasone，levofloxacin 及び prednisone が投与された。

The patient's past medications include:

METHOTREXATE for ATOPIC DERMATITIS ([redacted])

ELIDEL for ATOPIC DERMATITIS ([redacted])

KENALOG for ATOPIC DERMATITIS ([redacted])

CELLCEPT for ATOPIC DERMATITIS ([redacted])

IMURAN for ATOPIC DERMATITIS ([redacted])

OTEZLA for ATOPIC DERMATITIS ([redacted])

Causality for UPADACITINIB (Blinded)

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1) Pneumonia (10035664) (Pneumonia (10035664)) [v.23.0] [10035664]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Causality for TRIAMCINOLONE ACETONIDE (Open Label)

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1) Pneumonia (10035664) (Pneumonia (10035664)) [v.23.0] [10035664]

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

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

Dechallenge: Not Applicable

Causality for BETAMETHASONE DIPROPIONATE (Open Label)

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1) Pneumonia (10035664) (Pneumonia (10035664)) [v.23.0] [10035664]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS, OTHER, PNEUMONIA

- Investigator: Not applicable

- AbbVie: Not applicable

Alternative Etiology for TRIAMCINOLONE ACETONIDE (Open Label)

Event of RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS, OTHER, PNEUMONIA

- Investigator: Not reported

- AbbVie: Risk factors include history of smoking and pre-existing atopic dermatitis, as ex-smokers have an increased risk of developing pneumonia and patients with atopic dermatitis have an increased risk of developing systemic infections, including pneumonia.

Alternative Etiology for BETAMETHASONE DIPROPIONATE (Open Label)

Event of RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS, OTHER, PNEUMONIA

- Investigator: Not reported

- AbbVie: Risk factors include history of smoking and pre-existing atopic dermatitis, as ex-smokers have an increased risk of developing pneumonia and patients with atopic dermatitis have an increased risk of developing

systemic infections, including pneumonia.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CHEST CT:** HYPEREXPANDED LUNG VOLUME. MILD MEDIAL ANTERIOR RIGHT UPPER LOB PATCHY GROUND-GLASS OPACITIES.

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

[redacted] **20[redacted] CHEST X-RAY:** NO ACUTE PULMONARY PROCESS.

[redacted] **20[redacted] EKG:** NORMAL ECG - OVERALL STABLE FROM PRIOR [redacted] 20[redacted]

Subject [redacted] ([redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
バルトネラ症	X			X

Treatment Group	Age at Study Start	Sex	Race
UPA 15 MG QD/UPA 15 MG QD	1[redacted]	FEMALE	BLACK OR AFRICAN AMERICAN

Medical History	Onset Year
ATOPIC DERMATITIS	20[redacted]
ASTHMA	20[redacted]
SPONDYLOSIS	20[redacted]
ALLERGIC RHINITIS	20[redacted]
ATOPIC DERMATITIS	20[redacted]
NAUSEA	20[redacted]
ALLERGIC RHINITIS	NOT REPORTED
ASTHMA	NOT REPORTED

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

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

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
UPA	15 MG	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 112	112
UPA	15 MG	ORAL	QD	[redacted]20[redacted] / 113		

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
EUCERIN	454 g	BID	Y-M: 20[redacted]
SALBUTAMOL	90 OTHER: MCG	PRN	Y-M: 20[redacted]
MOMETASONE	100 OTHER: MCG	BID	Y-M: 20[redacted]
MONTELUKAST	5 mg	QD	Y-M: 20[redacted] / -295

FLUOCINONIDE	120 g	BID	Y-M: 20[redacted] / -261
TRIAMCINOLONE	0.1 %	BID	Y-M: 20[redacted] / -261
RANITIDINE	150 mg	BID	Y-M: 20[redacted] / -176
CLOTRIMAZOLE	1% g	BID	Y-M: 20[redacted] / -106

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
EUCERIN	454 g	BID	Y-M: 20[redacted]	NOT REPORTED
SALBUTAMOL	90 OTHER: MCG	PRN	Y-M: 20[redacted]	NOT REPORTED
FLUOCINONIDE	120 g	BID	Y-M: 20[redacted] / -261	NOT REPORTED
RANITIDINE	150 mg	BID	Y-M: 20[redacted] / -176	Y-M: 20[redacted] / 426
HYDROXYZINE	10 mg	QD	Y-M: 20[redacted] / 232	NOT REPORTED
LORATADINE	5 mg	QD	Y-M: 20[redacted] / 235	NOT REPORTED
MOMETASONE	200 OTHER: MCG	BID	Y-M: 20[redacted] / 235	Y-M: 20[redacted] / 441
COLECALCIFEROL	1000 OTHER: UNITS	BID	Y-M: 20[redacted] / 413	NOT REPORTED
IBUPROFEN	400 mg	QID	Y-M: 20[redacted] / 414	Y-M: 20[redacted] / 444
IOHEXOL	300 mg	OTHER: ONCE	Y-M: 20[redacted] / 426	Y-M: 20[redacted] / 426
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 427	Y-M: 20[redacted] / 428
ONDANSETRON	4 mg	TID	Y-M: 20[redacted] / 428	Y-M: 20[redacted] / 430
FENTANYL	50 OTHER: MCG	OTHER: ONCE	Y-M: 20[redacted] / 429	Y-M: 20[redacted] / 429
PROPOFOL	50 mg	OTHER: ONCE	Y-M: 20[redacted] / 429	Y-M: 20[redacted] / 429
AUGMENTIN	875-125 mg	BID	Y-M: 20[redacted] / 430	Y-M: 20[redacted] / 435
AZITHROMYCIN	250 mg	QD	Y-M: 20[redacted] / 434	Y-M: 20[redacted] / 450
MOMETASONE	200 OTHER: MCG	BID	Y-M: 20[redacted] / 441	NOT REPORTED
AQUAPHOR HEALING	41 %	BID	Y-M: 20[redacted] / 443	NOT REPORTED
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 443	NOT REPORTED
LACTOBACILLUS RHAMNOSUS	5 OTHER: BILLION CELL	QD	Y-M: 20[redacted] / 443	NOT REPORTED
RIFAMPICIN	300 mg	BID	Y-M: 20[redacted] / 443	NOT REPORTED
NAPROXEN	500 mg	BID	Y-M: 20[redacted] / 448	NOT REPORTED
PARACETAMOL	325 mg	PRN	Y-M: 20[redacted] / 448	NOT REPORTED
IOHEXOL	100 mL	OTHER: ONCE	Y-M: 20[redacted] / 450	Y-M: 20[redacted] / 450
DOXYCYCLINE	10 OTHER: MG/ML	OTHER: ONCE	Y-M: 20[redacted] / 450	Y-M: 20[redacted] / 451

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

Event Description	BARTONELLA
Preferred term	バルトネラ症
AE Onset Date / Rx Day	[redacted]20[redacted] / 414
Age at AE Onset	1[redacted]
Laboratory Testing	[redacted]20[redacted] (RX DAY 426): NPTST127-SARS-COV-2: NOT DETECTED [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 428): NPTST072-HUMAN RHINOVIRUS: DETECTED [NOT REPORTED - NOT REPORTED] RATIO; NPTST127-SARS-COV-2: NOT DETECTED [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED
Microbiology	[redacted]20[redacted] (RX DAY 427): BLOOD NPTST019-BARTONELLA ANTIBODY PANEL: Positive-BARTONELLA HENSELAE
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 429): BIOPSY OF RIGHT SUPRACLAVICULAR ABSCESS: ABSCESS RIGHT SUPRACLAVICULAR COMPONENT 1 MO AGO CALCOFLUOR WHITE STAIN NO YEAST OR FUNGAL ELEMENTS PRESENT FUNGAL CULTURE AND SMEAR NO FUNGUS ISOLATED AFTER 4 WEEKS
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者は米国の 1[redacted] 歳女性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬及びトリアムシノロンアセトニドを投与され，バルトネラ感染によるリンパ節炎を発現した。被験者は非喫煙者かつ非飲酒者であり，関連する病歴は喘息，アトピー性皮膚炎であった。

被験者は本試験開始時の 16 週間の二重盲検投与期に参加していた。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は盲検継続投与期に移行し，盲検下でウパダシチニブ投与が開始された。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者はバルトネラ感染によるリンパ節炎を発現した。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は救急科を受診し，頚部痛（右側）並びに関連した咽喉痛，咳嗽，及びうっ滞の診察を受けた。鎖骨上窩リンパ節の触診で圧痛及び可動性が認められた。胸部 X 線検査が行われ，異常は認められなかった。精製ツベルクリン皮膚テストが行われ，最終計測値は 0 mm であった。甲状腺刺激ホルモン，白血球及び血球細胞系統の値は正常であり，炎症性マーカー値に軽度の上昇が認められた。帰宅時診断は頚部リンパ節炎であった。20[redacted] 年 [redacted] 月 [redacted] 日，被験者はかかりつけ医を受診し，頚部腫瘤の腫瘤径減少が確認された。

その後，右側のリンパ節で腫脹及び疼痛の増強が自覚されたため，20[redacted] 年 [redacted] 月 [redacted] 日に被験者は救急科を再受診した。救急科入院時，右側頚部腫瘤の腫大及び圧痛が認められた。頚部腫脹及び頚部痛のため，頚部の可動域は制限されていた。被験者によれば発熱，寝汗，体重減少，嗄声，嚥下障害，音声変調，上気道性喘鳴，及び喘鳴はなかった。頭頚部への放射線照射治療を受けたこともなかった。バイタルサインに特記すべき異常はなかった。ウイルス検査の結果，ライノウイルスが検出され，*Bartonella* 属抗体検査パネルが陽性と確認された。被験者は自宅でネコを飼育していたが，本人が覚えている限りではネコによる引っかき傷の既往はなかった。最近の旅行歴はなかった。被験者からワクチン接種歴を新たに聴取し，A 型肝炎以外はワクチン接種を受けていること，20[redacted] 年にインフルエンザワクチン接種を受けたことが判明した。救急科で実施された検査では，赤血球沈降速度，C-反応性蛋白，乳酸脱水素酵素，及び総蛋白とアルブミンの乖離に値の増加が認められた。コンピュータ断層撮影（以下「CT」）検査で右鎖骨上窩に内部不均一な軟部組織吸収域の陰影（4×7 cm）が認められた。超音波ガイド下で頚部の生検が行われ，右鎖骨上部の膿瘍から 8 cc の排膿があった。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

20[redacted] 年 [redacted] 月 [redacted] 日，前頚部／胸部の腫瘤が呼吸困難の原因となっている可能性がないか相談するため，被験者は救急科を受診した。CT 検査が行われ，前回撮影像と比較して腫瘤径のわずかな増大が認められた。この他に臨床検査が行われ，前回実施時と比較して改善が認められた。被験者の状態は十分良好で帰宅可能であると判断された。

RIFADIN，ナプロキセン，イブプロフェン，フェンタニル，doxycycline，azithromycin，AUGMENTIN 及びアセトアミノフェンが投与された。

The patient's past medications include:

KENALOG for ATOPIC DERMATITIS ([redacted] 20[redacted] - 20[redacted])

LOTRIMIN for EMOLLIENT THERAPY ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Bartonella hensalae infection (10004144) (Cat scratch disease (10007729)) [v.23.1] [10004144]

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

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

Dechallenge: Not Applicable

2) Lymphadenitis (10025188) (Lymphadenitis (10025188)) [v.23.1] [10025188]

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

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

Dechallenge: Not Applicable

Causality for TRIAMCINOLONE ACETONIDE (Open Label)

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1) Bartonella hensalae infection (10004144) (Cat scratch disease (10007729)) [v.23.1] [10004144]

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

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

Dechallenge: Not Applicable

2) Lymphadenitis (10025188) (Lymphadenitis (10025188)) [v.23.1] [10025188]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of BARTONELLA LYMPHADENITIS

- Investigator: Not applicable

- AbbVie: event is more likely a vector borne infection, caused by exposure to cats. Cat Scratch Disease can result from a cat scratch/ bite or a flea bite, and can also be spread via contact with cat saliva through broken skin or mucosal surfaces. Lymphadenitis is more likely associated with concurrent cat-scratch disease.

Alternative Etiology for TRIAMCINOLONE ACETONIDE (Open Label)

Event of BARTONELLA LYMPHADENITIS

- Investigator: Not applicable

- AbbVie: event is more likely a vector borne infection, caused by exposure to cats. Cat Scratch Disease can result from a cat scratch/ bite or a flea bite, and can also be spread via contact with cat saliva through broken skin or mucosal surfaces. Lymphadenitis is more likely associated with concurrent cat-scratch disease.

RISK/BENEFIT STATEMENT:

There is no change to the risk/benefit profile for this study/product as a result of this individual report/event(s).

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ALBUMIN:** 4.2 no unit

[redacted] **20[redacted] BARTONELLA ANTIBODY PANEL:** positive - Bartonella henselae and Bartonella quintana IgG titers of 1:64 - 1:128, none show titers of 1:256 or above. Sera from 95% of patients with clinically defined cat scratch disease show IgG titers of 1:64 and above; 79% exhibit titers of 1:256 and above. IgM titers at 1:20 or higher have not been detected in the normal adult population.

[redacted] **20[redacted] BIOPSY:** ultrasound guided biopsy of neck mass: results not provided

[redacted] **20[redacted] BMI:** 27.46 kg/ m2

[redacted] **20[redacted] CHEST X-RAY:** no abnormality

[redacted] **20[redacted] CRP:** 12 no unit

[redacted] **20[redacted] CRP:** 37 no unit

[redacted] **20[redacted] CT SCAN:** showed a 4x7 cm heterogeneous soft tissue density in the right supraclavicular fossa

[redacted] **20[redacted] ESR:** 22 no unit

[redacted] **20[redacted] ESR:** 81 no unit

[redacted] **20[redacted] FUNGAL CULTURE:** no fungus isolated after 4 weeks (component 1 month ago - calcofluor white stain : no yeast or fungal elements present)

[redacted] **20[redacted] HEMOGLOBIN:** 12.3 no unit

[redacted] **20[redacted] LDH:** 281 no unit

[redacted] 20[redacted] **MCV:** 99 no unit

[redacted] 20[redacted] **O2 SATURATION:** 100% on room air

[redacted] 20[redacted] **PLATELET COUNT:** 398 no unit

[redacted] 20[redacted] **PPD:** read as 0 mm

[redacted] 20[redacted] **PREGNANCY TEST:** negative

[redacted] 20[redacted] **TOTAL PROTEIN:** 8.5 no unit

[redacted] 20[redacted] **TSH:** normal

[redacted] 20[redacted] **URIC ACID:** 5.3 no unit

[redacted] 20[redacted] **VIRAL TEST:** human rhinovirus (blood): detected

[redacted] 20[redacted] **WBC:** normal

[redacted] 20[redacted] **WBC:** 8.7 no unit

Subject [redacted] ([redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
感染性湿疹	X			X

Treatment Group	Age at Study Start	Sex	Race
UPA 30 MG QD/UPA 30 MG QD	1[redacted]	FEMALE	WHITE

Medical History	Onset Year
ATOPIC DERMATITIS	20[redacted]
RECURRENT TONSILLITIS	20[redacted]
BUG BITE ALLERGY	20[redacted]
POOR VISION	20[redacted]
ACNE	20[redacted]
ANXIETY	20[redacted]
ASTHMA	20[redacted]
ACNE	NOT REPORTED
ASTHMA	NOT REPORTED

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

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

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
UPA	30 MG	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 114	114
UPA	30 MG	ORAL	QD	[redacted]20[redacted] / 115		

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
HEPATITIS B IMMUNIZATION	NOT REPORTED	NOT REPORTED	Y: 20[redacted]
CILEST	1 OTHER: TABLET	QD	Y: 20[redacted]
MOMETASONE	0.1 %	QD	Y-M: 20[redacted] / -252
FLUTICASONE	125 mg	QD	Y-M: 20[redacted] / -84
FLUOCINONIDE	0.05 %	BID	Y-M: 20[redacted] / -48
OTHER EMOLLIENTS AND PROTECTIVES	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -21

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
CILEST	1 OTHER: TABLET	QD	Y: 20[redacted]	NOT REPORTED
FLUTICASONE	125 mg	QD	Y-M: 20[redacted] / -84	NOT REPORTED
OTHER EMOLLIENTS AND PROTECTIVES	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -21	NOT REPORTED
CEFTRIAXONE	2 g	QD	Y-M: 20[redacted] / 215	Y-M: 20[redacted] / 217
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 217	Y-M: 20[redacted] / 219

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

Event Description	SUPERINFECTED ECZEMA OF THE HANDS
Preferred term	感染性湿疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 215
Age at AE Onset	1[redacted]
Laboratory Testing	[redacted]20[redacted] (RX DAY 215): Leukocytes: 22.1 [4 - 10] 10^9/L; Neutrophils: 19.8 [2 - 7.5] 10^9/L; [redacted]20[redacted] (RX DAY 216): NPTST026-C REACTIVE PROTEIN: 112.0 [NOT REPORTED - 3] mg/L; [redacted]20[redacted] (RX DAY 217): Leukocytes: 7.8 [4 - 10] 10^9/L; NPTST026-C REACTIVE PROTEIN: 62.2 [NOT REPORTED - 3] mg/L; Neutrophils: 5.4 [2 - 7.5] 10^9/L; [redacted]20[redacted] (RX DAY 218): Leukocytes: 11.9 [4 - 10] 10^9/L; Neutrophils: 9 [2 - 7.5] 10^9/L
Microbiology	[redacted]20[redacted] (RX DAY 215): BLOOD NPTST021-BLOOD CULTURE: Negative; [redacted]20[redacted] (RX DAY 216): WOUND NPTST067-HERPES SIMPLEX VIRUS DETECTION: Negative; URINE NPTST150-URINE CULTURE: Negative; WOUND NPTST160-WOUND CULTURE: Positive-GROUP A STREPTOCOCCUS; STAPHYLOCOCCUS AUREUS
SAE Supplemental Procedure	NOT REPORTED
AE Stopped Rx Day	218
Duration of AE	4 DAYS

Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者はカナダの 1[redacted] 歳女性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，トリアムシノロンアセトニド及びヒドロコルチゾン酢酸エステルを投与され，両手の重複感染性湿疹を発現した。被験者は非喫煙者かつ飲酒者（2 杯未満／日）であり，関連する病歴はアトピー性皮膚炎であった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は両手の重複感染性湿疹を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，両手の重複感染性湿疹は消失した。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は両手の重複感染性湿疹のため入院した。被験者は発熱及び軽度の悪心を発現した。被験者は感染症内科に紹介され，抗生物質の経口投与を勧められた。入院中，被験者の状態は次第に改善した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

cephalexin，KEFLEX 及び ceftriaxone が投与された。

Causality for UPADACITINIB (Blinded)

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1) Eczema infected (10014199) (Eczema infected (10014199)) [v.22.1] [10014199]

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

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

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Causality for TRIAMCINOLONE ACETONIDE (Open Label)

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1) Eczema infected (10014199) (Eczema infected (10014199)) [v.22.1] [10014199]

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

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

Dechallenge: Not Applicable

Causality for HYDROCORTISONE ACETATE (Open Label)

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1) Eczema infected (10014199) (Eczema infected (10014199)) [v.22.1] [10014199]

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

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

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for UPADACITINIB (Blinded)

Event of SUPERINFECTED ECZEMA ON HER HANDS

- Investigator: Not applicable

- AbbVie: Event is more likely a complication of pre-existing atopic dermatitis.

Alternative Etiology for TRIAMCINOLONE ACETONIDE (Open Label)

Event of SUPERINFECTED ECZEMA ON HER HANDS

- Investigator: Not applicable

- AbbVie: Event is more likely a complication of pre-existing atopic dermatitis.

Alternative Etiology for HYDROCORTISONE ACETATE (Open Label)

Event of SUPERINFECTED ECZEMA ON HER HANDS

- Investigator: Not applicable

- AbbVie: Event is more likely a complication of pre-existing atopic dermatitis.

RISK/BENEFIT STATEMENT:

There is no change to the risk/benefit profile for this study/product as a result of this individual report/event(s).

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABSOLUTE NEUTROPHILS:** 19.8 X10**9/L (normal 2.0 to 7.5)

[redacted] **20[redacted] ABSOLUTE NEUTROPHILS:** 5.4 X10**9/L (normal 2.0 to 7.5)

[redacted] **20[redacted] ABSOLUTE NEUTROPHILS:** 9.0 X10**9/L (normal 2.0 to 7.5)

[redacted] **20[redacted] BLOOD CULTURE:** Negative

[redacted] **20[redacted] CRP:** 112 MG/L (normal <3.0)

[redacted] **20[redacted] CRP:** 43 MG/L (normal <3.0)

[redacted] **20[redacted] HERPES SIMPLEX VIRUS DETECTION:** Negative

[redacted] **20[redacted] URINE CULTURE:** Negative

[redacted] **20[redacted] WBC:** 22.1 X10**9/L (normal 4.0 to 10)

[redacted] **20[redacted] WBC:** 7.8 X10**9/L (normal 4.0 to 10.0)

[redacted] **20[redacted] WBC:** 11.9 X10**9/L (normal 4.0 to 10.0)

[redacted] **20[redacted] WOUND CULTURE:** Positive for group A strep

Subject [redacted] ([redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
播種性帯状疱疹	X	X		X

Treatment Group	Age at Study Start	Sex	Race
UPA 30 MG QD/UPA 30 MG QD	3[redacted]	MALE	WHITE

Medical History	Onset Year
VARICELLA	19[redacted]
ASTHMA	19[redacted]
ATOPIC DERMATITIS	19[redacted]
INHALANTS ALLERGY	19[redacted]
MITES ALLERGY	19[redacted]
PETS ALLERGY	19[redacted]
POLLEN ALLERGY	19[redacted]
NODULAR PRURIGO	20[redacted]
ASTHMA	NOT REPORTED

Prior Procedures	Procedure Year
Not reported.	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	13 CIGARETTE	15	20[redacted]
CIGARS	FORMER			
E-CIGARETTES	NEVER			
PIPES	FORMER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	2 - 4

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
UPA	30 MG	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 119	119
UPA	30 MG	ORAL	QD	[redacted]20[redacted] / 120	[redacted]20[redacted] / 159	40

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
HEPATITIS B IMMUNIZATION	NOT REPORTED	NOT REPORTED	Y: 19[redacted]
EMOLLIENTS AND PROTECTIVES	1 OTHER: APPLICATION	BID	Y: 20[redacted]
BETAMETHASONE	1 OTHER: APPLICATION	QD	Y-M: 20[redacted]-[redacted] / -43
CLOBETASOL	1 OTHER: APPLICATION	QD	Y-M: 20[redacted]-[redacted] / -43

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
EMOLLIENTS AND PROTECTIVES	1 OTHER: APPLICATION	BID	Y: 20[redacted]	ONGOING
ACICLOVIR	600 mg	TID	Y-M: 20[redacted]-[redacted] / 160	Y-M: 20[redacted]-[redacted] / 167
PARACETAMOL	975 mg	PRN	Y-M: 20[redacted]-[redacted] / 160	Y-M: 20[redacted]-[redacted] / 167
BETAMETHASONE	0.1 %	BID	Y-M: 20[redacted]-[redacted] / 161	Y-M: 20[redacted]-[redacted] / 163
CLOBETASOL	0.05 %	BID	Y-M: 20[redacted]-[redacted] / 161	Y-M: 20[redacted]-[redacted] / 167
PREGABALIN	50 mg	BID	Y-M: 20[redacted]-[redacted] / 161	Y-M: 20[redacted]-[redacted] / 174
FLUOCINONIDE	0.05 %	QD	Y-M: 20[redacted]-[redacted] / 163	Y-M: 20[redacted]-[redacted] / 163
HYDROXYZINE	25 mg	PRN	Y-M: 20[redacted]-[redacted] / 163	Y-M: 20[redacted]-[redacted] / 166
DEXAMETHASONE	0.25 %	BID	Y-M: 20[redacted]-[redacted] / 163	Y-M: 20[redacted]-[redacted] / 167
VALACICLOVIR	1000 mg	TID	Y-M: 20[redacted]-[redacted] / 168	Y-M: 20[redacted]-[redacted] / 174

Event #1: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Event of Interest - Serious Infections, Event of Interest - Herpes Zoster

Event Description	DISSEMINATED HERPES ZOSTER
Preferred term	播種性帯状疱疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 155
Age at AE Onset	3[redacted]
Laboratory Testing	NOT REPORTED
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 160): CHEST X RAY: NORMAL

AE Stopped Rx Day	174 (15 DAYS AFTER LAST TREATMENT)
Duration of AE	20 DAYS
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者はカナダの 3[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，ヒドロコルチゾン及びトリアムシノロンアセトニドを投与され，播種性帯状疱疹を発現した。被験者は元喫煙者（紙巻タバコ 13 本／日，15 年間），元パイプ喫煙者，元葉巻喫煙者かつ飲酒者（2～4 杯／日）であり，関連する病歴は水痘，喘息，アトピー性皮膚炎，吸入抗原アレルギー，ダニアレルギー，花粉アレルギー，結節性痒疹であった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は播種性帯状疱疹を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，播種性帯状疱疹は消失した。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は左前腕から広がった疼痛を伴う皮疹のため，入院した。20[redacted] 年 [redacted] 月 [redacted] 日，集簇した小水疱とともに腫脹した紅斑性局面が出現した。その後，症状は左側胸部及び左肩甲部に拡大した。20[redacted] 年 [redacted] 月 [redacted] 日，症状が進行したため，被験者は救急科を受診した。尺骨神経（第 8 頚神経・第 1 胸神経）支配域（皮節）及び第 2 腰神経支配域（皮節）に播種していた。病歴，身体的診察，及び水疱内容液を蛍光抗体直接法で検査した結果から確定診断された。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は重度の頭痛（非重篤）を自覚し始めた。頚神経支配域（皮節）に症状があったため，播種性帯状疱疹に関連した髄膜炎が疑われたものの，確定はされなかった。腰椎穿刺はできなかった。播種性帯状疱疹に対し，acyclovir 及びアセトアミノフェンがプレガバリンとともに投与開始された。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。被験者の病歴に水痘はあるが帯状疱疹はなく，帯状疱疹ワクチン接種歴はなかった。被験者は本事象を理由に試験を中止した。

プレガバリン，acyclovir 及びアセトアミノフェンが投与された。

The patient's past medications include:

BETADERM for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])
CLOBETASOL for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Herpes zoster disseminated (10065038) (Herpes zoster disseminated (10065038)) [v.23.0] [10065038]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes Rechallenge: No rechallenge was done, recurrence is not applicable

Causality for HYDROCORTISONE (Open Label)

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1) Herpes zoster disseminated (10065038) (Herpes zoster disseminated (10065038)) [v.23.0] [10065038]

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

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

Dechallenge: Not Applicable

Causality for TRIAMCINOLONE ACETONIDE (Open Label)

---

1) Herpes zoster disseminated (10065038) (Herpes zoster disseminated (10065038)) [v.23.0] [10065038]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of DISSEMINATED HERPES ZOSTER - Investigator: Not applicable. - AbbVie: Not applicable

Alternative Etiology for HYDROCORTISONE (Open Label)

Event of DISSEMINATED HERPES ZOSTER

- **Investigator:** More likely related to Upadacitinib/placebo.

- AbbVie: Weak temporal relationship. Last application was approximately 5 months prior to event onset.

Alternative Etiology for TRIAMCINOLONE ACETONIDE (OpenLabel)

Event of DISSEMINATED HERPES ZOSTER

- **Investigator**: More likely related to Upadacitinib/placebo.

- **AbbVie:** Weak temporal relationship. Last application was approximately 5 months prior to event onset.

RISK/BENEFIT STATEMENT: There is no change to the risk/benefit profile for this study/product as a result of this individual report/event(s).

Subject [redacted] ([redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
網膜剥離	X			

Treatment Group	Age at Study Start	Sex	Race
UPA 15 MG QD/UPA 15 MG QD	2[redacted]	MALE	ASIAN

Medical History	Onset Year
ATOPIC DERMATITIS	19[redacted]
MYOPIA	19[redacted]
ACUTE APPENDICITIS	20[redacted]
ALLERGIC RHINOCONJUCTIVITIS	20[redacted]
MYOPIA GRADE 2	20[redacted]
ALLERGIC RHINITIS	NOT REPORTED

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

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	CURRENT	0.5 CIGARETTE	5	
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
UPA	15 MG	ORAL	QD	[redacted]0[redacted] / 1	[redacted]20[redacted] / 105	105
UPA	15 MG	ORAL	QD	[redacted]20[redacted] / 106		

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CORTICOSTEROIDS, TOPICAL	1 OTHER: APPLICATION	PRN	Y: 19[redacted]
ALL OTHER NON-THERAPEUTIC PRODUCTS	1 OTHER: RADIATION	1 TIME PER WEEK	Y-M: 20[redacted]-[redacted]
HEPATITIS B IMMUNIZATION	NOT REPORTED	NOT REPORTED	Y-M: 20[redacted]-[redacted]
DESLORATADINE	5 mg	PRN	Y: 20[redacted]
PSORALENS FOR SYSTEMIC USE	1 OTHER: APPLICATION	1 TIME PER WEEK	Y-M: 20[redacted]-[redacted]
METHYLPREDNISOLONE	40 mg	QD	Y-M: 20[redacted]-[redacted] / -322
EMOLLIENTS AND PROTECTIVES	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]-[redacted] / -21

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
DESLORATADINE	5 mg	PRN	Y: 20[redacted]	NOT REPORTED
EMOLLIENTS AND PROTECTIVES	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]-[redacted] / -21	NOT REPORTED
GENTAMICIN	1 OTHER: APPLICATION	QD	Y-M: 20[redacted]-[redacted] / 45	Y-M: 20[redacted]-[redacted] / 54
GENTAMICIN	5 mL	OTHER: 4 TIMES DAILY	Y-M: 20[redacted]-[redacted] / 45	Y-M: 20[redacted]-[redacted] / 54

Event #1: Serious Adverse Event

Event Description	RETINAL DETACHMENT OF LEFT EYE
Preferred term	網膜剥離
AE Onset Date / Rx Day	[redacted]20[redacted] / 43
Age at AE Onset	2[redacted]
Laboratory Testing	NOT REPORTED
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted]20[redacted](RX DAY 46): VITRECTOMY + CRYOAPPLICATION + ENDOLASER + SILICONE FILLING LEFT EYE: DISMISSED [redacted] IN RECOVERING STATE; [redacted]20[redacted] (RX DAY 54): CONTROL WITH AUTOREFRACTOMETER, TONOMETRY, FUNDUS: GOOD STATE LEFT EYE; [redacted]20[redacted] (RX DAY 57): CONTROL WITH AUTOREFRACTOMETER, TONOMETRY: GOOD STATE LEFT EYE; [redacted]0[redacted] (RX DAY 149): EXCHANGE OF LEFT EYE LENSE AND REMOVAL OF SILICON OIL: PROCEDURE COMPLETED
AE Stopped Rx Day	47
Duration of AE	5 DAYS

Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	PATIENT WOKE UP AND COULD NOT SEE CLEARLY, SIGHT WAS BLURRED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者はオーストリアの 2[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，モメタゾンフランカルボン酸エステル，ヒドロコルチゾン酢酸エステル及びピメクロリムスを投与され，左眼の網膜剥離を発現した。被験者は喫煙者（紙巻タバコ 0.5 本／日，5 年間）かつ非飲酒者で，関連する病歴はアトピー性皮膚炎，アレルギー性鼻炎結膜炎及び近視（グレード 2）であった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は左眼の網膜剥離を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，左眼の網膜剥離は消失した。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は起床してから，視界がぼやけてよく見えない状態であった。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は両眼の霧視（左眼-3，右眼-7）のため入院した。20[redacted] 年 [redacted] 月 [redacted] 日，左眼の硝子体切除，凍結療法，眼内レーザー及びシリコン充填術が完了した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

20[redacted] 年 [redacted] 月 [redacted] 日，左眼内レンズ交換及びシリコンオイルの除去が行われた。

DORZASTAD，DIAMOX, DEXAGENTA DROPS，DEXAGENTA OINTMENT 及び KETOVISION が投与された。

The patient's past medications include:

UNKNOWN TOPICAL CORTICOSTEROID for ATOPIC DERMATITIS (19[redacted] - [redacted] [redacted] 20[redacted])

URBASON for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Retinal detachment (10038848) (Retinal detachment (10038848)) [v.23.0] [10038848]

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

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

Dechallenge: Not Applicable

Causality for MOMETASONE FUROATE (Open Label)

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1) Retinal detachment (10038848) (Retinal detachment (10038848)) [v.23.0] [10038848]

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

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

Dechallenge: Not Applicable

Causality for HYDROCORTISONE ACETATE (Open Label)

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1) Retinal detachment (10038848) (Retinal detachment (10038848)) [v.23.0] [10038848]

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

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

Dechallenge: Not Applicable

Causality for PIMECROLIMUS (Open Label)

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1) Retinal detachment (10038848) (Retinal detachment (10038848)) [v.23.0] [10038848]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of RETINAL DETACHMENT OF LEFT EYE

- Investigator: Not applicable

- AbbVie: Event not consistent with study drug's mechanism of action and is more likely due to the subjects pre-existing atopic dermatitis (Takahashi,., et.al., Retinal detachment associated with atopic dermatitis. British Journal of Ophthalmology 1996; 80: 54-57).

Alternative Etiology for MOMETASONE FUROATE (Open Label)

Event of RETINAL DETACHMENT OF LEFT EYE

- Investigator: Not applicable

- AbbVie: Event not consistent with study drug's mechanism of action and is more likely due to the subjects pre-existing atopic dermatitis (Takahashi,., et.al., Retinal detachment associated with atopic dermatitis. British Journal of Ophthalmology 1996; 80: 54-57).

Alternative Etiology for HYDROCORTISONE ACETATE (Open Label)

Event of RETINAL DETACHMENT OF LEFT EYE

- Investigator: Not applicable

- AbbVie: Event not consistent with study drug's mechanism of action and is more likely due to the subjects pre-existing atopic dermatitis (Takahashi,., et.al., Retinal detachment associated with atopic dermatitis. British Journal of Ophthalmology 1996; 80: 54-57).

Alternative Etiology for PIMECROLIMUS (Open Label)

Event of RETINAL DETACHMENT OF LEFT EYE

- Investigator: More likely related to Upadactinib/Placebo(if applicable), Mometasone and Hydrocortisone.

- AbbVie: Event not consistent with study drug's mechanism of action and is more likely due to the subjects pre-existing atopic dermatitis (Takahashi,., et.al., Retinal detachment associated with atopic dermatitis. British Journal of Ophthalmology 1996; 80: 54-57).

RISK/BENEFIT STATEMENT:

There is no change to the risk/benefit profile for this study/product as a result of this individual report/event(s).

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CONTROL WITH AUTOREFRACTOMETER, TONOMETRY:** GOOD STATE LEFT EYE

[redacted] **20[redacted] CONTROL WITH AUTOREFRACTOMETER, TONOMETRY, FUNDUS:** GOOD STATE LEFT EYE

Subject [redacted] ([redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
ヘモグロビン減少				X
大腸感染	X			X

Treatment Group	Age at Study Start	Sex	Race
PLACEBO/UPA 15 MG QD	4[redacted]	MALE	WHITE

Medical History	Onset Year
ASTHMA	19[redacted]
ATOPIC DERMATITIS	19
TONSILLITIS	19
APPENDICITIS	19
BURSITIS KNEE LEFT	19
DAMAGED AND WORN CARTILAGE	19
BURSITIS KNEE RIGHT	19
ALLERGIC RHINITIS	19
SINUSITIS	19
ALCOHOL ABUSE	20
DEPRESSION	20
PSYCHOSIS	20
ADRENAL INSUFFICIENCY	20
KERATOACANTHOMA	20
INSOMNIA	20
SWELLING LYMPHATIC GLANDS IN GROIN BILATERAL	20
SWOLLEN LEFT ANKLE	20
ALLERGIC RHINITIS	NOT REPORTED
ASTHMA	NOT REPORTED

Prior Procedures	Procedure Year
PRIOR PROCEDURES: TONSILLECTOMIE	19[redacted]
PRIOR PROCEDURES: APPENDIX SURGERY	19[redacted]
PRIOR PROCEDURES: SURGERY BURSITIS KNEE LEFT	19[redacted]
PRIOR PROCEDURES: SUGERY BURSITIS KNEE RIGHT	19[redacted]
PRIOR PROCEDURES: ENDONASAL SINUS SURGERY	19[redacted]
PRIOR PROCEDURES: EXCISION KERATOACANTHOMA	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	CURRENT	25 CIGARETTE	32	
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	More than 4

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
PLACEBO		ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 113	113
UPA	15 MG	ORAL	QD	[redacted]20[redacted] / 114		

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
MOMETASONE	0,1 %	QD	Y: 19[redacted]
METHYLPREDNISOLONE	VARIABLE mg	1 TIME PER WEEK	Y: 19[redacted]
DUOVENT	1 OTHER: INHALATION	BID	Y: 19[redacted]
UREA	1 OTHER: APPLICATION	BID	Y: 20[redacted]
BETAMETHASONE	0,1 %	BID	Y-M: 20[redacted]-[redacted]
ALL OTHER NON-THERAPEUTIC PRODUCTS	1 OTHER: APPLICATION	OTHER: 2 TIMES A WEEK	Y-M: 20[redacted]-[redacted]
TACROLIMUS	1 OTHER: APPLICATION	QD	Y-M: 20[redacted]-[redacted]
DISULFIRAM	200 mg	QD	Y: 20[redacted]
ESCITALOPRAM	20 mg	QD	Y: 20[redacted]
PIPAMPERONE	40 mg	QD	Y: 20[redacted]
BETAMETHASONE	0,05 %	QD	Y-M: 20[redacted]-[redacted]
METHOTREXATE	15 mg	1 TIME PER WEEK	Y-M: 20[redacted]-[redacted]
LORMETAZEPAM	2 mg	QD	Y-M: 20[redacted]-[redacted] / -185
BETAMETHASONE	0,121 %	QD	Y-M: 20[redacted]-[redacted] / -155
METHOTREXATE	15 mg	1 TIME PER WEEK	Y-M: 20[redacted]-[redacted] / -146
HYDROXYZINE	25 mg	QD	Y-M: 20[redacted]-[redacted] / -27

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
DUOVENT	1 OTHER: INHALATION	BID	Y: 19[redacted]	NOT REPORTED
DISULFIRAM	200 mg	QD	Y: 20[redacted]	NOT REPORTED
ESCITALOPRAM	20 mg	QD	Y: 20[redacted]	NOT REPORTED
PIPAMPERONE	40 mg	QD	Y: 20[redacted]	NOT REPORTED
LORMETAZEPAM	2 mg	QD	Y-M: 20[redacted] / -185	NOT REPORTED
HYDROXYZINE	25 mg	QD	Y-M: 20[redacted] / -27	NOT REPORTED
EMOLLIENTS AND PROTECTIVES	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / 142	NOT REPORTED
IBUPROFEN	600 mg	BID	Y-M: 20[redacted] / 220	Y-M: 20[redacted] / 230
FUSIDIC ACID	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / 226	Y-M: 20[redacted] / 285
DICLOFENAC	75 mg	QD	Y-M: 20[redacted] / 230	Y-M: 20[redacted] / 230
BEKFORM	2 OTHER: PUFFS	BID	Y-M: 20[redacted] / 233	NOT REPORTED
BEFACT	0,02 mg	QD	Y-M: 20[redacted] / 239	Y-M: 20[redacted] / 288
PIMECROLIMUS	10 OTHER: MG/G	BID	Y-M: 20[redacted] / 365	NOT REPORTED
DICLOFENAC	75 mg	QD	Y-M: 20[redacted] / 376	Y-M: 20[redacted] / 378
AZITHROMYCIN	500 mg	QD	Y-M: 20[redacted] / 380	Y-M: 20[redacted] / 384

Event #1: Event of Interest - Anemia

Event Description	SIGNIFICANT DECREASE OF HEMOGLOBIN
Preferred term	ヘモグロビン減少
AE Onset Date / Rx Day	[redacted]20[redacted] / 225
Age at AE Onset	4[redacted]
Laboratory Testing	NOT APPLICABLE
Microbiology	NOT APPLICABLE
SAE Supplemental Procedure	NOT APPLICABLE
AE Stopped Rx Day	259
Duration of AE	35 DAYS
Toxicity Grade	2
Relation to Study Drug by Investigator	UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY
Investigator Alternative Etiology	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	INFECTIOUS COLITIS
Preferred term	大腸感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 379

Age at AE Onset	4[redacted]
Laboratory Testing	[redacted]20[redacted] (RX DAY 380): Basophils: 46 [0 - 200] 10^9/L; Basophils/Leukocytes: 0.5 [0 - 2] %; Creatine Kinase: 171 [55 - 170] U/L; Eosinophils: 291 [0 - 600] 10^9/L; Eosinophils/Leukocytes: 3.2 [1 - 6] %; Erythrocytes: 4.3 [4.5 - 5.9] 10^12/L; Hematocrit: 0.43 [0.41 - 0.53] FRACTION OF 1; Hemoglobin: 150 [135 - 175] G/L; Leukocytes: 9100 [4000 - 10000] 10^9/L; Lymphocytes: 1110 [1000 - 4000] 10^9/L; Lymphocytes/Leukocytes: 12.2 [20 - 45] %; Monocytes: 1060 [200 - 1000] 10^9/L; Monocytes/Leukocytes: 11.6 [2 - 12] %; NPTST033-CLOSTRIDIUM: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST089-MEAN CORPUS HEMOGLOBIN: 34.5 [26 - 34] PG; NPTST091-MEAN CORPUSCULAR HEMOGLOBIN CON: 34.7 [31 - 37] %; NPTST092-MEAN CORPUSCULAR VOLUME: 99.5 [80 - 100] FL; NPTST099-PARASITES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST147-UREUM: 13 [19 - 43] MG/DL; NPTST156-VITAMINE B12: 169 [239 - 931] PG/ML; Neutrophils: 6600 [2100 - 7000] 10^9/L; Neutrophils/Leukocytes: 72.5 [45 - 70] %; Platelets: 268 [150 - 500] 10^9/L
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 380): RECTOSIGMOIDSCOPY: DIAGNOSIS OF INFECTIOUS COLITIS AND PRESENCE OF POLYP
AE Stopped Rx Day	384
Duration of AE	6 DAYS
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	REASONABLE POSSIBILITY OF RELATIONSHIP TOWARDS DICLOFENAC (CONCOMITANT MEDICATION)
Discontinued Study Drug Due to the Event	NO
SAE Criteria	OTHER MEDICALLY IMPORTANT SERIOUS EVENT

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

NON SERIOUS EVENTS

Haemoglobin decreased. Study drug interrupted.

Subject [redacted] ([redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
口腔咽頭痛	X			
扁桃周囲膿瘍	X			X
自殺企図	X			

Treatment Group	Age at Study Start	Sex	Race
UPA 15 MG QD	2[redacted]	FEMALE	WHITE

Medical History	Onset Year
ATOPIC DERMATITIS	20[redacted]
ERYTHEMA NODOSUM	20[redacted]
FAINTNESS	20[redacted]
HYPOTENSION	20[redacted]
DEPRESSION	20[redacted]
SLEEP DISORDERS	20[redacted]

Prior Procedures	Procedure Year
Not reported.	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	CURRENT	20 CIGARETTE	4	
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
UPA	15 MG	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 79	79

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
HYDROCORTISONE	UNK OTHER: UNK	QD	Y: 20[redacted]
EMOLLIENTS AND PROTECTIVES	UNK OTHER: UNK	BID	Y: 20[redacted]
BETAMETHASONE	UNK OTHER: UNK	QD	Y: 20[redacted]

HEPTAMINOL	UNK OTHER: UNK	PRN	Y: 20[redacted]
INTRAUTERINE CONTRACEPTIVE DEVICE	UNK OTHER: UNK	OTHER: CONTINUOUS	Y: 20[redacted]
FLUTICASONE	UNK OTHER: UNK	QD	Y-M: 20[redacted]-[redacted] / -101

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
EMOLLIENTS AND PROTECTIVES	UNK OTHER: UNK	BID	Y: 20[redacted]	ONGOING
HEPTAMINOL	UNK OTHER: UNK	PRN	Y: 20[redacted]	ONGOING
INTRAUTERINE CONTRACEPTIVE DEVICE	UNK OTHER: UNK	OTHER: CONTINUOUS	Y: 20[redacted]	ONGOING
BETAMETHASONE	0.1 %	OTHER: UNKNOWN	Y-M: 20[redacted]-[redacted] / 1	Y-M: 20[redacted]-[redacted] / 22
MOMETASONE	UNKNOWN ug	QD	Y-M: 20[redacted]-[redacted] / 13	Y-M: 20[redacted]-[redacted] / 30
PREDNISOLONE			Y-M: 20[redacted]-[redacted] / 16	Y-M: 20[redacted]-[redacted] / 19
AMOXICILLIN	3 g	QD	Y-M: 20[redacted]-[redacted] / 16	Y-M: 20[redacted]-[redacted] / 23
PARACETAMOL	AS NEEDED mg	PRN	Y-M: 20[redacted]-[redacted] / 16	Y-M: 20[redacted]-[redacted] / 23
AMOXICILLIN	1 g	TID	Y-M: 20[redacted]-[redacted] / 56	ONGOING
METRONIDAZOLE	500 mg	BID	Y-M: 20[redacted]-[redacted] / 56	ONGOING
PREDNISOLONE	60 mg	QD	Y-M: 20[redacted]-[redacted] / 56	Y-M: 20[redacted]-[redacted] / 59
ACETYLCYSTEINE	150 mg/kg	OTHER: 1 HOUR	Y-M: 20[redacted]-[redacted] / 79	Y-M: 20[redacted]-[redacted] / 79
DEXCHLORPHENIRAMINE	5MG/1 ML mg	OTHER: 1 INFUSION	Y-M: 20[redacted]-[redacted] / 79	Y-M: 20[redacted]-[redacted] / 79
IBUPROFEN	UNKNOWN mg	OTHER: ONCE	Y-M: 20[redacted]-[redacted] / 79	Y-M: 20[redacted]-[redacted] / 79
INVESTIGATIONAL DRUG	50 mg/kg	OTHER: DURING 4 HOURS	Y-M: 20[redacted]-[redacted] / 79	Y-M: 20[redacted]-[redacted] / 79
PARACETAMOL	16 g	OTHER: ONCE	Y-M: 20[redacted]-[redacted] / 79	Y-M: 20[redacted]-[redacted] / 79
TRAMADOL	700 mg	OTHER: ONCE	Y-M: 20[redacted]-[redacted] / 79	Y-M: 20[redacted]-[redacted] / 79
INVESTIGATIONAL DRUG	100 mg/kg	OTHER: DURING 16HOURS	Y-M: 20[redacted]-[redacted] / 79	Y-M: 20[redacted]-[redacted] / 80

Event #1: Serious Adverse Event

Event Description	TONSILLAR PHLEGMON INFECTION, THROAT PAIN SINCE ONE DAY
Preferred term	口腔咽頭痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 13
Age at AE Onset	2[redacted]
Laboratory Testing	NOT REPORTED
Microbiology	NOT REPORTED
SAE Supplemental Procedure	NOT REPORTED
AE Stopped Rx Day	16
Duration of AE	4 DAYS
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	THE CAUSE OF EVENT IS STILL UNKNOWN
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

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

Event Description	TONSILLAR PHLEGMON INFECTION, THROAT PAIN SINCE ONE DAY
Preferred term	扁桃周囲膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 13
Age at AE Onset	2[redacted]
Laboratory Testing	NOT REPORTED
Microbiology	NOT REPORTED
SAE Supplemental Procedure	NOT REPORTED
AE Stopped Rx Day	16
Duration of AE	4 DAYS
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	THE CAUSE OF EVENT IS STILL UNKNOWN
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Event #3: Serious Adverse Event

Event Description	SUICIDE ATTEMPT
Preferred term	自殺企図
AE Onset Date / Rx Day	[redacted]20[redacted] / 79
Age at AE Onset	2[redacted]
Laboratory Testing	[redacted]20[redacted](RX DAY 79): NPTST098-PARACETOLEMY: 9.9 [10 - 30] MG/L
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 79): ECG: NORMAL
AE Stopped Rx Day	81 (2 DAYS AFTER LAST TREATMENT)
Duration of AE	3 DAYS
Toxicity Grade	4

Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT, IS LIFE THREATENING

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者はフランスの 2[redacted] 歳女性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬及びベタメタゾン吉草酸エステルを投与され，扁桃蜂窩織炎感染及び咽喉痛を発現した。被験者は喫煙者（紙巻タバコ 20 本／日，4 年間）かつ飲酒者（2 杯未満／日）であり，関連する病歴はアトピー性皮膚炎及び結節性紅斑であった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は扁桃蜂窩織炎感染及び咽喉痛を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，扁桃蜂窩織炎感染及び咽喉痛は消失した。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は咽喉痛のため入院した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

mometasone，amoxicilline，プレドニゾロン及び DOLIPRANE が投与された。

The patient's past medications include:

LOCOID for ATOPIC DERMATITIS (20[redacted] - 20[redacted])

DIPROLENE for ATOPIC DERMATITIS (20[redacted] - [redacted] 20[redacted])

FLIXOVATE for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Throat pain (10043523) (Oropharyngeal pain (10068319)) [v.23.0] [10043523]

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

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

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

2) Phlegmonous angina (10074276) (Peritonsillar abscess (10034686)) [v.23.0] [10074276]

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

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

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Causality for BETAMETHASONE VALERATE (Open Label)

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1) Throat pain (10043523) (Oropharyngeal pain (10068319)) [v.23.0] [10043523]

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

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

Dechallenge: Not Applicable

2) Phlegmonous angina (10074276) (Peritonsillar abscess (10034686)) [v.23.0] [10074276]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of TONSILLAR PHLEGMON INFECTION, THROAT PAIN SINCE ONE DAY

- Investigator: The cause of event is still unknown

- AbbVie: Risk factors for tonsillar phlegmon infection include current smoking status and subject's age and event of throat pain is more likely related to concurrent tonsillar phlegmon infection.

Alternative Etiology for BETAMETHASONE VALERATE (Open Label)

Event of TONSILLAR PHLEGMON INFECTION, THROAT PAIN SINCE ONE DAY

- Investigator: The cause of event is still unknown.

- AbbVie: Risk factors for tonsillar phlegmon infection include current smoking status and subject's age and event of throat pain is more likely related to concurrent tonsillar phlegmon infection.

RISK/BENEFIT STATEMENT:

There is no change to the risk/benefit profile for this study/product as a result of this individual report/event(s).

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者はフランスの 2[redacted] 歳女性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，ベタメタゾン吉草酸エステル及びフルチカゾンプロピオン酸エステルを投与され，自殺企図を発現した。被験者は喫煙者（紙巻タバコ 20 本／日，4 年間）かつ飲酒者（2 杯未満／日）であり，関連する病歴はアトピー性皮膚炎，浮動性めまい感，低血圧，うつ病及び睡眠障害であった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は自殺企図を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，自殺企図は消失した。

20[redacted] 年 [redacted] 月 [redacted] 日，自殺企図のため入院した。被験者は paracetamol，ibuprofene 及び tramadol を過量投与した。入院時，被験者は眠気を呈していた。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

NAC が投与された。

The patient's past medications include:

LOCOID for ATOPIC DERMATITIS (20[redacted] - 20[redacted])

DIPROLENE for ATOPIC DERMATITIS (20[redacted] - [redacted] 20[redacted])

FLIXOVATE for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

PREDNISOLONE for TONSILLAR PHLEGMON and SORE THROAT ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Suicide attempt (10042464) (Suicide attempt (10042464)) [v.23.1] [10042464]

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

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

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Causality for BETAMETHASONE VALERATE (Open Label)

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1) Suicide attempt (10042464) (Suicide attempt (10042464)) [v.23.1] [10042464]

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

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

Dechallenge: Not Applicable

Causality for FLUTICASONE PROPIONATE (Open Label)

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1) Suicide attempt (10042464) (Suicide attempt (10042464)) [v.23.1] [10042464]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of SUICIDE ATTEMPT

- Investigator: Not applicable.

- AbbVie: Event is more likely related to pre-existing depression and atopic dermatitis. Patients with atopic dermatitis are at significantly increased risk of suicidal ideation and suicide attempts.

Alternative Etiology for BETAMETHASONE VALERATE (Open Label)

Eventof SUICIDE ATTEMPT

- Investigator: More likely related to Upadacitinib/Placebo

- AbbVie: Etiology of the event is not consistent with the study drug's mechanism of action. Additionally, lack of temporal association, with last dose of study drug over 7 weeks prior to the event.

Alternative Etiology for FLUTICASONE PROPIONATE (Open Label)

Event of SUICIDE ATTEMPT

- Investigator: More likely related to Upadacitinib/Placebo

- AbbVie: Etiology of the event is not consistent with the study drug's mechanism of action. Additionally, lack of temporal association, with last dose of study drug approximately 6 weeks prior to the event.

RISK/BENEFIT STATEMENT:

There is no change to the risk/benefit profile for this study/product as a result of this individual report/event(s).

Relevant Laboratory & Other Diagnostic Tests

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

[redacted] **20[redacted] PARACETOLEMY:** 9.9 MG/L (normal 10 to 30)

Subject [redacted] ([redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
医療機器関連感染	X			X

Treatment Group	Age at Study Start	Sex	Race
PLACEBO/UPA 15 MG QD	5[redacted]	MALE	WHITE

Medical History	Onset Year
ARTERIAL HYPERTENSION	20[redacted]
HYPERLIPIDAMIA	20[redacted]
ATOPIC DERMATITIS	20[redacted]
ATOPIC DERMATITIS	20[redacted]

Prior Procedures	Procedure Year
PRIOR PROCEDURES: JOINT PROTHESIS LEFT ANKLE	19[redacted]

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

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
PLACEBO		ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 100	100
UPA	15 MG	ORAL	QD	[redacted]20[redacted] / 101		

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
VALSARTAN	320/25 mg	QD	Y-M: 20[redacted]
ATORVASTATIN	10 mg	QD	Y-M: 20[redacted]
DIMETINDENE	40 gtt	QD	Y-M: 20[redacted] / -237
ALL OTHER NON-THERAPEUTIC PRODUCTS	1 OTHER: APPLICATION	QD	Y-M: 20[redacted] / -151
MOMETASONE	1 OTHER: APPLICATION	QD	Y-M: 20[redacted] / -151
HYDROCORTISONE	1 OTHER: APPLICATION	QD	Y-M: 20[redacted] / -145
UREA	1 OTHER: APPLICATION	QD	Y-M: 20[redacted] / -145
TACROLIMUS	1 OTHER: APPLICATION	QD	Y-M: 20[redacted] / -136

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
VALSARTAN	320/25 mg	QD	Y-M: 20[redacted]	ONGOING
ATORVASTATIN	10 mg	QD	Y-M: 20[redacted]	ONGOING
DIMETINDENE	40 gtt	QD	Y-M: 20[redacted] / -237	ONGOING
HYDROCORTISONE	1 OTHER: APPLICATION	QD	Y-M: 20[redacted] / -145	NOT REPORTED
UREA	1 OTHER: APPLICATION	QD	Y-M: 20[redacted] / -145	NOT REPORTED
CLINDAMYCIN	600 mg	TID	Y-M: 20[redacted] / 330	NOT REPORTED
CO-DIOVAN	320/25 mg	QD	Y-M: 20[redacted] / 330	NOT REPORTED
DALTEPARIN	5000 OTHER: IE	QD	Y-M: 20[redacted] / 330	NOT REPORTED
PANTOPRAZOLE	20 mg	QD	Y-M: 20[redacted] / 330	NOT REPORTED
METAMIZOLE	500 mg	TID	Y-M: 20[redacted] / 330	Y-M: 20[redacted] / 363
DALTEPARIN	5000 IU	QD	Y-M: 20[redacted] / 450	NOT REPORTED
METAMIZOLE	500 mg	PRN	Y-M: 20[redacted] / 450	NOT REPORTED
VALORON N	50/4 mg	BID	Y-M: 20[redacted] / 450	NOT REPORTED
CLINDAMYCIN	600MG mg	TID	Y-M: 20[redacted] / 450	Y-M: 20[redacted] / 477
RIFAMPICIN	600MG mg	QD	Y-M: 20[redacted] / 450	Y-M: 20[redacted] / 477

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

Event Description	LATE PERIPROTHETIC INFECTION OF UPPER ANKLE JOINT PROSTHESIS LEFT
Preferred term	医療機器関連感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 327
Age at AE Onset	5[redacted]
Laboratory Testing	NOT REPORTED
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 330): EXPLANTATION UPPER ANKLE TEP LEFT, DEBRIDEMENT,LAVAGE AND IMPLANTATION OF ANTIBIOTIC CEMENTSPACER: INFLAMMATION DECLINING
AE Stopped Rx Day	338
Duration of AE	12 DAYS
Toxicity Grade	3

Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

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

Event Description	LATE PERIPROTHETIC INFECTION
Preferred term	医療機器関連感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 449
Age at AE Onset	5[redacted]
Laboratory Testing	NOT REPORTED
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 450): SURGICAL ARTHRODESIS OF LEFT ANKLE JOINT: PERFORMED WITHOUT COMPLICATIONS
AE Stopped Rx Day	455
Duration of AE	7 DAYS
Toxicity Grade	2
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者はドイツの 5[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，prednicarbate，モメタゾンフランカルボン酸エステル及びベタメタゾンジプロピオン酸エステルを投与され，左足関節の遅発性人工関節周囲感染（脛骨コンポーネント周囲）及び遅発性人工関節周囲感染を発現した。被験者は非喫煙者かつ飲酒者（2 杯未満／日）であり，関連する病歴は自動車事故，足関節部骨折，アトピー性皮膚炎で，左足関節の人工関節置換術による治療歴があった。

被験者は本試験開始時の 16 週間の二重盲検投与期に参加していた。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は盲検継続投与期に移行し，盲検下でウパダシチニブ投与が開始された。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は左足関節の遅発性人工関節周囲感染（脛骨コンポーネント周囲）を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，左足関節の遅発性人工関節周囲感染（脛骨コンポーネント周囲）は消失した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は遅発性人工関節周囲感染を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，遅発性人工関節周囲感染は消失した。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は境界明瞭な腫脹，左足関節近位部の軽度発赤，アキレス腱及び腓腹部の圧痛を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は入院した。20[redacted] 年 [redacted] 月 [redacted] 日，患部のデブリードマン及び洗浄を行い，人工足関節を抜去した。抗生物質含有セメントスペーサーを留置した。抗生物質が静脈内投与され，炎症は消退した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は入院した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は足関節の外科的な関節固定術を受け，合併症の発現はなく手術は奏功した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

clindamycin，VALSACOR COMP，FRAGMIN，リファンピシン，NOVALGIN 及び TILIDIN が投与された。

The patient's past medications include:

MOMEGALEN for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

PROTOPIC for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

---

1) Prosthesis related infection (10065011) (Device related infection (10064687)) [v.23.1] [10065011]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

2) Prosthesis related infection (10065011) (Device related infection (10064687)) [v.23.1] [10065011]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

Causality for PREDNICARBATE (Open Label)

---

1) Prosthesis related infection (10065011) (Device related infection (10064687)) [v.23.1] [10065011]

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

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

Dechallenge: Not Applicable

2) Prosthesis related infection (10065011) (Device related infection (10064687)) [v.23.1] [10065011]

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

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

Dechallenge: Not Applicable

Causality for MOMETASONE FUROATE (Open Label)

---

1) Prosthesis related infection (10065011) (Device related infection (10064687)) [v.23.1] [10065011]

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

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

Dechallenge: Not Applicable

2) Prosthesis related infection (10065011) (Device related infection (10064687)) [v.23.1] [10065011]

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

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

Dechallenge: Not Applicable

Causality for BETAMETHASONE DIPROPIONATE (Open Label)

---

1) Prosthesis related infection (10065011) (Device related infection (10064687)) [v.23.1] [10065011]

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

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

Dechallenge: Not Applicable

2) Prosthesis related infection (10065011) (Device related infection (10064687)) [v.23.1] [10065011]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of LATE PERIPROTHETIC INFECTION UPPER ANKLE-JOINT PROSTHESIS LEFT

- Investigator: Not applicable

- AbbVie: Not applicable

Event of LATE PERIPROTHETIC INFECTION

- Investigator: Not applicable

- AbbVie: Not applicable

Alternative Etiology for PREDNICARBATE (Open Label)

Event of LATE PERIPROTHETIC INFECTION UPPER ANKLE-JOINT PROSTHESIS LEFT

- Investigator: More likely related to Upadacitinib/Placebo.

- AbbVie: Weak temporal relationship. Last dose of study drug was approximately 6 months prior to event onset.

Event of LATE PERIPROTHETIC INFECTION

- Investigator: More likely related to Upadacitinib/Placebo.

- AbbVie: Weak temporal relationship. Last dose of study drug was approximately 10 months prior to event onset.

Alternative Etiology for MOMETASONE FUROATE (Open Label)

Event of LATE PERIPROTHETIC INFECTION UPPER ANKLE-JOINT PROSTHESIS LEFT

- Investigator: More likely related to Upadacitinib/Placebo.

- AbbVie: Weak temporal relationship. Last dose of study drug was approximately 6 months prior to event onset.

Event of LATE PERIPROTHETIC INFECTION

- Investigator: More likely related to Upadacitinib/Placebo.

- AbbVie: Weak temporal relationship. Last dose of study drug was approximately 10 months prior to event onset.

Alternative Etiology for BETAMETHASONE DIPROPIONATE (Open Label)

Event of LATE PERIPROTHETIC INFECTION UPPER ANKLE-JOINT PROSTHESIS LEFT

- Investigator: More likely related to Upadacitinib/Placebo.

- AbbVie: Weak temporal relationship. Last dose of study drug was approximately 9 months prior to event onset.

Event of LATE PERIPROTHETIC INFECTION

- Investigator: More likely related to Upadacitinib/Placebo.

- AbbVie: Weak temporal relationship. Last dose of study drug was approximately 13 months prior to event onset.

RISK/BENEFIT STATEMENT:

There is no change to the risk/benefit profile for this study/product as a result of this individual report/event(s).

Company Remarks

Subject [redacted] ([redacted])

Reason for Narrative

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

Treatment Group	Age at Study Start	Sex	Race
UPA 15 MG QD/UPA 15 MG QD	2[redacted]	MALE	WHITE

Medical History	Onset Year
ASTHMA	19[redacted]
ATOPIC DERMATITIS	19[redacted]
ALLERGIC RHINITIS	19[redacted]
ALLERGIC RHINITIS	NOT REPORTED
ASTHMA	NOT REPORTED

Prior Procedures	Procedure Year
Not reported.	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	10 CIGARETTE	8	20[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	2 - 4

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
UPA	15 MG	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 117	117
UPA	15 MG	ORAL	QD	[redacted]20[redacted] / 118	[redacted]20[redacted] / 194	77

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BETAMETHASONE	1 OTHER: APPLICATION	PRN	Y: 19[redacted]
PIMECROLIMUS	1 OTHER: APPLICATION	QD	Y-M: 20[redacted]-[redacted]
ALL OTHER NON-THERAPEUTIC PRODUCTS	1 OTHER: TREATMENT	OTHER: 3 TIMES A WEEK	Y-M: 20[redacted]-[redacted]
ALL OTHER NON-THERAPEUTIC PRODUCTS	1 OTHER: TREATMENT	OTHER: 3 TIMES A WEEK	Y-M: 20[redacted]-[redacted]
CETOMACROGOL	1 OTHER: APPLICATION	BID	Y: 20[redacted]
HEPATITIS B IMMUNIZATION	NOT REPORTED	NOT REPORTED	Y-M: 20[redacted]-[redacted]
TACROLIMUS	1 OTHER: APPLICATION	QD	Y-M: 20[redacted]-[redacted] / -273

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
CETOMACROGOL	1 OTHER: APPLICATION	BID	Y: 20[redacted]	ONGOING

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

Event Description	ACUTE APPENDICITIS
Preferred term	虫垂炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 48
Age at AE Onset	2[redacted]
Laboratory Testing	[redacted]20[redacted] (RX DAY 48): Leukocytes: 15.4 [4 - 11] 10^9/L; Neutrophils: 12.2 [2 - 7.7] 10^9/L
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 48): ABDOMINAL ULTRASOUND: INFLAMMED APPENDIX; LAPAROSCOPIC APPENDECTOMY: NORMAL PROCEDURE WITH NO COMPLICATIONS.
AE Stopped Rx Day	49
Duration of AE	2 DAYS
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

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

Investigator No.: [redacted]

Subject Number: 18023001

Protocol Number: M16-047

本被験者はイスラエルの 2[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，ベタメタゾン吉草酸エステル及びヒドロコルチゾンを投与され，急性虫垂炎を発現した。被験者は元喫煙者（紙巻タバコ 10 本／日，8 年間）かつ適量飲酒者であり，関連する病歴はアトピー性皮膚炎，アレルギー性鼻炎及び喘息であった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は急性虫垂炎を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，急性虫垂炎は消失した。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は右側腹痛及び嘔吐を呈し，救急治療室を受診した。身体的診察で反跳痛を伴う右上腹部痛が認められた。超音波検査で急性虫垂炎と確認された。同日，被験者は入院し，腹腔鏡下虫垂切除術を受け，合併症なく経過した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

The patient's past medications include:

BETACORTEN OINTMENT for ATOPIC DERMATITIS (19[redacted] - [redacted] [redacted] 20[redacted])

ELIDEL for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

PROTOPIC for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

Causality for ABT-494 (Blinded)

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1) Acute appendicitis (10000677) (Appendicitis (10003011)) [v.21.1] [10000677]

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

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

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Causality for BETAMETHASONE VALERATE (Open Label)

---

1) Acute appendicitis (10000677) (Appendicitis (10003011)) [v.21.1] [10000677]

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

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

Dechallenge: Not Applicable

Causality for HYDROCORTISONE (Open Label)

---

1) Acute appendicitis (10000677) (Appendicitis (10003011)) [v.21.1] [10000677]

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABT-494 (Blinded)

Event of ACUTE APPENDICITIS

- Investigator: Not Applicable

- AbbVie: EVENT IS COMMON IN THE GENERAL POPULATION; IT COMPRISES 5 TO 10 PERCENT OF EMERGENCY DEPARTMENT (ED) VISIT. (KENDALL, JL. EVALUATION OF THE ADULT WITH ABDOMINAL PAIN IN THE EMERGENCY DEPARTMENT. IN: UPTODATE, POST TW (ED), UPTODATE, WALTHAM, MA. (ACCESSED ON [redacted] 20[redacted].))

Alternative Etiology for BETAMETHASONE VALERATE (Open Label)

Event of ACUTE APPENDICITIS

- Investigator: Not applicable

- AbbVie: EVENT IS COMMON IN THE GENERAL POPULATION; IT COMPRISES 5 TO 10 PERCENT OF EMERGENCY DEPARTMENT (ED) VISIT. (KENDALL, JL. EVALUATION OF THE ADULT WITH ABDOMINAL PAIN IN THE EMERGENCY DEPARTMENT. IN: UPTODATE, POST TW (ED), UPTODATE, WALTHAM, MA. (ACCESSED ON [redacted] 20[redacted].))

Alternative Etiology for HYDROCORTISONE (Open Label)

Event of ACUTE APPENDICITIS

- Investigator: Not applicable

- AbbVie: EVENT IS COMMON IN THE GENERAL POPULATION; IT COMPRISES 5 TO 10 PERCENT OF EMERGENCY DEPARTMENT (ED) VISIT. (KENDALL, JL. EVALUATION OF THE ADULT WITH ABDOMINAL PAIN IN THE EMERGENCY DEPARTMENT. IN: UPTODATE, POST TW (ED), UPTODATE, WALTHAM, MA. (ACCESSED ON [redacted] 20[redacted].))

RISK/BENEFIT STATEMENT:

There is no change to the risk/benefit profile for this study/product as a result of this individual report/event(s).

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] NEUTROPHILS ABS:** 12.2 10^3/uL

[redacted] **20[redacted] ULTRASOUND:** Inflamed appendix

[redacted] **20[redacted] WHITE BLOOD CELLS:** 15.4 10^3/uL

Subject [redacted] ([redacted])

Reason for Narrative

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

Treatment Group	Age at Study Start	Sex	Race
UPA 30 MG QD/UPA 30 MG QD	2[redacted]	FEMALE	WHITE

Medical History	Onset Year
ATOPIC DERMATITIS	19[redacted]
DUST ALLERGY	20[redacted]
STAMEN ALLERGY	20[redacted]
URTICARIA	20[redacted]
HERPES SIMPLEX	20[redacted]
DEPRESSION	20[redacted]
THROAT ACHE	20[redacted]
UPPER RESPIRATORY TRACT INFECTION	20[redacted]

Prior Procedures	Procedure Year
Not reported.	

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

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
UPA	30 MG	ORAL	QD	[redacted] / 1	[redacted] / 105	105
UPA	30 MG	ORAL	QD	[redacted] / 106		

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
HEPATITIS B IMMUNIZATION	NOT REPORTED	NOT REPORTED	NOT REPORTED
DIFLUCORTOLONE	0.1 %	PRN	Y: 20[redacted]
MARVELON	0.02 mg	QD	Y: 20[redacted]
FEXOFENADINE	180 mg	PRN	Y: 20[redacted]
LACTIDERM	1 OTHER: APPLICATION	BID	Y: 20[redacted]
FUCICORT	0.1 %	BID	Y-M: 20[redacted] / -182
PRED-G S.O.P.	0.5 %	BID	Y-M: 20[redacted] / -182
BETAMETHASONE	0.1 %	OTHER: 2 TIMES PER WEEK	Y-M: 20[redacted] / -143
TACROLIMUS	0.03 %	BID	Y-M: 20[redacted] / -143
CITALOPRAM	20 mg	QD	Y-M: 20[redacted] / -81
BETAMETHASONE	0.1 %	QD	Y-M: 20[redacted] / -4
HYDROCORTISONE	1 %	QD	Y-M: 20[redacted] / -4

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
MARVELON	0.02 mg	QD	Y: 20[redacted]	ONGOING
FEXOFENADINE	180 mg	PRN	Y: 20[redacted]	ONGOING
LACTIDERM	1 OTHER: APPLICATION	BID	Y: 20[redacted]	ONGOING
CITALOPRAM	20 mg	QD	Y-M: 20[redacted] / -81	ONGOING
ACICLOVIR	650 mg	TID	Y-M: 20[redacted] / 372	Y-M: 20[redacted] / 379
MUPIROCIN	1 OTHER: APPLICATION	QD	Y-M: 20[redacted] / 372	Y-M: 20[redacted] / 379

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

Event Description	HERPES ZOSTER
Preferred term	帯状疱疹
AE Onset Date / Rx Day	[redacted] / 372
Age at AE Onset	2[redacted]
Laboratory Testing	NOT REPORTED
Microbiology	[redacted] (RX DAY 372): WOUND NPTST066-HERPES PCR: Positive-LOWER BACK AND LIP VZV POSITIVE
SAE Supplemental Procedure	NOT REPORTED
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Toxicity Grade	3

Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]
Program Source Code [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者はイスラエルの 2[redacted] 歳女性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，ベタメタゾン吉草酸エステル，ヒドロコルチゾン及び tacrolimus を投与され，帯状疱疹を発現した。被験者は非喫煙者かつ飲酒者（2 杯未満／日）であり，関連する病歴は蕁麻疹，単純ヘルペス，アトピー性皮膚炎であった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は帯状疱疹を発現した。

被験者は本試験開始時の 16 週間の二重盲検投与期に参加していた。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は盲検継続投与期に移行し，盲検下でウパダシチニブ投与が開始された。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は腰背部痛及び腰背部の発疹を発現し，皮膚科病棟に入院した。薬剤（名称の報告なし）が静脈内投与された。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

本事象発現前の帯状疱疹ワクチン接種歴はなかった。

The patient's past medications include:

BACTROBAN for HERPES SIMPLEX RECURRENCE and HERPES SIMPLEX RECURRENCE ([redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

---

1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.23.1] [10019974]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: No

Causality for BETAMETHASONE VALERATE (Open Label)

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1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.23.1] [10019974]

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

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

Dechallenge: Not Applicable

Causality for HYDROCORTISONE (Open Label)

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1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.23.1] [10019974]

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

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

Dechallenge: Not Applicable

Causality for TACROLIMUS (Open Label)

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1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.23.1] [10019974]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of HERPES ZOSTER

- Investigator: NOT APPLICABLE

- AbbVie: not applicable

Alternative Etiology for BETAMETHASONE VALERATE (Open Label)

Event of HERPES ZOSTER

- Investigator: More likely related to ABT-494/Placebo

- AbbVie: Weak temporal relation as the last dose of Betamethasone Valerate was more than 11 months prior to event onset.

Alternative Etiology for HYDROCORTISONE (Open Label)

Event of HERPES ZOSTER

- Investigator: More likely related to ABT-494/Placebo

- AbbVie: Weak temporal relation as the last dose of Hydrocortisone was more than 11 months prior to event onset.

Alternative Etiology for TACROLIMUS (Open Label)

Event of HERPES ZOSTER

- Investigator: More likely related to ABT-494/Placebo

- AbbVie: Weak temporal relation as the last dose of Tacrolimus was more than 11 months prior to event onset.

非重篤な有害事象

帯状疱疹が発現した。2 つの神経支配域（第 12 胸神経及び第 1 腰神経）に分布した。治験薬の投与は中断された。

Subject [redacted] ([redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
感染性滑液包炎	X			X
馬尾症候群	X			
単純ヘルペス	X			X
関節膿瘍	X			X

Treatment Group	Age at Study Start	Sex	Race
PLACEBO/UPA 30 MG QD	3[redacted]	MALE	WHITE

Medical History	Onset Year
ASTHMA	19[redacted]
ALLERGIC RHINITIS	19[redacted]
HERPES SIMPLEX	20[redacted]
ATOPIC DERMATITIS	20[redacted]
ALLERGIC RHINITIS	NOT REPORTED
ASTHMA	NOT REPORTED

Prior Procedures	Procedure Year
PRIOR PROCEDURES: GALLBLANDER REMOVAL SURGERY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	1 CIGARETTE	0.5	20[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
PLACEBO		ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 112	112
UPA	30 MG	ORAL	QD	[redacted]20[redacted] / 113		

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
ALL OTHER NON-THERAPEUTIC PRODUCTS	2 J/CM2 gtt	OTHER: 3 TIMES PER WEEK	Y-M: 20[redacted]
CETIRIZINE	10MG mg	BID	Y-M: 20[redacted]
CICLOSPORIN	4 MG/KG mg/kg	BID	Y-M: 20[redacted]
BETAMETHASONE	TWICE DAILY %	BID	Y-M: 20[redacted] / -284
UREA	5% %	BID	Y-M: 20[redacted] / -9

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
CETIRIZINE	10MG mg	BID	Y-M: 20[redacted]	NOT REPORTED
UREA	5% %	BID	Y-M: 20[redacted] / -9	NOT REPORTED
BENZOYL PEROXIDE	5% TWICE DAILY %	BID	Y-M: 20[redacted] / 141	NOT REPORTED
CLOXACILLIN	2 GR 4 TIMES DAILY INTRAVENOUS g	QID	Y-M: 20[redacted] / 368	Y-M: 20[redacted] / 370
DICLOXACILLIN	500 MG mg	QID	Y-M: 20[redacted] / 371	Y-M: 20[redacted] / 381
IBUPROFEN	400 mg	TID	Y-M: 20[redacted] / 477	Y-M: 20[redacted] / 485
TRAMADOL	50 mg	TID	Y-M: 20[redacted] / 477	Y-M: 20[redacted] / 485
PARACETAMOL	1 g	QID	Y-M: 20[redacted] / 477	Y-M: 20[redacted] / 492
CEFAZOLIN	2 g	PRN	Y-M: 20[redacted] / 478	Y-M: 20[redacted] / 478
DICLOXACILLIN	500 mg	TID	Y-M: 20[redacted] / 490	Y-M: 20[redacted] / 493
CLOXACILLIN	2 g	QID	Y-M: 20[redacted] / 494	Y-M: 20[redacted] / 498
ENOXAPARIN	40 mg	QD	Y-M: 20[redacted] / 494	Y-M: 20[redacted] / 498
VALACICLOVIR	500 mg	BID	Y-M: 20[redacted] / 494	Y-M: 20[redacted] / 500

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

Event Description	BACTERIAL BURSITIS WITH ABSCESS OLECRANON RIGHT ELBOW
Preferred term	感染性滑液包炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 368

Age at AE Onset	3[redacted]
Laboratory Testing	NOT REPORTED
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 369): DRAINANGE OF ABSCESS: NO SIDE EFFECTS, GOD EFFECT OF PROCEDURE
AE Stopped Rx Day	371
Duration of AE	4 DAYS
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	TRAUMA
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

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

Event Description	BACTERIAL BURSITIS WITH ABSCESS OLECRANON RIGHT ELBOW
Preferred term	関節膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 368
Age at AE Onset	3[redacted]
Laboratory Testing	NOT REPORTED
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 369): DRAINANGE OF ABSCESS: NO SIDE EFFECTS, GOD EFFECT OF PROCEDURE
AE Stopped Rx Day	371
Duration of AE	4 DAYS
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	TRAUMA
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Event #3: Serious Adverse Event

Event Description	CAUDA EQUINA SYNDROME
Preferred term	馬尾症候群
AE Onset Date / Rx Day	[redacted]20[redacted] / 473
Age at AE Onset	3[redacted]
Laboratory Testing	NOT REPORTED
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 477): MRI LUMBOSACRALCOLUMNA: RESULT OF A LARGE SEQUENCE FROM L4/L5 FILLING IN THE SPINAL CANAL, AFFECTING THE NERVEROOTS FROM L5 AND ONWARDS.; [redacted]20[redacted] (RX DAY 478): SURGERY L4/5 LEFT SIDE AND DECOMPRESSION OF NERVEROOTS IN LUMBALCOLUMNA: RESULT PENDING, PHYSICAL THERAPY FOR 3 WEEKS AFTER SURGERY.

AE Stopped Rx Day	479
Duration of AE	7 DAYS
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	PATIENT WORKS WITH CAR PARTS AND CAR TIRES, POSSIBLE CAUSE OF EVENT WAS WHILE LIFTING HEAVY PARTS
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Event #4: Serious Adverse Event, Event of Interest - Serious Infections

Event Description	HERPES SIMPLEX INFECTION, FACE/UNDER LEFT EYE
Preferred term	単純ヘルペス
AE Onset Date / Rx Day	[redacted]20[redacted] / 494
Age at AE Onset	3[redacted]
Laboratory Testing	[redacted]20[redacted] (RX DAY 498): Hemoglobin: 135 [130 - 170] G/L; Leukocytes: 5.7 [4 - 11] 10^9/L; Lymphocytes: 1 [0.8 - 5] 10^9/L; Monocytes: 0.6 [0.1 - 1.5] 10^9/L; NPTST138-TROMBOCYTES: 361 [150 - 450] 10^9/L; Neutrophils: 3.7 [1.6 - 8.3] 10^9/L
Microbiology	[redacted]20[redacted] (RX DAY 494): WOUND NPTST003-AEROBIC CULTIVATION: Positive-YELLOW STAPHYLOCOCCI; WOUND NPTST069-HSV 1 DNA: Positive-SECRETION FROM WOUND UNDER EYE; WOUND NPTST070-HSV 2 DNA: Negative-SECRETION FROM WOUND UNDER EYE; WOUND NPTST159-VZV DNA: Negative-SECRETION FROM WOUND UNDER EYE
SAE Supplemental Procedure	NOT REPORTED
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者はノルウェーの 3[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，モメタゾンフランカルボン酸エステル，ヒドロコルチゾン及びクロベタゾールプロピオン酸エステルを投与され，右肘頭部の膿瘍を伴う細菌性滑液包炎を発現した。被験者は元喫煙者（紙巻タバコ 1 本／日，0.5 年間）かつ飲酒者（2 杯未満／日）であり，関連する病歴はアトピー性皮膚炎であった。

被験者は本試験開始時の 16 週間の二重盲検投与期に参加していた。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は盲検継続投与期に移行し，盲検下でウパダシチニブ投与が開始された。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は右肘頭部の膿瘍を伴う細菌性滑液包炎を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，右肘頭部の膿瘍を伴う細菌性滑液包炎は消失した。

2 週間前，被験者は右肘関節部に外傷を負った。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は疼痛及び発熱を呈し，入院した。右肘関節部に膿瘍が認められた。20[redacted] 年 [redacted] 月 [redacted] 日，膿瘍のドレナージが行われ，副作用はなく，処置が奏功した。抗生物質の投与も行われた。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

cloxacillin 及び dicloxacillin が投与された。

The patient's past medications include:

SANDIMMUN NEORAL for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

BETNOVAT 0.1 CREAM for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

PREDNISOLON for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

---

1) Bursitis infective (10061022) (Bursitis infective (10061022)) [v.23.0] [10061022]

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

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

Dechallenge: Not Applicable

2) Joint abscess (10058981) (Joint abscess (10058981)) [v.23.0] [10058981]

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

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

Dechallenge: Not Applicable

Causality for MOMETASONE FUROATE (Open Label)

---

1) Bursitis infective (10061022) (Bursitis infective (10061022)) [v.23.0] [10061022]

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

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

Dechallenge: Not Applicable

2) Joint abscess (10058981) (Joint abscess (10058981)) [v.23.0] [10058981]

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

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

Dechallenge: Not Applicable

Causality for HYDROCORTISONE (Open Label)

---

1) Bursitis infective (10061022) (Bursitis infective (10061022)) [v.23.0] [10061022]

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

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

Dechallenge: Not Applicable

2) Joint abscess (10058981) (Joint abscess (10058981)) [v.23.0] [10058981]

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

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

Dechallenge: Not Applicable

Causality for CLOBETASOL PROPIONATE (Open Label)

---

1) Bursitis infective (10061022) (Bursitis infective (10061022)) [v.23.0] [10061022]

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

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

Dechallenge: Not Applicable

2) Joint abscess (10058981) (Joint abscess (10058981)) [v.23.0] [10058981]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of BACTERIAL BURSITIS WITH ABSCESS OLECRANON RIGHT ELBOW

- Investigator: Trauma

- AbbVie: Event more likely related to trauma to that territory 2 weeks prior as noted by PI.

Alternative Etiology for MOMETASONE FUROATE (Open Label)

Event of BACTERIAL BURSITIS WITH ABSCESS OLECRANON RIGHT ELBOW

- Investigator: Trauma

- AbbVie: Event more likely related to trauma to that territory 2 weeks prior as noted by PI. In addition weak temporal relationship since last dose was about 8 months prior to event.

Alternative Etiology for HYDROCORTISONE (Open Label)

Event of BACTERIAL BURSITIS WITH ABSCESS OLECRANON RIGHT ELBOW

- Investigator: Trauma

- AbbVie: Event more likely related to trauma to that territory 2 weeks prior as noted by PI. In addition weak temporal relationship since last dose was about 9 months prior to event.

Alternative Etiology for CLOBETASOL PROPIONATE (Open Label)

Event of BACTERIAL BURSITIS WITH ABSCESS OLECRANON RIGHT ELBOW

- Investigator: Trauma

- AbbVie: Event more likely related to trauma to that territory 2 weeks prior as noted by PI. In addition weak temporal relationship since last dose was about 10.5 months prior to event.

RISK/BENEFIT STATEMENT:

There is no change to the risk/benefit profile for this study/product as a result of this individual report/event(s).

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者はノルウェーの 3[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，モメタゾンフランカルボン酸エステル，ヒドロコルチゾン及びクロベタゾールプロピオン酸エステルを投与され，馬尾症候群を発現した。被験者は元喫煙者（紙巻タバコ 1 本／日，0.5 年間）かつ飲酒者（2 杯未満／日）であり，関連する病歴はアトピー性皮膚炎であった。

被験者は本試験開始時の 16 週間の二重盲検投与期に参加していた。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は盲検継続投与期に移行し，盲検下でウパダシチニブ投与が開始された。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は馬尾症候群を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，馬尾症候群は消失した。

20[redacted] 年 [redacted] 月 [redacted] 日，急性背部痛，並びに殿部，大腿部及び左下肢の電撃痛に対し予定されていた外科手術のため，被験者は入院した。磁気共鳴画像検査が行われ，第 4／第 5 腰椎椎間以下の脊

柱管に広範囲の充満像が認められ，第 5 腰神経以下の神経根が障害されていた。20[redacted] 年 [redacted] 月 [redacted] 日，第 4／第 5 腰椎椎間位のマイクロサージェリーが行われ，左側の神経根が除圧された。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

cefazolin，イブプロフェン，paracetamol 及び tramadol が投与された。

The patient's past medications include:

UVBTL01 for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

SANDIMMUN NEORAL for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

BETNOVAT 0,1 CREAM for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

PREDNISOLON for ATOPIC DERMATITIS RESCUE THERAPY ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Cauda equina syndrome (10007821) (Cauda equina syndrome (10007821)) [v.23.0] [10007821]

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

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

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Causality for MOMETASONE FUROATE (Open Label)

---

1) Cauda equina syndrome (10007821) (Cauda equina syndrome (10007821)) [v.23.0] [10007821]

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

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

Dechallenge: Not Applicable

Causality for HYDROCORTISONE (Open Label)

---

1) Cauda equina syndrome (10007821) (Cauda equina syndrome (10007821)) [v.23.0] [10007821]

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

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

Dechallenge: Not Applicable

Causality for CLOBETASOL PROPIONATE (Open Label)

---

1) Cauda equina syndrome (10007821) (Cauda equina syndrome (10007821)) [v.23.0] [10007821]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of CAUDA EQUINA SYNDROME

- Investigator: Patient works with car parts and car tires, possible cause of event was while lifting heavy parts.

- AbbVie: more likely related to large sequence from L4,L5 filling the spinal cord and affecting nerve roots at the level of L5 as seen per MRI results. Additional risk factor includes lifting heavy weights as reported by PI.

Alternative Etiology for MOMETASONE FUROATE (Open Label)

Event of CAUDA EQUINA SYNDROME

- Investigator: Patient works with car parts and car tires, possible cause of event was while lifting heavy parts.

- AbbVie: More likely related to large sequence from L4,L5 filling the spinal cord and affecting nerve roots at the level of L5 as seen per MRI results. Additional risk factor includes lifting heavy weights as reported by PI.

Alternative Etiology for HYDROCORTISONE (Open Label)

Event of CAUDA EQUINA SYNDROME

- Investigator: Patient works with car parts and car tires, possible cause of event was while lifting heavy parts.

- AbbVie: more likely related to large sequence from L4,L5 filling the spinal cord and affecting nerve roots at the level of L5 as seen per MRI results. Additional risk factor includes lifting heavy weights as reported by PI.

Alternative Etiology for CLOBETASOL PROPIONATE (Open Label)

Event of CAUDA EQUINA SYNDROME

- Investigator: Patient works with car parts and car tires, possible cause of event was while lifting heavy parts.

- AbbVie: more likely related to large sequence from L4,L5 filling the spinal cord and affecting nerve roots at the level of L5 as seen per MRI results. Additional risk factor includes lifting heavy weights as reported by PI.

Relevant Laboratory & Other Diagnostic Tests

[redacted] [redacted] **20[redacted] MRI:** Result of a large sequence from L4/L5 filling in the spinal canal, affecting the nerve roots from L5 and onwards.

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者はノルウェーの 3[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，モメタゾンフランカルボン酸エステル，ヒドロコルチゾン及びクロベタゾールプロピオン酸エステルを投与され，単純ヘルペス感染（顔面，左眼下方）を発現した。被験者は元喫煙者（紙巻タバコ 1 本／日，0.5 年間）かつ飲酒者（2 杯未満／日）であり，関連する病歴は喘息，単純ヘルペス，アトピー性皮膚炎であった。

被験者は本試験開始時の 16 週間の二重盲検投与期に参加していた。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は盲検継続投与期に移行し，盲検下でウパダシチニブ投与が開始された。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は単純ヘルペス感染（顔面，左眼下方）を発現した。

顔面が感染し，左眼下方に腫脹及び痂皮形成が認められた。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は一般開業医を受診し，ヘルペスの症状再燃の疑いと診断された。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は入院し，

ヘルペスの症状再燃及び細菌感染に対する治療を受けた。抗ウイルス薬及び抗生物質が投与された。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

cloxacillin，VALTREX 及び KLEXANE が投与された。

The patient's past medications include:

SANDIMMUN NEORAL for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

BETNOVAT for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

PREDNISOLON for ATOPIC DERMATITIS RESCUE THERAPY ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Herpes simplex (10019948) (Herpes simplex (10019948)) [v.23.0] [10019948]

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

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

Dechallenge: No

Causality for MOMETASONE FUROATE (Open Label)

---

1) Herpes simplex (10019948) (Herpes simplex (10019948)) [v.23.0] [10019948]

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

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

Dechallenge: Not Applicable

Causality for HYDROCORTISONE (Open Label)

---

1) Herpes simplex (10019948) (Herpes simplex (10019948)) [v.23.0] [10019948]

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

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

Dechallenge: Not Applicable

Causality for CLOBETASOL PROPIONATE (Open Label)

---

1) Herpes simplex (10019948) (Herpes simplex (10019948)) [v.23.0] [10019948]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of HERPES SIMPLEX INFECTION, FACE/UNDER LEFT EYE

- Investigator: Not applicable.

- AbbVie: Event more likely related to pre-existing recurrent herpes simplex infections.

Alternative Etiology for MOMETASONE FUROATE (Open Label)

Event of HERPES SIMPLEX INFECTION, FACE/UNDER LEFT EYE

- Investigator: More likely related to Upadacitinib/Placebo.

- AbbVie: Event more likely related to pre-existing recurrent herpes simplex infections.

Alternative Etiology for HYDROCORTISONE (Open Label)

Event of HERPES SIMPLEX INFECTION, FACE/UNDER LEFT EYE

- Investigator: More likely related to Upadacitinib/Placebo.

- AbbVie: Event more likely related to pre-existing recurrent herpes simplex infections.

Alternative Etiology for CLOBETASOL PROPIONATE (Open Label)

Event of HERPES SIMPLEX INFECTION, FACE/UNDER LEFT EYE

- Investigator: More likely related to Upadacitinib/Placebo.

- AbbVie: Event more likely related to pre-existing recurrent herpes simplex infections.

RISK/BENEFIT STATEMENT:

There is no change to the risk/benefit profile for this study/product as a result of this individual report/event(s).

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] AEROBIC CULTIVATION (WOUND):** Positive - yellow Staphylococci

[redacted] **20[redacted] HEMOGLOBIN:** 13.5 G/DL (normal 13.0 to 17.0)

[redacted] **20[redacted] HSV 1 DNA (WOUND):** Positive: secretion from wound under eye

[redacted] **20[redacted] HSV 2 DNA (WOUND):** Negative - Secretion from wound under eye

[redacted] **20[redacted] NEUTROPHILS ABS:** 3.7 X10**9/L (normal 1.6 to 8.13)

[redacted] **20[redacted] VZV DNA (WOUND):** Negative - secretion from wound under eye

[redacted] **20[redacted] WHITEBLOOD CELLS:** 5.7 X10**9/L (normal 4.0 to 11.0)

Subject [redacted] ([redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
貧血				X
ヘモグロビン減少	X	X		X

Treatment Group	Age at Study Start	Sex	Race
UPA 30 MG QD/UPA 30 MG QD	6[redacted]	MALE	WHITE

Medical History	Onset Year
HYPERTENSION	19[redacted]
HEPATITIS	19[redacted]
ATOPIC DERMATITIS	20[redacted]
INTERVERTEBRAL DISC HERNIATION	20[redacted]
SPINAL PAIN	20[redacted]
BENIGN PROSTATA HYPERTROPHY	20[redacted]
CYST OF KIDNEY	20[redacted]
LEFT LOWER LEG MUSCLE PARESIS	20[redacted]
OSTEOPOROSIS	20[redacted]
SPINAL STENOSIS	20[redacted]
STEATOSIS HEPATIS	20[redacted]

Prior Procedures	Procedure Year
PRIOR PROCEDURES: APPENDECTOMY	19[redacted]
PRIOR PROCEDURES: SURGERY OF INTERVERTEBRAL DISC HERNIATION	20[redacted]
PRIOR PROCEDURES: SURGERY OF KERATHOACANTHOMA	20[redacted]
PRIOR PROCEDURES: SPINE SURGERY	20[redacted]
PRIOR PROCEDURES: SPINE SURGERY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	15 CIGARETTE	53	20[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
UPA	30 MG	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 110	110
UPA	30 MG	ORAL	QD	[redacted]20[redacted] / 111	[redacted]20[redacted] / 126	16

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BCG Vaccine	NOT REPORTED	NOT REPORTED	Y: 19[redacted]
BCG Vaccine	NOT REPORTED	NOT REPORTED	Y: 19[redacted]
AMLODIPINE	5 mg	QD	Y: 19[redacted]
METOPROLOL	50 mg	QD	Y: 19[redacted]
VASERETIC	20/12,5 mg	QD	Y: 19[redacted]
ALL OTHER NON-THERAPEUTIC PRODUCTS	1 IU	QD	Y: 20[redacted]
CICLOSPORIN	200 mg	QD	Y-M: 20[redacted]-[redacted]
METHYLPREDNISOLONE	4 mg	QD	Y: 20[redacted]
FENTANYL	50 ug	OTHER: EVERY 72 HOURS	Y-M: 20[redacted]-[redacted]
FAMOTIDINE	20 mg	QD	Y: 20[redacted]
CLOBETASOL	1 IU	QD	Y-M: 20[redacted]-[redacted] / -65
CLOBETASOL	1 OTHER: FINGERTIP	QD	Y-M: 20[redacted]-[redacted] / -65
ERGOCALCIFEROL	3000 IU	QD	Y-M: 20[redacted]-[redacted] / -65
ATODERM	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]-[redacted] / -10

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
AMLODIPINE	5 mg	QD	Y: 19[redacted]	ONGOING
METOPROLOL	50 mg	QD	Y: 19[redacted]	ONGOING
VASERETIC	20/12,5 mg	QD	Y: 19[redacted]	ONGOING
FENTANYL	50 ug	OTHER: EVERY 72 HOURS	Y-M: 20[redacted]-[redacted]	ONGOING
ERGOCALCIFEROL	3000 IU	QD	Y-M: 20[redacted]-[redacted] / -65	ONGOING
ATODERM	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]-[redacted] / -10	ONGOING
SOLUZIONE BORO SALICILICA	1 OTHER: APPLICATION	OTHER: AS NEEDED	Y-M: 20[redacted]-[redacted] / 54	ONGOING

Event #1: Event of Interest - Anemia

Event Description	ANAEMIA
Preferred term	貧血
AE Onset Date / Rx Day	[redacted]20[redacted] / 85
Age at AE Onset	6[redacted]
Laboratory Testing	NOT APPLICABLE
Microbiology	NOT APPLICABLE
SAE Supplemental Procedure	NOT APPLICABLE
AE Stopped Rx Day	125
Duration of AE	41 DAYS
Toxicity Grade	3
Relation to Study Drug by Investigator	UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY
Investigator Alternative Etiology	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Event of Interest - Anemia

Event Description	FURTHER DECREASE OF HAEMOGLOBIN LEVEL
Preferred term	ヘモグロビン減少
AE Onset Date / Rx Day	[redacted]20[redacted] / 126
Age at AE Onset	6[redacted]
Laboratory Testing	[redacted]20[redacted] (RX DAY 125): Erythrocytes: 1.5 [4.7 - 6.1] 10^12/L; Hematocrit: 0.17 [0.39 - 0.5] UNIT NOT REPORTED; Hemoglobin: 59 [130 - 165] G/L; Leukocytes: 11.5 [4.5 - 10.8] 10^9/L; NPTST056-FERRITIN: 904.7 [30 - 400] UG/L; NPTST058-FOLATE: 16.1 [10.4 - 42.4] NMOL/L; NPTST075-IRON: 10.4 [10.6 - 28.3] UMOL/L; NPTST155-VITAMIN B12: 233.6 [145 - 637] PMOL/L; [redacted]20[redacted] (RX DAY 128): Erythrocytes: 2.3 [4.7 - 6.1] 10^12/L; Hematocrit: 0.22 [0.39 - 0.5] UNIT NOT REPORTED; Hemoglobin: 79 [130 - 165] G/L; Leukocytes: 9.2 [4.5 - 10.8] 10^9/L; [redacted]20[redacted] (RX DAY 129): Erythrocytes: 2.8 [4.7 - 6.1] 10^12/L; Hematocrit: 0.26 [0.39 - 0.5] UNIT NOT REPORTED; Hemoglobin: 94 [130 - 165] G/L; Leukocytes: 10.5 [4.5 - 10.8] 10^9/L; [redacted]20[redacted] (RX DAY 130): Erythrocytes: 2.9 [4.7 - 6.1] 10^12/L; Hematocrit: 0.27 [0.39 - 0.5] UNIT NOT REPORTED; Hemoglobin: 98 [130 - 165] G/L; Leukocytes: 9.1 [4.5 - 10.8] 10^9/L
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted]20[redacted](RX DAY 125): BONE MARROW BIOPSY: NEGATIV; [redacted]20[redacted] (RX DAY 127): ABDOMINAL ULTRASOUND: HEPATOMEGALY, CHOLECYSTOPATHY, KIDNEY CYST,; CHEST XRAY: NEGATIV
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

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

Investigator No.: [redacted]

S Subject Number: [redacted]

Protocol Number: M16-047

本被験者はハンガリーの6[redacted]歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，モメタゾンフランカルボン酸エステル，ヒドロコルチゾン及びクロベタゾールプロピオン酸エステルを投与され，ヘモグロビン値の更なる低下を発現した。被験者は元喫煙者（紙巻タバコ 15 本／日，53 年間）かつ飲酒者（2 杯未満／日）であり，関連する病歴は高血圧，肝炎，アトピー性皮膚炎，ケラトアカントーマ，良性前立腺肥大，腎嚢胞及び脂肪肝であった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者はヘモグロビン値の更なる低下を発現した。

20[redacted] 年 [redacted] 月 [redacted] 日から同年 [redacted] 月 [redacted] 日まで，被験者は貧血（非重篤）を発現していた。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者はヘモグロビン値の更なる低下を発現し，加療を目的に入院した。赤血球濃厚液が輸血された。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。被験者は本試験を中止した。

赤血球濃厚液が輸血された。

The patient's past medications include:

CLOBETASOL PROPIONATE for ATOPIC DERMATITIS ([redacted] [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

---

1) Decreased hemoglobin (10011964) (Haemoglobin decreased (10018884)) [v.22.0] [10011964]

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

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

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Causality for MOMETASONE FUROATE (Open Label)

---

1) Decreased hemoglobin (10011964) (Haemoglobin decreased (10018884)) [v.22.0] [10011964]

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

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

Dechallenge: Not Applicable

Causality for HYDROCORTISONE (Open Label)

---

1) Decreased hemoglobin (10011964) (Haemoglobin decreased (10018884)) [v.22.0] [10011964]

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

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

Dechallenge: Not Applicable

Causality for CLOBETASOL PROPIONATE (Open Label)

---

1) Decreased hemoglobin (10011964) (Haemoglobin decreased (10018884)) [v.22.0] [10011964]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of FURTHER DECREASE OF HEMOGLOBIN LEVEL

- Investigator: Not applicable.

- AbbVie: Risk factors include pre-existing autoimmune disorder of atopic dermatitis and subject's advanced age.

Alternative Etiology for MOMETASONE FUROATE (Open Label)

Event of FURTHER DECREASE OF HEMOGLOBIN LEVEL

- Investigator: Not reported.

- AbbVie: Lack of temporal association with last dose of mometasone furoate 4 months prior to onset of event.

Alternative Etiology for HYDROCORTISONE (Open Label)

Event of FURTHER DECREASE OF HEMOGLOBIN LEVEL

- Investigator: Not reported.

- AbbVie: Lack of temporal association with last dose of hydrocortisone 4 months prior to onset of event.

Alternative Etiology for CLOBETASOL PROPIONATE (Open Label)

Event of FURTHER DECREASE OF HEMOGLOBIN LEVEL

- Investigator: Not reported.- AbbVie: Lack of temporal association with last dose of clobetasol propionate 5 months prior to onset of event.

RISK/BENEFIT STATEMENT:

There is no change to the risk/benefit profile for this study/product as a result of this individual report/event(s).

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMINAL ULTRASOUND:** Hepatomegaly, cholecystopathy, kidney cyst.

[redacted] **20[redacted] BONE MARROW BIOPSY:** Negative

[redacted] **20[redacted] CXR:** Negative

[redacted] **20[redacted] FERRITIN:** 904.7 MCG/L (normal 30 to 400)

[redacted] **20[redacted] FOLATE:** 16.1 NMOL/L (normal 10.4 to 42.4)

[redacted] **20[redacted] HCT:** 0.17 NO UNITS (normal 0.39 to 0.5)

[redacted] **20[redacted] HCT:** 0.22 NO UNITS (normal 0.39 to 0.5)

[redacted] **20[redacted] HCT:** 0.26 NO UNITS (normal 0.39 to 0.5)

[redacted] **20[redacted] HCT:** 0.27 NO UNITS (normal 0.39 to 0.5)

Unknown date HEMOGLOBIN: Further decrease

[redacted] **20[redacted] HGB:** 59 G/L (normal 130 to 165)

[redacted] **20[redacted] HGB:** 79 G/L (normal 130 to 165)

[redacted] **20[redacted] HGB:** 94 G/L (normal 130 to 165)

[redacted] **20[redacted] HGB:** 98 G/L (normal 130 to 165)

[redacted] **20[redacted] IRON:** 10.4 MCMOL/L (normal 10.6 to 28.3)

[redacted] **20[redacted] RBC:** 1.53 X10**12/L (normal 4.7 to 6.1)

[redacted] **20[redacted] RBC:** 2.29 X10**12/L (normal 4.7 to 6.1)

[redacted] **20[redacted] RBC:** 2.89 X10**12/L (normal 4.7 to 6.1)

[redacted] **20[redacted] VITAMIN B12:** 233.6 PMOL/L (normal 145 to 637)

[redacted] **20[redacted] WBC:** 9.23 X10**9/L (normal 4.5 to 10.8)

[redacted] **20[redacted] WBC:** 10.52 GIGA/L (normal 4.5 to 6.1)

[redacted] **20[redacted] WBC:** 9.12 X10**9/L (normal 4.5 to 10.8)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 11.49 X10**9/L (normal 4.5 to 10.8)

Subject [redacted] ([redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
出血性十二指腸潰瘍	X			

Treatment Group	Age at Study Start	Sex	Race
UPA 15 MG QD/UPA 15 MG QD	2[redacted]	MALE	ASIAN

Medical History	Onset Year
ATOPIC DERMATITIS	19[redacted]
ATOPIC DERMATITIS	20[redacted]
SCOLIOSIS	20[redacted]
ALLERGIC RHINITIS	NOT REPORTED
FISH ALLERGY	NOT REPORTED
FOOD ALLERGY	NOT REPORTED
SHRIMP ALLERGY	NOT REPORTED

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

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

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
UPA	15 MG	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 113	113
UPA	15 MG	ORAL	QD	[redacted]20[redacted] / 114		

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
HEPATITIS B IMMUNIZATION	NOT REPORTED	NOT REPORTED	NOT REPORTED
LORATADINE	NA OTHER: NA	OTHER: NA	Y: 20[redacted]
MOMETASONE	NA OTHER: NA	OTHER: NA	Y: 20[redacted]
TACROLIMUS	NA OTHER: NA	OTHER: NA	Y: 20[redacted]
OTHER EMOLLIENTS AND PROTECTIVES	APPROPRIATE mL	BID	Y: 20[redacted]
BCG VACCINE	2 OTHER: BOTTLE	OTHER: QOD	Y: 20[redacted]
GLYCYRRHIZA GLABRA	NA OTHER: NA	OTHER: NA	Y: 20[redacted]
LEVOCETIRIZINE	5 mg	OTHER: QN	Y: 20[redacted]
KETOTIFEN	1 mg	OTHER: QN	Y-M: 20[redacted]-[redacted] / -28

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
OTHER EMOLLIENTS AND PROTECTIVES	APPROPRIATE mL	BID	Y: 20[redacted]	NOT REPORTED
BATROXOBIN	1 OTHER: U	BID	Y-M: 20[redacted]-[redacted] / 324	Y-M: 20[redacted]-[redacted] / 325
TEPRENONE	50 mg	TID	Y-M: 20[redacted]-[redacted] / 324	Y-M: 20[redacted]-[redacted] / 326
ASCORBIC ACID	2 g	QD	Y-M: 20[redacted]-[redacted] / 324	Y-M: 20[redacted]-[redacted] / 327
PANTOPRAZOLE	60 mg	BID	Y-M: 20[redacted]-[redacted] / 324	Y-M: 20[redacted]-[redacted] / 327
PYRIDOXINE	0.2 g	QD	Y-M: 20[redacted]-[redacted] / 324	Y-M: 20[redacted]-[redacted] / 327
AMOXICILLIN	1 g	BID	Y-M: 20[redacted]-[redacted] / 327	Y-M: 20[redacted]-[redacted] / 337
BISMUTH	0.2 g	BID	Y-M: 20[redacted]-[redacted] / 327	Y-M: 20[redacted]-[redacted] / 337
CLARITHROMYCIN	0.5 g	BID	Y-M: 20[redacted]-[redacted] / 327	Y-M: 20[redacted]-[redacted] / 337
PANTOPRAZOLE	40 mg	BID	Y-M: 20[redacted]-[redacted] / 328	Y-M: 20[redacted]-[redacted] / 390
TAMSULOSIN	0.2 mg	OTHER: QN	Y-M: 20[redacted]-[redacted] / 340	Y-M: 20[redacted]-[redacted] / 368
CEFIXIME	100 mg	BID	Y-M: 20[redacted]-[redacted] / 366	Y-M: 20[redacted]-[redacted] / 380
FOSFOMYCIN	3 g	OTHER: QOD	Y-M: 20[redacted]-[redacted] / 366	Y-M: 20[redacted]-[redacted] / 380

ADAPALENE	APPROPRIATE g	OTHER: QN	Y-M: 20[redacted] / 366	Y-M: 20[redacted] / 431

Event #1: Serious Adverse Event

Event Description	DUODENAL ULCER WITH BLEEDING
Preferred term	出血性十二指腸潰瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 324
Age at AE Onset	2[redacted]
Laboratory Testing	[redacted]20[redacted] (RX DAY 324): Erythrocytes: 4.4 [4.3 - 5.8] 10^12/L; Hematocrit: 0.39 [0.4 - 0.5] FRACTION OF 1; Hemoglobin: 132 [130 - 175] G/L; Leukocytes: 4.6 [3.5 - 9.5] 10^9/L; NPTST001-ACTIVATED PARTIAL THROMBOPLASTI: 27.2 [23.5 - 36] SEC; NPTST112-PROTHRORNBIN TIME: 12.1 [10 - 14] SEC; Platelets: 210 [125 - 350] 10^9/L; Prothrombin Intl. Normalized Ratio: 1.06 [0.85 - 1.15] RATIO; [redacted]20[redacted] (RX DAY 329): NPTST125-ROUTINE STOOL TEST: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED
Microbiology	[redacted]20[redacted] (RX DAY 324): OTHER BIOPSY NPTST060-GASTROSCOPE BIOPSY: Positive-CHRONIC MODERATE SUPERFICIAL GASTRIC (SINUS) MUCOSA (ACTIVITY)?HELICOBACTER PYLORI POSITIVE
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 324): CHEST RADIOGRAPHY: SUSPICIOUS NODULES AND A FEW STRIP SHADOW IN THE LEFT LUNG ARE SUGGESTED TO BE CONFIRMED BY CT SCAN.; ELECTROCARDIOGRAM: SINUS BRADYCARDIA; GASTROSCOPE: DUODENAL GLOBULAR ULCER WITH BLEEDING (IB)?HEMOSTASIS FOR DUODENAL BULBAR ULCER?SUPERFICIAL GASTRITIS; HEMOSTASIS FOR DUODENAL BULBAR ULCER: A SMALL PIECE OF TITANIUM IS CLIPPED , NO OBVIOUS BLEEDING WAS SEEN, HYPEREMIA AND EDEMA OF THE SURROUNDING MUCOSA.; LIVER, GALLBLADDER, PANCREAS, SPLEEN AND KIDNEY?COLOR DOPPLER ULTRASONOGRAPHY: LIVER, GALLBLADDER, PANCREAS, SPLEEN AND KIDNEY NO OBVIOUS ABNORMALITY. LEFT RENAL CALCIUM LACTOGENESIS CONSIDERED.; [redacted]20[redacted] (RX DAY 325): CHEST CT PLAIN SCAN: TWO LUNG FIBROUS FOCI, BILATERAL PLEURA THICKENED; [redacted]20[redacted] (RX DAY 390): GASTROSCOPE: SUPERFICIAL GASTRITIS
AE Stopped Rx Day	390
Duration of AE	67 DAYS
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者は中国の 2[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，モメタゾンフランカルボン酸エステル，tacrolimus 及び desonide を投与され，出血を伴う十二指腸潰瘍を発現した。被験者は非喫煙者かつ非飲酒者であり，関連する病歴はアトピー性皮膚炎であった。

被験者は本試験開始時の 16 週間の二重盲検投与期に参加していた。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は盲検継続投与期に移行し，盲検下でウパダシチニブ投与が開始された。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は出血を伴う十二指腸潰瘍を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，出血を伴う十二指腸潰瘍は消失した。

20[redacted] 年 [redacted] 月 [redacted] 日，黒色便を伴う腹痛が 1 ヵ月持続していたため，被験者は精査を目的に入院した。同日，胃内視鏡検査が行われ，十二指腸球部の潰瘍，表層性胃炎，潰瘍周辺粘膜の充血及び浮腫が認められた。十二指腸潰瘍にクリッピングを施して止血した。生検で *H. pylori* が確認された。その後，身体的診察所見は改善し，腹痛，腹部膨満，血便排泄，メレナの症状は出なかった。20[redacted] 年 [redacted] 月 [redacted] 日，潰瘍は残存していたが被験者は退院した。

20[redacted] 年 [redacted] 月 [redacted] 日，胃内視鏡検査が行われ，十二指腸に明らかな異常は認められなかった。有害事象は消失したと判断された。

テプレノン，HEMOCOAGULASE BOTHROPS ATROX，pantoprazole sodium，ビタミン C，ビタミン B6，クラリスロマイシン，COLLOIDAL BISMUTH PECTIN 及び amoxicillin が投与された。

The patient's past medications include:

LORATADINE TABLETS for ATOPIC DERMATITIS (20[redacted] - 20[redacted])

BCG POLYSACCHARIDE AND NUCLEIC ACID INJECTION for ATOPIC DERMATITIS (20[redacted] - 20[redacted])

COMPOUND GLYCYRRHIZIN TABLETS for ATOPIC DERMATITIS (20[redacted] - [redacted] 20[redacted])

LEVOCETIRIZINE HYDROCHORIDE TABLETS for ATOPIC DERMATITIS (20[redacted] - [redacted] [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] [redacted] 20[redacted], [redacted] May 20[redacted] - [redacted] [redacted] 20[redacted], [redacted] [redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

KETOTIFAN FUMARATE DISPERSIBLE TABLETS for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Duodenal ulcer bleeding (10071802) (Duodenal ulcer haemorrhage (10013839)) [v.23.0] [10071802]

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

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

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Causality for MOMETASONE FUROATE (Open Label)

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1) Duodenal ulcer bleeding (10071802) (Duodenal ulcer haemorrhage (10013839)) [v.23.0] [10071802]

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

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

Dechallenge: Not Applicable

Causality for TACROLIMUS (Open Label)

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1) Duodenal ulcer bleeding (10071802) (Duodenal ulcer haemorrhage (10013839)) [v.23.0] [10071802]

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

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

Dechallenge: Not Applicable

Causality for DESONIDE (Open Label)

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1) Duodenal ulcer bleeding (10071802) (Duodenal ulcer haemorrhage (10013839)) [v.23.0] [10071802]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of DUODENAL ULCER WITH BLEEDING

- Investigator: Not applicable.

- AbbVie: Event of duodenal ulcer is more likely related to H.pylori infection noted in gastroscopy with bleeding being a complication of duodenal ulcer.

Alternative Etiology for MOMETASONE FUROATE (Open Label)

Event of DUODENAL ULCER WITH BLEEDING

- Investigator: Event more likely related to Upadacitinib/placebo.

- AbbVie: Event of duodenal ulcer is more likely related to H.pylori infection noted in gastroscopy with bleeding being a complication of duodenal ulcer.

Alternative Etiology for TACROLIMUS (Open Label)

Event of DUODENAL ULCER WITH BLEEDING

- Investigator: Event more likely related to Upadacitinib/placebo.

- AbbVie: Event of duodenal ulcer is more likely related to H.pylori infection noted in gastroscopy with bleeding being a complication of duodenal ulcer.

Alternative Etiology for DESONIDE (Open Label)

Event of DUODENAL ULCER WITH BLEEDING

- Investigator: Event more likely related to Upadacitinib/placebo.

- AbbVie: Event of duodenal ulcer is more likely related to H.pylori infection noted in gastroscopy with bleeding being a complication of duodenal ulcer.

RISK/BENEFIT STATEMENT:

There is no change to the risk/benefit profile for this study/product as a result of this individual report/event(s).

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMINAL ULTRASOUND:** Liver, gallbladder, pancreas, spleen and kidney: No obvious abnormality. Left renal calcium lactogenesis considered.

[redacted] **20[redacted] APTT:** 27.2 SEC (normal 23.5 to 36.0)

[redacted] **20[redacted] BIOPSY:** Gastroscope biopsy: Chronic moderate superficial gastric (sinus) mucosa (activity); Helicobacter pylori positive.

[redacted] **20[redacted] CHEST CT:** Two lung fibrous foci, bilateral pleura thickened.

[redacted] **20[redacted] CHEST XRAY:** Suspicious nodules and a few strip shadow in the left lung are suggested to be confirmed by CT scan.

[redacted] **20[redacted] EKG:** Sinus bradycardia

[redacted] **20[redacted] GASTROSCOPY:** Duodenal globular ulcer with bleeding; hemostasis for duodenal bulbar ulcer; superficial gastritis.

[redacted] **20[redacted] GASTROSCOPY:** no obvious abnormalities in the duodenum. Superficial gastritis.

[redacted] **20[redacted] HEMATOCRIT:** 39 % (normal 40 to 50)

[redacted] **20[redacted] HEMOGLOBIN:** 132 G/L (normal 130 to 175)

[redacted] **20[redacted] INR:** 1.06 (No units) (normal 0.85 to 1.14)

[redacted] **20[redacted] PLATELET COUNT:** 210 X10**9/L (normal 125 to 350)

[redacted] **20[redacted] PROTHROMBIN TIME:** 12.1 SEC (normal 10.0 to 14.0)

[redacted] **20[redacted] RBC:** 4.38 X10**12/L (normal 4.30 to 5.80)

[redacted] **20[redacted] STOOL ANALYSIS:** Negative

[redacted] **20[redacted] WBC:** 4.6 X10**9/L (normal 3.5 to 9.5)

Subject [redacted] ([redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
裂孔原性網膜剥離	X			

Treatment Group	Age at Study Start	Sex	Race
UPA 30 MG QD/UPA 30 MG QD	2[redacted]	MALE	ASIAN

Medical History	Onset Year
ALLERGIC ASTHMA	20[redacted]
ALLERGIC RHINITIS	20[redacted]
ATOPIC DERMATITIS	20[redacted]
EYES MYOPIA	20[redacted]
SINUS BRADYCARDIA	20[redacted]
ALLERGIC RHINITIS	NOT REPORTED
ASTHMA	NOT REPORTED

Prior Procedures	Procedure Year
Not reported.	

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

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
UPA	30 MG	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 119	119
UPA	30 MG	ORAL	QD	[redacted]20[redacted] / 120		

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BCG Vaccine	NOT REPORTED	NOT REPORTED	Y: 19[redacted]
HYDROCORTISONE	A MODERATE AMOUNT OF g	BID	Y: 20[redacted]
CAMPHOR W/MENTHOL	A MODERATE AMOUNT OF g	BID	Y: 20[redacted]
DIPROSPAN	1 ML mL	OTHER: ONCE	Y-M: 20[redacted]-[redacted]
PIMECROLIMUS	A MODERATE AMOUNT OF g	BID	Y-M: 20[redacted]-[redacted]
TACROLIMUS	A MODERATE AMOUNT OF g	BID	Y-M: 20[redacted]-[redacted]
HALOMETASONE	A MODERATE AMOUNT OF mg	BID	Y-M: 20[redacted]-[redacted]
EMOLLIENTS AND PROTECTIVES	A MODERATE AMOUNT OF g	BID	Y-M: 20[redacted]-[redacted] / -18

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
EMOLLIENTS AND PROTECTIVES	A MODERATE AMOUNT OF g	BID	Y-M: 20[redacted]-[redacted] / -18	NOT REPORTED
ATROPINE	0.5 g	OTHER: ST	Y-M: 20[redacted]-[redacted] / 124	Y-M: 20[redacted]-[redacted] / 124
BROMFENAC	2 OTHER: DROPS	OTHER: ST	Y-M: 20[redacted]-[redacted] / 124	Y-M: 20[redacted]-[redacted] / 124
HYALURONIC ACID	100 OTHER: DROPS	TID	Y-M: 20[redacted]-[redacted] / 124	Y-M: 20[redacted]-[redacted] / 124
PREDNISONE	2 OTHER: DROPS	OTHER: ST	Y-M: 20[redacted]-[redacted] / 124	Y-M: 20[redacted]-[redacted] / 124
TOBRADEX	0.1 g	OTHER: QN	Y-M: 20[redacted]-[redacted] / 124	Y-M: 20[redacted]-[redacted] / 124
TROPICAMIDE	1 OTHER: DROPS	BID	Y-M: 20[redacted]-[redacted] / 124	Y-M: 20[redacted]-[redacted] / 124
ATROPINE	0.5 g	TID	Y-M: 20[redacted]-[redacted] / 124	Y-M: 20[redacted]-[redacted] / 126
LEVOFLOXACIN	1 OTHER: DROPS	QID	Y-M: 20[redacted]-[redacted] / 124	Y-M: 20[redacted]-[redacted] / 126
INDOCYANINE GREEN	1 OTHER: A PIECE OF	QD	Y-M: 20[redacted]-[redacted] / 126	Y-M: 20[redacted]-[redacted] / 126
DEXAMETHASONE	5 mg	QD	Y-M: 20[redacted]-[redacted] / 127	Y-M: 20[redacted]-[redacted] / 127

GENTAMICIN	1 OTHER: A PIECE OF	QD	Y-M: 20[redacted]-[redacted] / 127	Y-M: 20[redacted]-[redacted] / 127
LIDOCAINE	1 OTHER: A PIECE OF	QD	Y-M: 20[redacted]-[redacted] / 127	Y-M: 20[redacted]-[redacted] / 127
OFLOXACIN	1 OTHER: A PIECE OF	QD	Y-M: 20[redacted]-[redacted] / 127	Y-M: 20[redacted]-[redacted] / 127
PROXYMETACAINE	1 OTHER: A PIECE OF	QD	Y-M: 20[redacted]-[redacted] / 127	Y-M: 20[redacted]-[redacted] / 127
SODIUM CHLORIDE	A MODERATE AMOUNT OF %	QD	Y-M: 20[redacted]-[redacted] / 127	Y-M: 20[redacted]-[redacted] / 127
ATROPINE	0.5 g	OTHER: QN	Y-M: 20[redacted]-[redacted] / 128	Y-M: 20[redacted]-[redacted] / 144
BROMFENAC	1 OTHER: DROPS	BID	Y-M: 20[redacted]-[redacted] / 128	Y-M: 20[redacted]-[redacted] / 144
LEVOFLOXACIN	1 OTHER: DROPS	QID	Y-M: 20[redacted]-[redacted] / 128	Y-M: 20[redacted]-[redacted] / 144
PREDNISONE	2 OTHER: DROPS	QID	Y-M: 20[redacted]-[redacted] / 128	Y-M: 20[redacted]-[redacted] / 144
TOBRADEX	0.1 g	OTHER: QN	Y-M: 20[redacted]-[redacted] / 128	Y-M: 20[redacted]-[redacted] / 144
TROPICAMIDE	1 OTHER: DROPS	BID	Y-M: 20[redacted]-[redacted] / 128	Y-M: 20[redacted]-[redacted] / 144
LEVOFLOXACIN	1 OTHER: DROPS	TID	Y-M: 20[redacted]-[redacted] / 201	Y-M: 20[redacted]-[redacted] / 205
TROPICAMIDE	2 OTHER: DROPS	TID	Y-M: 20[redacted]-[redacted] / 201	Y-M: 20[redacted]-[redacted] / 205
ATROPINE	0.5 g	OTHER: ST	Y-M: 20[redacted]-[redacted] / 205	Y-M: 20[redacted]-[redacted] / 205
DEXAMETHASONE	0.5 g	OTHER: ST	Y-M: 20[redacted]-[redacted] / 205	Y-M: 20[redacted]-[redacted] / 205
DEXAMETHASONE	5 mg	QD	Y-M: 20[redacted]-[redacted] / 205	Y-M: 20[redacted]-[redacted] / 205
GENTAMICIN	1 OTHER: A PIECE OF	QD	Y-M: 20[redacted]-[redacted] / 205	Y-M: 20[redacted]-[redacted] / 205
HYALURONIC ACID	1 OTHER: A PIECE OF	QID	Y-M: 20[redacted]-[redacted] / 205	Y-M: 20[redacted]-[redacted] / 205
LEVOFLOXACIN	1 OTHER: DROPS	OTHER: ST	Y-M: 20[redacted]-[redacted] / 205	Y-M: 20[redacted]-[redacted] / 205
OFLOXACIN	1 OTHER: A PIECE OF	QD	Y-M: 20[redacted]-[redacted] / 205	Y-M: 20[redacted]-[redacted] / 205
PREDNISOLONE	1 OTHER: DROPS	OTHER: ST	Y-M: 20[redacted]-[redacted] / 205	Y-M: 20[redacted]-[redacted] / 205
PROXYMETACAINE	1 OTHER: A PIECE OF	QD	Y-M: 20[redacted]-[redacted] / 205	Y-M: 20[redacted]-[redacted] / 205
SODIUM CHLORIDE	A MODERATE AMOUNT OF OTHER: A MODERATE AMOUNT OF	QD	Y-M: 20[redacted]-[redacted] / 205	Y-M: 20[redacted]-[redacted] / 205
TROPICAMIDE	2 OTHER: DROPS	OTHER: ST	Y-M: 20[redacted]-[redacted] / 205	Y-M: 20[redacted]-[redacted] / 205
ATROPINE	0.5 g	QD	Y-M: 20[redacted]-[redacted] / 206	Y-M: 20[redacted]-[redacted] / 223
DEXAMETHASONE	0.5 g	OTHER: QN	Y-M: 20[redacted]-[redacted] / 206	Y-M: 20[redacted]-[redacted] / 223

LEVOFLOXACIN	1 OTHER: DROPS	QID	Y-M: 20[redacted]-[redacted] Y-M: 20[redacted]-[redacted] / / 206 223
PREDNISOLONE	2 OTHER: DROPS	QID	Y-M: 20[redacted]-[redacted] Y-M: 20[redacted]-[redacted] / / 206 223
TROPICAMIDE	2 OTHER: DROPS	BID	Y-M: 20[redacted]-[redacted] Y-M: 20[redacted]-[redacted] / / 206 223

Event #1: Serious Adverse Event

Event Description	RHEGMATOGENOUS RETINAL DETACHMENT OF THE RIGHT EYE
Preferred term	裂孔原性網膜剥離
AE Onset Date / Rx Day	[redacted]20[redacted] / 124
Age at AE Onset	2[redacted]
Laboratory Testing	NOT REPORTED
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 124): ECG: NODAL TACHYCARDIA; EYES ULTRASOUND: VITREOUS OPACITY IN BOTH EYES, RETINAL DETACHMENT.; [redacted]20[redacted] (RX DAY 127): RETINAL REDUCTION WITH SCLERAL RING IN RIGHT EYE: PATIENTS RECOVER
AE Stopped Rx Day	130
Duration of AE	7 DAYS
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #2: Serious Adverse Event

Event Description	RHEGMATOGENOUS RETINAL DETACHMENT OF LEFT EYE
Preferred term	裂孔原性網膜剥離
AE Onset Date / Rx Day	[redacted]20[redacted] / 201
Age at AE Onset	2[redacted]
Laboratory Testing	NOT REPORTED
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 201): LEFT EYE B ULTRASONIC: VITREOUS OPACITY IN LEFT EYE, DETACHED RETINA.; LEFT EYE OCT: LEFT EYE RETINAL DETACHMENT, NO MACULAR INVOLVEMENT.; [redacted]20[redacted] (RX DAY 205): LEFT EYE SCLERAL BUCKLING RETINAL REPAIRS: THE OPERATION SMOOTHLY,NO COMPLICATIONS.
AE Stopped Rx Day	208
Duration of AE	8 DAYS
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	NOT REPORTED

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

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者は中国の 2[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，モメタゾンフランカルボン酸エステル，desonide 及び tacrolimus を投与され，右眼の裂孔原性網膜剥離を発現した。被験者は非喫煙者かつ非飲酒者であり，関連する病歴はアトピー性皮膚炎及び両眼の近視であった。

被験者は本試験開始時の 16 週間の二重盲検投与期に参加していた。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は盲検継続投与期に移行し，盲検下でウパダシチニブ投与が開始された。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は右眼の裂孔原性網膜剥離を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，右眼の裂孔原性網膜剥離は消失した。

本事象に先行し，20[redacted] 年 [redacted] 月 [redacted] 日から同年 [redacted] 月 [redacted] 日まで，眼底浮腫（非重篤）が発現していた。

右眼の状態が 15 日間悪化し続け，両眼視力低下が 3 ヵ月持続したため，20[redacted] 年 [redacted] 月 [redacted] 日，被験者は入院した。同日，被験者は左眼の併発白内障及び左眼の網膜剥離（いずれも非重篤）を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は右眼の網膜強膜締結術及び術後の局所抗炎症療法を受けた。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

治験責任医師の報告によれば，被験者には近視（400 degrees）があったほか，顔面に発疹があり両眼周囲の皮膚を時々こすっていた。右眼の損傷及び外傷は認められなかった。治験責任医師が確認したところ，被験者に糖尿病及び眼科手術歴はなかった。眼疾患や眼症状の家族歴もなかった。

COMPOUND TROPICAMIDE EYE DROPS，TOBRAMYCIN/DEXAMETHASONE EYE CREAM，PREDNISONE ACETATE EYE DROPS，ATROPINE SULFATE EYE GEL，bromfenac sodium，LEVOFLOXACIN EYE DROPS，インドシアニングリーン，デキサメタゾンリン酸エステルナトリウム，ゲンタマイシン硫酸塩，OFLOXACIN EYE CREAM，塩化ナトリウム及びリドカイン塩酸塩が投与された。

The patient's past medications include:

HYDROCORTISONE BUTYRATE CREAM for ATOPIC DERMATITIS (20[redacted] - [redacted] 20[redacted])

MENTHOLATUM SKIN CREAM MOISTURIZER for ATOPIC DERMATITIS (20[redacted] - [redacted] 20[redacted])

DIPROSPAN for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

PIMECROLIMUS CREAM for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

TACROLIMUS OINTMENT for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

HALOMETASONE for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

IODIZED LECITHIN for FUNDUS EDEMA ([redacted] 20[redacted] - [redacted] 20[redacted])

MECOBALAMIN for FUNDUS EDEMA ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Rhegmatogenous retinal detachment (10065569) (Rhegmatogenous retinal detachment (10065569)) [v.22.1] [10065569]

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

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

Dechallenge: Not Applicable

Causality for MOMETASONE FUROATE (Open Label)

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1) Rhegmatogenous retinal detachment (10065569) (Rhegmatogenous retinal detachment (10065569)) [v.22.1] [10065569]

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

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

Dechallenge: Not Applicable

Causality for DESONIDE (Open Label)

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1) Rhegmatogenous retinal detachment (10065569) (Rhegmatogenous retinal detachment (10065569)) [v.22.1] [10065569]

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

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

Dechallenge: Not Applicable

Causality for TACROLIMUS (Open Label)

---

1) Rhegmatogenous retinal detachment (10065569) (Rhegmatogenous retinal detachment (10065569)) [v.22.1] [10065569]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of RHEGMATOGENOUS RETINAL DETACHMENT OF THE RIGHT EYE

- Investigator: Not applicable

- AbbVie: The event is more likely related to pre-existing myopia. Additional risk factor includes facial rash with resulting eye rubbing per the investigator.

Alternative Etiology for MOMETASONE FUROATE (Open Label)

Event of RHEGMATOGENOUS RETINAL DETACHMENT OF THE RIGHT EYE

- Investigator: More likely related to Upadacitinib/placebo

- AbbVie: The event is more likely relatedto pre-existing myopia. Additional risk factor includes facial rash with resulting eye rubbing per the investigator.

Alternative Etiology for DESONIDE (Open Label)

Event of RHEGMATOGENOUS RETINAL DETACHMENT OF THE RIGHT EYE

- **Investigator:** More likely related to Upadacitinib/placebo

- **AbbVie:** The event is more likely related to pre-existing myopia. Additional risk factor includes facial rash with resulting eye rubbing per the investigator.

Alternative Etiology for TACROLIMUS (Open Label)

Event of RHEGMATOGENOUS RETINAL DETACHMENT OF THE RIGHT EYE

- **Investigator:** More likely related to Upadacitinib/placebo

- **AbbVie:** The event is more likely related to pre-existing myopia. Additional risk factor includes facial rash with resulting eye rubbing per the investigator.

RISK/BENEFIT STATEMENT:

There is no change to the risk/benefit profile for this study/product as a result of this individual report/event(s).

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] **ULTRASOUND EYES:** Vitreous opacity in both eyes, retinal detachment.

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者は中国の 2[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，モメタゾンフランカルボン酸エステル，desonide 及び tacrolimus を投与され，左眼の裂孔原性網膜剥離を発現した。被験者は非喫煙者で禁酒しており，関連する病歴はアトピー性皮膚炎及び両眼の近視であった。

被験者は本試験開始時の 16 週間の二重盲検投与期に参加していた。20[redacted] 年[redacted] 月[redacted] 日，被験者は盲検継続投与期に移行し，盲検下でウパダシチニブ投与が開始された。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は左眼の裂孔原性網膜剥離を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，左眼の裂孔原性網膜剥離は消失した。

本事象発現に先行し，20[redacted] 年 [redacted] 月，被験者は左眼の併発白内障及び左眼の網膜剥離（いずれも非重篤）を発現した。

治験責任医師は，関連するリスク因子として被験者が 3 ヵ月前に繰り返し目をこすっていたことを挙げた。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は左眼の裂孔原性網膜剥離及び霧視のため入院した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は左眼の網膜再建術（強膜内陥術）を受けた。20[redacted] 年 [redacted] 月 [redacted] 日，合併症なく経過し，被験者は退院した。

SODIUM HYALURONATE EYE DROPS，LEVOFLOXACIN EYE DROPS，COMPOUND TOPICAMIDE EYE DROPS，ATROPINE SULFATE EYE GEL，デキサメタゾンリン酸エステルナトリウム，ゲンタマイシン硫酸塩，PROMEVACAINE HYDROCHLORIDE EYE DROPS, OFLOXACIN EYE CREAM 及び PREDNISOLONE ACETATE EYE DROPS が投与された。

The patient's past medications include:

HYDROCORTISONE BUTEPRATE EYE DROPS for ATOPIC DERMATITIS (20[redacted] - 20[redacted])

MENTHOLATUM AD for ATOPIC DERMATITIS (20[redacted] - [redacted] 20[redacted])

DIPROSPAN for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

PIMECROLIMUS for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

TACROLIMUS for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

HALOMETASONE for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

ATROPINE SULFATE EYE GEL for RHEGMATOGENOUS RETINAL DETACHMENTOF THE RIGHT EYE, COMPLICATED CATARACT IN THE LEFT EYE and RETINAL DETACHMENT OF THE LEFT EYE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

COMPOUND TOPICAMIDE EYE DROPS for RHEGMATOGENOUS RETINAL DETACHMENTOF THE RIGHT EYE, COMPLICATED CATARACT IN THE LEFT EYE and RETINAL DETACHMENT OF THE LEFT EYE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

PREDNISONE ACETATE EYE DROPS for RHEGMATOGENOUS RETINAL DETACHMENTOF THE RIGHT EYE, COMPLICATED CATARACT IN THE LEFT EYE and RETINAL DETACHMENT OF THE LEFT EYE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

SODIUM BROMOFENAC EYE DROPS for RHEGMATOGENOUS RETINAL DETACHMENTOF THE RIGHT EYE, COMPLICATED CATARACT IN THE LEFT EYE and RETINAL DETACHMENT OF THE LEFT EYE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

TOBRAMYCIN/DEXAMETHASONE EYE CREAM for RHEGMATOGENOUS RETINAL DETACHMENTOF THE RIGHT EYE, COMPLICATED CATARACT IN THE LEFT EYE and RETINAL DETACHMENT OF THE LEFT EYE ([redacted])

Causality for UPADACITINIB (Blinded)

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1) Rhegmatogenous retinal detachment (10065569) (Rhegmatogenous retinal detachment (10065569)) [v.23.1] [10065569]

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

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

Dechallenge: Not Applicable

Causality for MOMETASONE FUROATE (Open Label)

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1) Rhegmatogenous retinal detachment (10065569) (Rhegmatogenous retinal detachment (10065569)) [v.23.1] [10065569]

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

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

Dechallenge: Not Applicable

Causality for DESONIDE (Open Label)

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1) Rhegmatogenous retinal detachment (10065569) (Rhegmatogenous retinal detachment (10065569)) [v.23.1] [10065569]

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

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

Dechallenge: Not Applicable

Causality for TACROLIMUS (Open Label)

---

1) Rhegmatogenous retinal detachment (10065569) (Rhegmatogenous retinal detachment (10065569)) [v.23.1] [10065569]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of RHEGMATOGENOUS RETINAL DETACHMENT OF LEFT EYE

- Investigator: Not applicable

- AbbVie: Risk factors include pre-existing myopia of eyes, recent retinal detachment of both eyes in the last 6 months and repeated rubbing of eye three months prior as reported by PI.

Alternative Etiology for MOMETASONE FUROATE (Open Label)

Event of RHEGMATOGENOUS RETINAL DETACHMENT OF LEFT EYE

- Investigator: More likely related to Upadacitinib/placebo

- AbbVie: Risk factors include pre-existing myopia of eyes, recent retinal detachment of both eyes in the last 6 months and repeated rubbing of eye three months prior as reported by PI.

Alternative Etiology for DESONIDE (Open Label)

Event of RHEGMATOGENOUS RETINAL DETACHMENT OF LEFT EYE

- Investigator: More likely related to Upadacitinib/placebo

- AbbVie: Risk factors include pre-existing myopia of eyes, recent retinal detachment of both eyes in the last 6 months and repeated rubbing of eye three months prior as reported by PI.

Alternative Etiology for TACROLIMUS (Open Label)

Event of RHEGMATOGENOUS RETINAL DETACHMENT OF LEFT EYE

- Investigator: More likely related to Upadacitinib/placebo

- AbbVie: Risk factors include pre-existing myopia of eyes, recent retinal detachment of both eyes in the last 6 months and repeated rubbing of eye three months prior as reported by PI.

RISK/BENEFIT STATEMENT:

There is no change to the risk/benefit profile for this study/product as a result of this individual report/event(s).

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] LEFT EYE B ULTRASOUND: VITREOUS OPACITY IN LEFT EYE, DETACHED RETINA.

[redacted] 20[redacted] LEFT EYE OPHTHALMOLOGICAL EXAMINATION: LEFT EYE RETINAL DETACHMENT, NO MACULAR INVOLVEMENT.

[redacted] 20[redacted] ULTRASOUND EYE: Vitreous opacity in both eyes, retinal detachment.

Subject [redacted] ([redacted])

Reason for Narrative

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

Treatment Group	Age at Study Start	Sex	Race
UPA 15 MG QD/UPA 15 MG QD	4[redacted]	FEMALE	ASIAN

Medical History	Onset Year
CHICKEN POX	19[redacted]
ATOPIC DERMATITIS	20[redacted]
ATOPIC DERMATITIS	20[redacted]
UPPER RESPIRATORY TRACT INFECTION	20[redacted]
ALLERGIC RHINITIS	NOT REPORTED
FOOD ALLERGY	NOT REPORTED
FOOD ALLERGY: SHRIMP	NOT REPORTED
FOOD ALLERGY: CRAB	NOT REPORTED
FOOD ALLERGY: MANGO	NOT REPORTED

Prior Procedures	Procedure Year
Not reported.	

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

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
UPA	15 MG	ORAL	QD	08JUL2019 / 1	27OCT2019 / 112	112
UPA	15 MG	ORAL	QD	28OCT2019 / 113	18AUG2020 / 408	296

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
FLUOCINOLONE ACETONIDE	0.005 %	BID	Y-M: 20[redacted]
CICLOSPORIN	150 mg	QD	Y-M: 20[redacted] / -341
KETOCONAZOLE	2 %	OTHER: 2 DAYS PER WEEK	Y-M: 20[redacted] / -179
MOMETASONE	0.1 %	QD	Y-M: 20[redacted] / -179
MOMETASONE	0.1% OTHER: 1:10 MIXING PARAFIN/ VASELINE	QD	Y-M: 20[redacted] / -179
MOMETASONE	0.1% OTHER: MIXING 1:4	QD	Y-M: 20[redacted] / -179
TACROLIMUS	0.1 %	BID	Y-M: 20[redacted] / -179
BUDESONIDE	50 OTHER: MCG/DOSE	OTHER: 2 DOSE(S) DAILY	Y-M: 20[redacted] / -131
PROMETHAZINE	10 mg	PRN	Y-M: 20[redacted] / -131
COAL TAR	UNKNOWN mL	OTHER: ONCE PER DAY, TWO DAYS PER WEEK	Y-M: 20[redacted] / -128
AUGMENTIN	375 mg	TID	Y-M: 20[redacted] / -60
COAL TAR	200 mL	OTHER: 2 DAYS PER WEEK	Y-M: 20[redacted] / -32
METHYLPREDNISOLONE	0.1 %	QD	Y-M: 20[redacted] / -32
AQUEOUS	UNKNOWN g	TID	Y-M: 20[redacted] / -26
ULTRABASE	UNKNOWN OTHER: 50% + 50%	BID	Y-M: 20[redacted] / -21

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
AQUEOUS	UNKNOWN g	TID	Y-M: 20[redacted] / -26	ONGOING
ULTRABASE	UNKNOWN OTHER: 50% + 50%	BID	Y-M: 20[redacted] / -21	ONGOING
SIMVASTATIN	5 mg	QD	Y-M: 20[redacted] / 151	ONGOING
TACROLIMUS	0.03 %	PRN	Y-M: 20[redacted] / 225	Y-M: 20[redacted] / 410
MOMETASONE	UNKNOWN OTHER: 0.1% MIX WITH AQ 1:10	QD	Y-M: 20[redacted] / 239	ONGOING
UREA	10 %	TID	Y-M: 20[redacted] / 239	ONGOING
MOMETASONE	0.1 %	QD	Y-M: 20[redacted] / 259	ONGOING
ACICLOVIR	800 mg	OTHER: 5 TIMES A DAY	Y-M: 20[redacted] / 409	Y-M: 20[redacted] / 410
KETOCONAZOLE	2 %	OTHER: DAILY, 2 DAYS PER WEEK	Y-M: 20[redacted] / 410	ONGOING

ACICLOVIR	UNKNOWN mg	OTHER: UNKNOWN	Y-M: 20[redacted] / 410 Y-M: 20[redacted] / 415
PIP/TAZO	UNKNOWN mg	OTHER: UNKNOWN	Y-M: 20[redacted] / 410 Y-M: 20[redacted] / 415
FUSIDIC ACID	2 %	BID	Y-M: 20[redacted] / 410 Y-M: 20[redacted] / 421
GANCICLOVIR	1.5 mg	BID	Y-M: 20[redacted] / 410 Y-M: 20[redacted] / 421
PARACETAMOL	500 mg	OTHER: Q6H	Y-M: 20[redacted] / 410 Y-M: 20[redacted] / 421
PREGABALIN	50 mg	PRN	Y-M: 20[redacted] / 410 Y-M: 20[redacted] / 421
TEARS NATURALE FORTE	1 OTHER: DROP	OTHER: Q2H	Y-M: 20[redacted] / 410 Y-M: 20[redacted] / 421
CIPROFLOXACIN	0.3 %	OTHER: 2 DROPS Q2H	Y-M: 20[redacted] / 419 Y-M: 20[redacted] / 430
GANCICLOVIR	1.5 mg	BID	Y-M: 20[redacted] / 419 Y-M: 20[redacted] / 430
PARACETAMOL	500 mg	OTHER: Q6H	Y-M: 20[redacted] / 419 Y-M: 20[redacted] / 430
PREGABALIN	50 mg	OTHER: TDS PRN	Y-M: 20[redacted] / 419 Y-M: 20[redacted] / 430
TEARS NATURALE FORTE	1 OTHER: DROP	OTHER: Q2H	Y-M: 20[redacted] / 419 Y-M: 20[redacted] / 430
FUSIDIC ACID	2 %	BID	Y-M: 20[redacted] / 421 ONGOING

Event #1: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Event of Interest - Serious Infections, Event of Interest - Herpes Zoster

Event Description	HERPES ZOSTER
Preferred term	帯状疱疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 408
Age at AE Onset	4[redacted]
Laboratory Testing	NOT REPORTED
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 410): EYE ASSESSMENT: LEFT CORNEA CLEAR, STAIN NEGATIVE, ACQ, NO OBVIOUS CELLS/FIBRIN/HYPOPYON
AE Stopped Rx Day	431 (23 DAYS AFTER LAST TREATMENT)
Duration of AE	24 DAYS
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	IMMUNOSUPPRESSANT
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者は香港の 4[redacted] 歳女性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，ヒドロコルチゾン酢酸エステル，モメタゾンフランカルボン酸エステル，tacrolimus 及び methylprednisolone aceponate を投与され，帯状疱疹を発現した。被験者は非喫煙者かつ非飲酒者であり，関連する病歴は水痘，アトピー性皮膚炎であった。

被験者は本試験開始時の 16 週間の二重盲検投与期に参加していた。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は盲検継続投与期に移行し，盲検下でウパダシチニブ投与が開始された。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は帯状疱疹を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，帯状疱疹は消失した。

被験者には 20[redacted] 年 [redacted] 月 [redacted] 日から持続する頭痛があり，その後，左側顔面に小水疱性皮疹を発現した。一般開業医の診察で帯状疱疹と診断され，acyclovir が投与された。眼科の診察で眼帯状疱疹が認められ，20[redacted] 年 [redacted] 月 [redacted] 日に治験薬の投与が中止された。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は三叉神経第 1 枝支配域の小水疱性皮疹のため入院した。20[redacted] 年 [redacted] 月 [redacted] 日，眼科による再評価が行われ，左眼角膜は正常で染色所見異常なし，前房の細胞微塵なし／フィブリンなし／蓄膿なし，水晶体深部は正常で結膜の充血なし／水腫なしと判断された。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

被験者の既往歴に水痘はあるが帯状疱疹はなく，帯状疱疹ワクチン接種歴はなかった。

治験責任医師によれば，被験者は治験期間中に顔面のヘルペス性状湿疹も発現していたが，帯状疱疹には関連しないと判断された。

本事象を理由にウパダシチニブの投与は中止された。

PANADOL，FUCIDIN，NATURAL TEARS，ガンシクロビル，プレガバリン，シプロフロキサシン，TAZOCIN，acyclovir 及び KETOKONAZOLE SHAMPOO が投与された。

The patient's past medications include:

SYNALAR for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

CYCLOSPORIN A (TEVA) CAPSULE for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

ELOMET (MOMETASONE FUROATE) OINTMENT for ATOPIC DERMATITIS ([redacted] [redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

NIZORAL SHAMPOO for ATOPIC DERMATITIS ([redacted] [redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

PROTOPIC (TACROLIMUS) OINTMENT for ATOPIC DERMATITIS ([redacted] [redacted] 20[redacted] - [redacted] 20[redacted])

PHENERGAN for ATOPIC DERMATITIS ([redacted])

RHINOCORT AQUA (BUDESONIDE AQUEOUS) NASAL SPRAY for ATOPIC DERMATITIS ([redacted])

IONIL T SHAMPOO for ATOPIC DERMATITIS ([redacted])

AUGMENTIN TABLET for ATOPIC DERMATITIS ([redacted])

METHYLPREDNISOLONE ACEPONATE for ATOPIC DERMATITIS ([redacted])

ATARAX for ATOPIC DERMATITIS ([redacted])

ACYCLOVIR SUSPENSION for ATOPIC DERMATITIS ([redacted])

FUCIDIN for ATOPIC DERMATITIS ([redacted])

PINETARSOL BATH OIL for ATOPIC DERMATITIS ([redacted])

TELFAST for ATOPIC DERMATITIS ([redacted])

CLOTRIMAZOLE for URINE YEAST ([redacted])

Causality for UPADACITINIB (Blinded)

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1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.23.1] [10019974]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Causality for HYDROCORTISONE ACETATE (Open Label)

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1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.23.1] [10019974]

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

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

Dechallenge: Not Applicable

Causality for MOMETASONE FUROATE (Open Label)

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1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.23.1] [10019974]

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

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

Dechallenge: Not Applicable

Causality for TACROLIMUS (Open Label)

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1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.23.1] [10019974]

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

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

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Causality for METHYLPREDNISOLONE ACEPONATE (Open Label)

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1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.23.1] [10019974]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of HERPES ZOSTER

- Investigator: Immunosuppressant

- AbbVie: Not applicable

Alternative Etiology for HYDROCORTISONE ACETATE (Open Label)

Event of HERPES ZOSTER

- Investigator: Immunosuppressant

- AbbVie: Topical administration results in negligible systemic absorption and would thus not be implicated in reactivation of varicella zoster virus.

Alternative Etiology for MOMETASONE FUROATE (Open Label)

Event of HERPES ZOSTER

- Investigator: Immunosuppressant

- AbbVie: Topical administration results in negligible systemic absorption and would thus not be implicated in reactivation of varicella zoster virus.

Alternative Etiology for TACROLIMUS (Open Label)

Event of HERPES ZOSTER

- Investigator: Immunosuppressant

- AbbVie: Topical administration results in negligible systemic absorption and would thus not be implicated in reactivation of varicella zoster virus.

Alternative Etiology for METHYLPREDNISOLONE ACEPONATE (Open Label)

Event of HERPES ZOSTER

- Investigator: Immunosuppressant

- AbbVie: Topical administration results in negligible systemic absorption and would thus not be implicated in reactivation of varicella zoster virus.

RISK/BENEFIT STATEMENT:

There is no change to the risk/benefit profile for this study/product as a result of this individual report/event(s).

Company Remarks

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] DERMATOLOGICAL EXAMINATION:** HZ V1/HZ ophthalmicus/cellulitis, BSA 5% eczatous antecubital fossa, upper back.

[redacted] **20[redacted] EYE EXAMINATION:** Left cornea clear, stain negative, ACQ, no obvious cells/fibrin/hypopyon

[redacted] **20[redacted] EYE EXAMINATION:** Clinically all vesicles dried, be stained negative, no pseudodendrites/ dendrites, not congested, ACQ not shallow, lens clear, be disc pink no swelling, no ARN/vitritis

[redacted] **20[redacted] EYE PRESSURE:** 18; no units

[redacted] **20[redacted] LEFT EYE SWAB:** Positive for varicella zoster

非重篤な有害事象

帯状疱疹が単一の神経支配域で発現した。治験薬の投与は中止され，試験も中止された。

Subject [redacted] ([redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
皮膚播種性帯状疱疹	X			X

Treatment Group	Age at Study Start	Sex	Race
UPA 15 MG QD/UPA 15 MG QD	2[redacted]	MALE	ASIAN

Medical History	Onset Year
ASTHMA	19[redacted]
ATOPIC DERMATITIS	19[redacted]
FOOD ALLERGY(EGG WHITE, SALMON)	19[redacted]
ASTHMA	NOT REPORTED
FOOD ALLERGY	NOT REPORTED

Prior Procedures	Procedure Year
Not reported.	

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

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
UPA	15 MG	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 112	112
UPA	15 MG	ORAL	QD	[redacted]20[redacted] / 113		

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
HERPES ZOSTER IMMUNIZATION	NOT REPORTED	NOT REPORTED	Y: 19[redacted]
OLOPATADINE	5 mg	BID	Y-M: 20[redacted]
DIFLUPREDNATE	OPTOMUM DPSE OTHER: NA	BID	Y-M: 20[redacted]
HEPARINOID	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
KETOCONAZOLE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
HYDROCORTISONE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
HYDROPHILIC	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
BECLOMETASONE	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
BETAMETHASONE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
ZINC	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
HEPARINOID	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
KETOCONAZOLE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
HYDROCORTISONE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
BETAMETHASONE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
KETOCONAZOLE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
HEPARINOID	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
BECLOMETASONE	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
DIFLUPREDNATE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
HEPARINOID	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
BETAMETHASONE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
CELESTAMINE	1 OTHER: T	TID	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
BETAMETHASONE	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
KETOCONAZOLE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
FLUOCINONIDE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
DIFLUPREDNATE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
HEPARINOID	OPTIMUM DOSE OTHER: NA	PRN	Y-M: 20[redacted]
KETOCONAZOLE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
KETOCONAZOLE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
FLUOCINONIDE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]

BIOTIN	1.5 g	TID	Y-M: 20[redacted]
CLOSTRIDIUM BUTYRICUM	1 g	TID	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
BETAMETHASONE	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
DIFLUPREDNATE	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
HEPARINOID	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
DIFLUPREDNATE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
KETOCONAZOLE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
PRANLUKAST	112.5 mg	BID	Y-M: 20[redacted]
BETAMETHASONE	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
BETAMETHASONE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
BETAMETHASONE	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
BUTENAFINE	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
CLOBETASOL	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
HEPARINOID	OPTIMUM DOSE OTHER: NA	PRN	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
BETAMETHASONE	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
HYDROCORTISONE	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
LANOCONAZOLE	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
CLOBETASOL	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
DIFLUPREDNATE	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
KETOCONAZOLE	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
CLOBETASOL	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
HYDROCORTISONE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
OLOPATADINE	1 OTHER: TAB	BID	Y-M: 20[redacted]
BETAMETHASONE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
CLOBETASOL	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
HYDROCORTISONE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
CLOBETASOL	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
HYDROCORTISONE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
CLOBETASOL	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
CLOBETASOL	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
HYDROCORTISONE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
HEPARINOID	OPTIMUM DOSE OTHER: NA	PRN	Y-M: 20[redacted]
CLOBETASOL	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
BETAMETHASONE	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
HYDROCORTISONE	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
TACROLIMUS	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
HYDROCORTISONE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
KETOCONAZOLE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
BETAMETHASONE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
HEPARINOID	OPTIMUM DOSE OTHER: NA	PRN	Y-M: 20[redacted]

DIFLUPREDNATE	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
KETOCONAZOLE	OPTIMUM DOSE OTHER: NA	QD	Y-M: 20[redacted]
BETAMETHASONE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
CLOBETASOL	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted]
BETAMETHASONE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted] / -342
DEPRODONE	1 OTHER: PATCH	QD	Y-M: 20[redacted] / -342
BETAMETHASONE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted] / -244
CLOBETASOL	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted] / -244
HEPARINOID	OPTIMUM DOSE OTHER: NA	PRN	Y-M: 20[redacted] / -202
CLOBETASOL	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted] / -153
SALICYLIC ACID	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted] / -153
BETAMETHASONE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted] / -125
KETOCONAZOLE	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted] / -125
CLOBETASOL	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted] / -49
CLOBETASOL	OPTIMUM DOSE OTHER: NA	TID	Y-M: 20[redacted] / -49
WHITE SOFT PARAFFIN	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted] / -7

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
BIOTIN	1.5 g	TID	Y-M: 20[redacted]	NOT REPORTED
CLOSTRIDIUM BUTYRICUM	1 g	TID	Y-M: 20[redacted]	NOT REPORTED
PRANLUKAST	112.5 mg	BID	Y-M: 20[redacted]	NOT REPORTED
OLOPATADINE	1 OTHER: TAB	BID	Y-M: 20[redacted]	NOT REPORTED
WHITE SOFT PARAFFIN	OPTIMUM DOSE OTHER: NA	BID	Y-M: 20[redacted] / -7	NOT REPORTED
ACICLOVIR	250 mg	TID	Y-M: 20[redacted] / 238	Y-M: 20[redacted] / 245
PARACETAMOL	200 mg	TID	Y-M: 20[redacted] / 238	Y-M: 20[redacted] / 259
REBAMIPIDE	100 mg	TID	Y-M: 20[redacted] / 238	Y-M: 20[redacted] / 259

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

Event Description	CUTANEOUS GENERALIZED HERPES ZOSTER
Preferred term	皮膚播種性帯状疱疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 234
Age at AE Onset	2[redacted]
Laboratory Testing	[redacted]20[redacted] (RX DAY 238): Lymphocytes: 0.8 [0.96 - 3.1] 10^9/L; [redacted]20[redacted] (RX DAY 239): Lymphocytes: 1.37 [0.96 - 3.1] 10^9/L
Microbiology	NOT REPORTED
SAE Supplemental Procedure	NOT REPORTED
AE Stopped Rx Day	251
Duration of AE	18 DAYS
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	NOT REPORTED

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

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者は日本の 2[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，フルオシノロンアセトニド及びプレドニゾロンを投与され，皮膚播種性帯状疱疹を発現した。被験者は非喫煙者かつ非飲酒者であり，関連する病歴はアトピー性皮膚炎であった。

被験者は本試験開始時の 16 週間の二重盲検投与期に参加していた。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は盲検継続投与期に移行し，盲検下でウパダシチニブ投与が開始された。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は皮膚播種性帯状疱疹を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，皮膚播種性帯状疱疹は消失した。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は入院した。受診時，被験者の体温は約 38°C であった。被験者は，右胸部から背部にかけて暗赤色の紅斑を伴う小水疱を，体幹及び体肢に小水疱及び丘疹を発現していた。罹患範囲による分類は，右胸部から背部にかけての皮膚病変は単一分節であり，体幹上部及び下腿の皮膚病変は播種性であった。被験者の病歴及び身体的診察の所見から皮膚播種性帯状疱疹と診断された。20[redacted] 年 [redacted] 月 [redacted] 日，薬剤投与を中断したため，アトピー性皮膚炎が増悪した。20[redacted] 年 [redacted] 月 [redacted] 日，播種性帯状疱疹の潰瘍病変は乾燥及び上皮形成した。被験者は回復したと判断され，治験薬投与が再開された。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

アシクロビル及び FLUCORT が投与された。

The patient's past medications include:

ALLELOCK for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

HIRUDOID for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted]ug 20[redacted])

MYSER for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

PROTOPIC for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

NIZORAL for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

LOCOID for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

HYDROPHILIC OINTMENT for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

PROPADERM for ATOPIC DERMATITIS ([redacted])

RINDERON for ATOPIC DERMATITIS ([redacted])

ZINC OXIDE for ATOPIC DERMATITIS ([redacted])

CELESTAMINE for ATOPIC DERMATITIS ([redacted])

ANTEBATE for ATOPIC DERMATITIS ([redacted])

TOPSYM for ATOPIC DERMATITIS ([redacted])

VOLLEY for ATOPIC DERMATITIS ([redacted])

DERMOVATE for ATOPIC DERMATITIS ([redacted])

ASTAT for ATOPIC DERMATITIS ([redacted])

DELSPART for ATOPIC DERMATITIS ([redacted])

ECLAR PLASTER for ATOPIC DERMATITIS ([redacted])

SALICYLIC ACID for ATOPIC DERMATITIS ([redacted])

Causality for UPADACITINIB (Blinded)

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1) Herpes zoster cutaneous disseminated (10074297) (Herpes zoster cutaneous disseminated (10074297)) [v.22.1] [10074297]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Causality for FLUOCINOLONE ACETONIDE (Open Label)

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1) Herpes zoster cutaneous disseminated (10074297) (Herpes zoster cutaneous disseminated (10074297)) [v.22.1] [10074297]

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

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

Dechallenge: Not Applicable

Causality for PREDNISOLONE (Open Label)

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1) Herpes zoster cutaneous disseminated (10074297) (Herpes zoster cutaneous disseminated (10074297)) [v.22.1] [10074297]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of CUTANEOUS GENERALIZED HERPES ZOSTER

- Investigator: Not applicable

- AbbVie: Not applicable

Alternative Etiology for FLUOCINOLONE ACETONIDE (Open Label)

Event of CUTANEOUS GENERALIZED HERPES ZOSTER

- Investigator: More likely related to Upadacitinib/placebo

- AbbVie: Weak temporal association. Last dose of study drug was approximately 7 months prior to event onset.

Alternative Etiology for PREDNISOLONE (Open Label)

Event of CUTANEOUS GENERALIZED HERPES ZOSTER

- Investigator: More likely related to Upadacitinib/placebo

- AbbVie: Weak temporal association. Last dose of study drug was nearly 7 months prior to event onset.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] LYMPHOCYTES ABS:** 0.80 10^3/uL (normal 0.96 to 3.10)

[redacted] **20[redacted] LYMPHOCYTES ABS:** 1.37 10^3/uL (normal 0.96 to 3.10)

Subject [redacted] ([redacted])

Reason for Narrative

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

Treatment Group	Age at Study Start	Sex	Race
UPA 30 MG QD/UPA 30 MG QD	2[redacted]	MALE	ASIAN

Medical History	Onset Year
ATOPIC DERMATITIS	19[redacted]
ASTHMA BRONCHIAL	19[redacted]
SHELLFISH ALLERGY	19[redacted]
ALOPECIA AREATA	20[redacted]
FACE ACNE VULGARIS	20[redacted]
FOOT SPRAIN	20[redacted]
ASTHMA	NOT REPORTED
FOOD ALLERGY	NOT REPORTED

Prior Procedures	Procedure Year
Not reported.	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	3 CIGARETTE	0.5	20[redacted]
CIGARS	NEVER			
E-CIGARETTES	CURRENT	5 SESSIONS	1.5	
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
UPA	30 MG	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 112	112
UPA	30 MG	ORAL	QD	[redacted]20[redacted] / 113		

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BCG Vaccine	NOT REPORTED	NOT REPORTED	Y: 20[redacted]
BEPOTASTINE	10 mg	BID	Y-M: 20[redacted]
BETAMETHASONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]
BETAMETHASONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]
BETAMETHASONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]
HEPARINOID	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]
HYDROCORTISONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]
WHITE SOFT PARAFFIN	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]
HEPARINOID	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]
WHITE SOFT PARAFFIN	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]
HYDROCORTISONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]
BETAMETHASONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]
HEPARINOID	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]
WHITE SOFT PARAFFIN	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]
HEPARINOID	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -336
HYDROCORTISONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -308
WHITE SOFT PARAFFIN	1 OTHER: APPLICAITON	QD	Y-M: 20[redacted] / -308
HEPARINOID	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -56
FEXOFENADINE	60 mg	BID	Y-M: 20[redacted] / -42

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
WHITE SOFT PARAFFIN	1 OTHER: APPLICAITON	QD	Y-M: 20[redacted] / -308	NOT REPORTED

HEPARINOID	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]-[redacted] / -56	NOT REPORTED
FEXOFENADINE	60 mg	BID	Y-M: 20[redacted]-[redacted] / -42	NOT REPORTED
BETAMETHASONE	1 OTHER: APPLICATION	PRN	Y-M: 20[redacted]-[redacted] / 365	NOT REPORTED
HEPARINOID	1 OTHER: APPLICATION	PRN	Y-M: 20[redacted]-[redacted] / 365	NOT REPORTED
HYDROCORTISONE	1 OTHER: APPLICATION	PRN	Y-M: 20[redacted]-[redacted] / 365	NOT REPORTED
BETAMETHASONE	1 OTHER: APPLICATION	PRN	Y-M: 20[redacted]-[redacted] / 407	NOT REPORTED
PREDNISOLONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]-[redacted] / 407	NOT REPORTED
TRIAMCINOLONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]-[redacted] / 407	NOT REPORTED
ACICLOVIR	250 mg	BID	Y-M: 20[redacted]-[redacted] / 722	Y-M: 20[redacted]-[redacted] / 722
CARBOHYDRATES NOS W/POTASSIUM CHLORIDE/SODIUM	200 mL	BID	Y-M: 20[redacted]-[redacted] / 722	Y-M: 20[redacted]-[redacted] / 722
EVE QUICK	2 OTHER: TABLESTS	TID	Y-M: 20[redacted]-[redacted] / 722	Y-M: 20[redacted]-[redacted] / 722
RINGER-LACTATE	500 mL	BID	Y-M: 20[redacted]-[redacted] / 722	Y-M: 20[redacted]-[redacted] / 722
ACICLOVIR	250 mg	TID	Y-M: 20[redacted]-[redacted] / 723	Y-M: 20[redacted]-[redacted] / 728
CARBOHYDRATES NOS W/POTASSIUM CHLORIDE/SODIUM	200 mL	TID	Y-M: 20[redacted]-[redacted] / 723	Y-M: 20[redacted]-[redacted] / 728
VIDARABINE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]-[redacted] / 723	Y-M: 20[redacted]-[redacted] / 728
UFENAMATE	1 OTHER: APPLICATON	QD	Y-M: 20[redacted]-[redacted] / 723	Y-M: 20[redacted]-[redacted] / 735
LOXOPROFEN	60 mg	PRN	Y-M: 20[redacted]-[redacted] / 724	Y-M: 20[redacted]-[redacted] / 734
RINGER-LACTATE	500 mL	QD	Y-M: 20[redacted]-[redacted] / 725	Y-M: 20[redacted]-[redacted] / 729
EPINEPHRINE	0.2 mL	QD	Y-M: 20[redacted]-[redacted] / 726	Y-M: 20[redacted]-[redacted] / 726
LIDOCAINE	0.2 mL	QD	Y-M: 20[redacted]-[redacted] / 726	Y-M: 20[redacted]-[redacted] / 726

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

Event Description	HERPES ZOSTER
Preferred term	帯状疱疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 722
Age at AE Onset	2[redacted]
Laboratory Testing	[redacted]20[redacted] (RX DAY 722): Lymphocytes/Leukocytes: 26.2 [16.5 - 49.5] %; [redacted]20[redacted] (RX DAY 726): Lymphocytes/Leukocytes: 14.5 [16.5 - 49.5] %
Microbiology	[redacted]20[redacted] (RX DAY 726): BLOOD NPTST021-BLOOD CULTURE: Negative

SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 722): CT(CHEST): NOT CLINICAL SIGNIFICANCE.; CT(HEAD): NOT CLINICAL SIGNIFICANCE.; ECG: NOT CLINICAL SIGNIFICANCE.; X-RAY(CHEST): NOT CLINICAL SIGNIFICANCE.
AE Stopped Rx Day	730
Duration of AE	9 DAYS
Toxicity Grade	3
Relation to Study Drug by Investigator	MULTIPLE
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-047

本被験者は日本の 2[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，トリアムシノロンアセトニド及びプレドニゾロンを投与され，帯状疱疹を発現した。被験者は元喫煙者（紙巻きタバコ 3 本／日，6 ヵ月間），電子タバコ使用者（5 セッション／日，1.5 年間）かつ飲酒者（2 杯未満／日）であり，関連する病歴はアトピー性皮膚炎であった。

被験者は本試験開始時の 16 週間の二重盲検投与期に参加していた。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は盲検継続投与期に移行し，盲検下でウパダシチニブ投与が開始された。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は帯状疱疹を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，帯状疱疹は消失した。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は救急治療室を受診し，左側の頭痛並びに左側顔面の水疱及び疼痛を訴えた。同日，被験者は三叉神経支配域の帯状疱疹の疑いで入院した。病歴及び身体的診察の所見から診断された。皮膚症状は単一の神経支配域（皮節）に分布していた。抗ウイルス薬及び鎮痛薬が投与された。20[redacted] 年 [redacted] 月 [redacted] 日，入院以後に被験者が耳内の不快感及び開瞼困難を訴えたため，耳鼻咽喉科専門医の診察が行われたが，明らかな耳鼻科的異常は認められなかった。眼科専門医から眼瞼症状に対し Arasena-A ointment が処方された。20[redacted] 年 [redacted] 月 [redacted] 日，抗ウイルス薬の静脈内投与が中止された。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

ARASENA A，VICCLOX，LACTEC，SOLDEM 3A，COMBEC 及び loxoprofen が投与された。

The patient's past medications include:

TALION OD for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

RINDERON-V for ATOPIC DERMATITIS ([redacted] [redacted] 20[redacted] - [redacted] 20[redacted])

WHITE PETROLATUM for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.23.1] [10019974]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Causality for TRIAMCINOLONE ACETONIDE (Open Label)

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1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.23.1] [10019974]

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

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

Dechallenge: Not Applicable

Causality for PREDNISOLONE (Open Label)

---

1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.23.1] [10019974]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of HERPES ZOSTER

- Investigator: Not applicable

- AbbVie: not applicable

Alternative Etiology for TRIAMCINOLONE ACETONIDE (Open Label)

Event of HERPES ZOSTER

- Investigator: More likely related to Upadacitinib/Placebo

- AbbVie: Topical steroids have limited systemic absorption and are unlikely related to the event of herpes zoster.

Alternative Etiology for PREDNISOLONE (Open Label)

Event of HERPES ZOSTER

- Investigator: More likely related to Upadacitinib/Placebo

- AbbVie: Topical steroids have limited systemic absorption and are unlikely related to the event of herpes zoster.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **BLOOD CULTURE:** Not reported

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

[redacted] **CHEST X-RAY:** not clinical significance

[redacted] **CT CHEST:** not clinical significance

[redacted] **CT HEAD:** not clinical significance

[redacted] **ECG:** not clinical significance

[redacted] **LYMPHOCYTES:** 26.2 % (normal 16.5 to 49.5)

[redacted] **LYMPHOCYTES:** 14.5 % (normal 16.5 to 49.5)

M17-377 試験（投与 24 週時）

治験の標題： 中等症から重症のアトピー性皮膚炎：日本の青少年及び成人被験者におけるステロイド外用薬併用下のウパダシチニブの評価	
治験実施施設： 日本，42 施設	
治験調整医師： [redacted], MD	
公表文献（参考資料）： なし	
試験期間（年数）： 最初の被験者の初回来院日：2018 年 10 月 27 日 最後の被験者の最終来院日：20[redacted] 年 [redacted] 月 [redacted] 日（投与 24 週時）	開発のフェーズ：III
目的： 全身療法の対象である中等症から重症の日本人の青少年及び成人アトピー性皮膚炎患者において副腎皮質ステロイド外用薬併用下のウパダシチニブの安全性を評価する。	
被験者数（計画時と解析時）： 計画時：264 名，解析時：272 名	
診断と主要な組入れ基準： 選択基準は以下のとおりであった。 1）スクリーニング来院時に 12 歳以上 75 歳以下の成人男性及び女性，2）Hanifin & Rajka の診断基準に基づく慢性アトピー性皮膚炎であり，ベースラインの 3 年以上前に発症し，3）湿疹面積重症度指数（以下「EASI」）スコア 16 以上，バリデートされた治験責任医師による包括的評価–アトピー性皮膚炎（以下「vIGA-AD」）スコア 3 以上，アトピー性皮膚炎病変の体表面積（以下「BSA」）10%以上，及び毎日の最悪のかゆみの数値評価尺度（以下「NRS」）の週平均値 4 以上，の疾患活動性基準をすべて満たし，4）ベースライン前の少なくとも 7 日間，外用エモリエント（保湿剤）を 1 日 2 回使用している，5）副腎皮質ステロイド外用薬又はカルシニューリン阻害外用薬が効果不十分であったことを示す記録がある（ベースライン来院前 6 ヵ月以内），又はアトピー性皮膚炎に対するベースライン来院前 6 ヵ月以内の全身療法の記録がある。 主要な除外基準は以下のとおりであった。 1）ベースライン前の所定期間内にアトピー性皮膚炎の治療薬（［1］4 週以内のアトピー性皮膚炎に対する全身療法，［2］半減期［既知の場合］の 5 倍又は 12 週間，どちらか長い方の期間以内の生物学的製剤，［3］4 週以内の紫外線療法，レーザー療法，タンニングブース使用，又は疾患重症度に影響する若しくは疾患評価を妨げる可能性のある長時間の日光曝露，［4］4 週以内の経口又は非経口漢方薬，［5］2 週以内のマリファナ，［6］外用エモリエント［保湿剤］を除く 7 日以内の外用薬［副腎皮質ステロイド外用薬，カルシニューリン阻害外用薬，又はホスホジエステラーゼ 4 型阻害外用薬を含むがこれらに限定されない］）を使用している，2）被験者の安全性を確保するため，スクリーニング期間中に，以下の臨床検査値を認めた被験者を除外した：血清アスパラギン酸アミノトランスフェラーゼが基準値上限（以下「ULN」）の 2 倍超，血清アラニンアミノトランスフェラーゼが ULN の 2 倍超，推算糸球体濾過率が 40 mL/min/1.73 m^2 未満（成人は 4 変数を用いた Modification of Diet in Renal Disease 簡易式，青少年は Schwartz 式に基づく），総白血球数が 2500/μL 未満，好中球数（絶対値）が 1500/μL 未満，血小板数が 100000/μL 未満，リンパ球数（絶対値）が 800/μL 未満，及びヘモグロビン量が 10 g/dL 未満。	
治験方法： 本試験は全身療法の対象である中等症から重症の日本人の青少年及び成人アトピー性皮膚炎患者を対象として，	

副腎皮質ステロイド外用薬併用下でウパダシチニブを評価する第 III 相，ランダム化，二重盲検，多施設共同試験であった。アトピー性皮膚炎に対する外用薬が効果不十分であったことを示す記録がある（ベースライン来院前 6 ヵ月以内），又はアトピー性皮膚炎に対するベースライン来院前 6 ヵ月以内の全身療法の記録がある患者を適格とした。

本試験は，35 日間のスクリーニング期間，16 週間の二重盲検投与期，36 週間の盲検継続投与期（投与 16 週時～投与 52 週時），並びに非盲検長期継続投与期（投与 52 週時～投与 136 週時，又は製造販売承認申請の完全な中止まで継続）から構成され，治験薬の最終投与から約 30 日後に追跡調査来院を行った。

本試験は，すべての被験者が投与 52 週時を完了した後は非盲検となる。

適格性基準を満たした被験者を，3 つの治験薬投与群（ウパダシチニブ 15 mg 群，ウパダシチニブ 30 mg 群，又はプラセボ群）のいずれかに 1:1:1 の割合でランダム化し，副腎皮質ステロイド外用薬併用下で 1 日 1 回（以下「QD」）経口投与した。ベースライン疾患重症度（vIGA-AD：中等症 vs. 重症），及び年齢（18 歳未満 vs. 18～40 歳 vs. 40 歳超）による層別ランダム化を行った。

投与 16 週終了時に，プラセボ群の被験者を 1:1 の割合でウパダシチニブ 15 mg 群又は 30 mg 群に再度割り付け、QD 経口投与した。ベースライン時にウパダシチニブ 15 mg 群又は 30 mg 群に割り付けられた被験者は，長期継続投与期でもそれまでの用量を投与 136 週時の来院まで継続することとした。

副腎皮質ステロイド外用薬の治験薬との併用投与は投与 16 週時までは必須とし，投与 16 週終了後の必要性は治験責任（分担）医師の判断に基づき決定することとした。また，投与 16 週後は，ストロングクラスの副腎皮質ステロイド外用薬による治療をレスキュー治療とみなさないこととした。

投与 4～24 週時の間の連続する 2 回の規定来院時に EASI スコアのベースラインからの 50%以上の低下（以下「EASI 50」）未満となった被験者に対し，医学的に必要な場合（耐え難いアトピー性皮膚炎の症状をコントロールする必要がある），治験責任（分担）医師の判断でアトピー性皮膚炎に対するレスキュー治療を行うことができることとした。投与 24 週後は，規定来院又は規定外来院時に EASI 50 未満となった被験者に対し，全身療法のレスキュー治療を行うことができることとした。

最後の被験者が投与 24 週時及び投与 52 週時の来院を完了した時点で中間解析を実施する。投与 24 週時の中間解析後は，実施医療機関及び被験者は引き続き投与 52 週時まで盲検性が維持される。

2 回目の中間解析は，試験継続中の被験者が投与 52 週時来院を完了した時点で実施する。本解析では投与 52 週時の中間データベース固定までの安全性評価項目，及びすべての有効性データについて実施する。

外部のデータモニタリング委員会（以下「DMC」）が定期的に試験期間を通して非盲検安全性データをレビューした。DMC の主要な責務は，本試験参加中の被験者の安全を守ることである。

被験薬，用量 / 含量 / 濃度，投与法，ロット番号：

ウパダシチニブ 15 mg フイルムコート錠（経口），バルクロット番号：[redacted]，[redacted]

ウパダシチニブ 30 mg フイルムコート錠（経口），バルクロット番号：[redacted]，[redacted]

ウパダシチニブに対応するプラセボ，バルクロット番号：[redacted]

治療期間：二重盲検投与期：16 週間，盲検継続投与期及び非盲検長期継続投与期：最長 136 週間

対照薬，用量 / 含量 / 濃度，投与法，ロット番号：

該当なし

評価基準：

安全性：

試験期間を通して，有害事象，バイタルサインの変動，身体検査，心電図，臨床検査，及び製品苦情のデータを評価した。

薬物動態：

青少年の被験者のみに対し，治験薬の投与前に血液検体を採取し，ウパダシチニブの薬物動態データを評価した（投与 2，8，12，16 週時，及び早期中止来院時）。

有効性：

有効性の主要評価項目又は副次評価項目は規定していない。

探索的評価項目は以下のとおりであった。

- vIGA-AD スコアが 0 又は 1 であり，かつベースラインと比較して 2 グレード以上低下した被験者の割合
- EASI スコアがベースラインから 50%/75%/90%低下（以下「EASI 50/75/90」）を達成した被験者の割合
- EASI のベースラインからの変化量及び変化率
- 最悪のかゆみの NRS スコアがベースラインから 4 以上改善（低下）した被験者の割合
- 最悪のかゆみの NRS スコアのベースラインからの変化量及び変化率

統計手法：

安全性：

安全性は，安全性解析対象集団を用い，被験者が実際に受けた投与に基づいて，二重盲検投与期，盲検継続投与期，非盲検長期継続投与期，及び通期の安全性解析を実施した。成人と青少年の安全性の結果は別に提示した。安全性は，有害事象，身体検査，臨床検査，及びバイタルサインにより評価した。欠測値の補完は行わなかった。

有害事象は ICH 国際医薬用語集（以下「MedDRA」）を使用してコード化した。有害事象は，治験薬初回投与から治験薬最終投与後 30 日までに発現した又は重症度が悪化した事象と定義した。有害事象が発現した被験者の数及び割合を，MedDRA の器官別大分類（以下「SOC」）及び基本語（以下「PT」）を用いて，重症度別及び治験責任（分担）医師が評価した治験薬との因果関係別に示した。また，重篤な有害事象，死亡，中止に至った有害事象，及び特に注目すべき有害事象の要約（発現割合及び 100 人年あたりの発現件数）も提示した。治験薬投与前の有害事象についても別途要約した。

臨床検査項目及びバイタルサインについて，ベースラインからの平均変化量及び事前に規定した臨床的に重要な値に合致する被験者の割合を要約した。

有効性：

有効性の解析には，臨床的なアトピー性皮膚炎の評価の要約を用いた。仮説検定は実施しなかった。

薬物動態：

薬物動態評価用の検体は青少年のみから採取した。血漿中ウパダシチニブ濃度を被験者ごとに示した。各採血時間帯での要約統計量を，投与群ごとに算出した。

要約 / 結論：

有効性の結果：本試験では，中等症から重症のアトピー性皮膚炎患者に，ウパダシチニブ 15 mg QD，30 mg QD，又はプラセボが盲検下で 16 週間投与された（二重盲検投与期）。この二重盲検投与期の有効性を要約した。二重盲検投与期では，EASI 75，vIGA-AD スコアの 0 又は 1 の達成，かゆみの NRS の 4 以上減少などの評価項目で，プラセボ群と比較してウパダシチニブ 15 mg 群及び 30 mg 群はいずれも数値的に高い反応率を示した。また，有効性は，ウパダシチニブ 15 mg 群と比較してウパダシチニブ 30 mg 群で数値的に高かった。二重盲検投与期でウパダシチニブの投与を受けた被験者では，有効性の評価項目の改善効果は盲検継続投与期及び非盲検長期継続投与期を通して持続した。

薬物動態の結果：

薬物動態用の検体を採取した 6～24 時間の投与間隔内での血漿中ウパダシチニブ濃度の平均値の範囲は，青少年のウパダシチニブ 15 mg 群で 4.09～16.6 ng/mL，及び青少年のウパダシチニブ 30 mg 群で 3.65～15.7 ng/mL であった。

安全性の結果：

本試験では，ウパダシチニブはアトピー性皮膚炎患者に対し，おおむね安全で，忍容性も良好であった。ウパダシチニブの投与を受けた被験者で発現割合が高かった非重篤なざ瘡を除き，重大な安全性のリスクは新たに特定されなかった。有害事象を発現した被験者割合は，プラセボ対照期間を通してウパダシチニブ 15 mg 群及び 30 mg 群で類似しており，プラセボ群と比較してウパダシチニブ 15 mg 群及び 30 mg 群でわずかに高かった。データカットオフ日までにウパダシチニブの投与を受けたすべての被験者では，有害事象を発現した被験者の割合は，ウパダシチニブ 15 mg 群と比較してウパダシチニブ 30 mg 群でわずかに高かった。全体として，ウパダシチニブの投与を受けた被験者で発現割合が高かった有害事象（いずれかの投与群で発現割合が 5%以上）は，ざ瘡，上咽頭炎及び帯状疱疹であった。重篤な有害事象及び治験薬の投与中止に至った有害事象の発現割合は全体的に低く，2 つの投与群で類似していた。本試験中に死亡は認められなかった。

ざ瘡の発現割合はウパダシチニブの用量反応関係が認められ，プラセボ群と比較してウパダシチニブ 15 mg 群及び 30 mg 群で高かった。ざ瘡の重症度は，いずれも軽度又は中等度であった。本試験のプラセボ及びウパダシチニブの投与群全体でざ瘡の既往歴を有する被験者の割合は高かった。この原因は不明であるが，ざ瘡の有病率は若年層で高いため，本試験に登録されたアトピー性皮膚炎患者集団でもざ瘡の既往歴が高かった可能性がある。

アトピー性皮膚炎は本試験の対象疾患であるため，有害事象のアトピー性皮膚炎は既存疾患の悪化とした。これらの事象は予期された事象であり，アトピー性皮膚炎の発現割合はプラセボ群及びウパダシチニブ 15 mg 群と比較して，ウパダシチニブ 30 mg 群で低かったことは，アトピー性皮膚炎に対するウパダシチニブの治療効果を示している可能性がある。

プラセボ対照期間での特に注目すべき有害事象の発現件数は，ウパダシチニブ 15 mg 群及び 30 mg 群でおおむね低く，プラセボ群で特に注目すべき有害事象は認められなかった。データカットオフ日までにウパダシチニブの投与を受けたすべての被験者では，重篤な感染症はほとんど認められず，発現リスクの用量依存性も認められなかった。大部分の日和見感染はカポジ水痘様発疹（ヘルペス性状湿疹と同義）であった。ヘルペス性状湿疹は，アトピー性皮膚炎患者集団で最も多く認められるウイルス性の合併症であり，ヘルペス性状湿疹に高い感受性を有するアトピー性皮膚炎患者集団の部分集団もあることが報告されている。帯状疱疹は JAK 阻害薬では予期される有害事象であり，その発現割合は，ウパダシチニブ 15 mg 群と比較して，ウパダシチニブ 30 mg 群で高かった。

判定された主要心血管事象（出血性卒中と判定された小脳出血）はウパダシチニブ 15 mg 群の 1 名（1 件）で報告されたが，本被験者には関連するリスク因子はなかった。

全体として，貧血，好中球減少症，及びクレアチンホスホキナーゼ増加の発現割合はおおむね低く，ウパダシチニブ 15 mg 群と比較してウパダシチニブ 30 mg 群で高かった。これらの事象により治験薬の投与を中止した被験者はいなかった。JAK 阻害薬では，これらの臨床検査異常に対するウパダシチニブの用量依存性は予期されている。

成人及び青少年のいずれの被験者でも中等度の体重増加が認められたが，ベースラインからの平均変化量は 2 kg

未満であった。体重増加は成長期の青少年では予期されているものであるが，成人では様々な病因が考えられた。

プラセボ対照期間での青少年被験者での有害事象の発現割合は，すべての投与群で類似していた。また，データカットオフ日までにウパダシチニブの投与を受けたすべての被験者での有害事象の発現割合は，ウパダシチニブ 15 mg 群とウパダシチニブ 30 mg 群で同様であった。全体として，青少年の被験者で重篤な有害事象は認められず，治験薬の投与中止に至った有害事象は 1 件発現した。特に注目すべき有害事象は，青少年の被験者 3 名で発現し，日和見感染（カポジ水痘様発疹として報告された），クレアチンホスホキナーゼ増加，及びリンパ球形態異常（リンパ腫に分類）が各 1 名に認められた。このリンパ球形態異常は，血液検査で検出された異型リンパ球によるものであり，悪性腫瘍ではなかった。青少年に対する新たなリスクは認められなかった。

本試験では，データカットオフ日までに，悪性腫瘍，非黒色腫皮膚癌，消化管穿孔，リンパ球減少症，活動性結核，及び判定された血栓症関連事象は報告されなかった。

結論：

M17-377 試験では，投与 16 週時まで（二重盲検投与期），及び被験者全体のデータカットオフ日までの安全性の結果から，ウパダシチニブ 15 mg 及び 30 mg QD の良好な忍容性が示された。非重篤なざ瘡を除き，ウパダシチニブの投与を受けた被験者で新たな安全性のシグナルは認められなかった。探索的な有効性の解析結果では，プラセボと比較してウパダシチニブで数値的に高い反応率が認められ，その効果はデータカットオフ日まで持続した。データカットオフ時点の安全性及び探索的な有効性の結果に基づき，本試験のウパダシチニブ（15 mg 及び 30 mg QD）のベネフィット・リスクのプロファイルは，良好と考えられた。

表 1. 二重盲検投与期で有害事象を発現した被験者数及び発現割合：MedDRA 器官別大分類及び基本語別（二重盲検投与期の安全性解析対象集団）

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=90) n (%)	Active UPA 15 mg QD (N=91) n (%)	Active UPA 30 mg QD (N=91) n (%)	Active UPA Total (N=182) n (%)
Any adverse event	38 (42.2)	51 (56.0)	58 (63.7)	109 (59.9)
血液およびリンパ系障害	1 (1.1)	1 (1.1)	4 (4.4)	5 (2.7)
貧血	0	0	1 (1.1)	1 (0.5)
リンパ節痛	1 (1.1)	0	0	0
リンパ節症	0	1 (1.1)	0	1 (0.5)
好中球減少症	0	0	3 (3.3)	3 (1.6)
心臓障害	0	1 (1.1)	0	1 (0.5)
動悸	0	1 (1.1)	0	1 (0.5)
耳および迷路障害	1 (1.1)	0	0	0
耳痛	1 (1.1)	0	0	0
眼障害	1 (1.1)	1 (1.1)	1 (1.1)	2 (1.1)
アトピー性白内障	1 (1.1)	0	0	0
アレルギー性結膜炎	0	1 (1.1)	1 (1.1)	2 (1.1)
胃腸障害	3 (3.3)	5 (5.5)	7 (7.7)	12 (6.6)
腹部不快感	0	0	3 (3.3)	3 (1.6)
腹部膨満	0	0	1 (1.1)	1 (0.5)
上腹部痛	0	2 (2.2)	0	2 (1.1)
便秘	1 (1.1)	0	0	0
下痢	1 (1.1)	1 (1.1)	2 (2.2)	3 (1.6)
食中毒	0	1 (1.1)	0	1 (0.5)

Note: For subjects who do not enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug and no more than 30 days after the last dose of study drug.
For subjects who enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug in DB Period and before the first dose of study drug in BE Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=90) n (%)	Active UPA 15 mg QD (N=91) n (%)	Active UPA 30 mg QD (N=91) n (%)	Active UPA Total (N=182) n (%)
血便排泄	0	1 (1.1)	0	1 (0.5)
粘液便	0	1 (1.1)	0	1 (0.5)
悪心	1 (1.1)	0	0	0
口内炎	0	0	2 (2.2)	2 (1.1)
一般・全身障害および投与部位の状態	1 (1.1)	5 (5.5)	7 (7.7)	12 (6.6)
胸痛	0	0	1 (1.1)	1 (0.5)
疲労	0	1 (1.1)	0	1 (0.5)
倦怠感	0	1 (1.1)	2 (2.2)	3 (1.6)
末梢性浮腫	0	0	1 (1.1)	1 (0.5)
発熱	1 (1.1)	4 (4.4)	3 (3.3)	7 (3.8)
肝胆道系障害	1 (1.1)	0	0	0
胆石症	1 (1.1)	0	0	0
感染症および寄生虫症	25 (27.8)	29 (31.9)	33 (36.3)	62 (34.1)
気管支炎	1 (1.1)	0	2 (2.2)	2 (1.1)
よう	0	0	1 (1.1)	1 (0.5)
蜂巣炎	1 (1.1)	1 (1.1)	0	1 (0.5)
結膜炎	0	1 (1.1)	1 (1.1)	2 (1.1)
膀胱炎	0	0	1 (1.1)	1 (0.5)
感染性腸炎	0	0	1 (1.1)	1 (0.5)
丹毒	0	1 (1.1)	0	1 (0.5)

Note: For subjects who do not enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug and no more than 30 days after the last dose of study drug.
For subjects who enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug in DB Period and before the first dose of study drug in BE Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=90) n (%)	Active UPA 15 mg QD (N=91) n (%)	Active UPA 30 mg QD (N=91) n (%)	Active UPA Total (N=182) n (%)
毛包炎	2 (2.2)	3 (3.3)	2 (2.2)	5 (2.7)
せつ	2 (2.2)	2 (2.2)	0	2 (1.1)
胃腸炎	1 (1.1)	0	1 (1.1)	1 (0.5)
ウイルス性胃腸炎	0	0	1 (1.1)	1 (0.5)
歯肉炎	0	0	1 (1.1)	1 (0.5)
単純ヘルペス	2 (2.2)	2 (2.2)	2 (2.2)	4 (2.2)
ヘルペスウイルス感染	0	1 (1.1)	0	1 (0.5)
帯状疱疹	0	0	4 (4.4)	4 (2.2)
麦粒腫	0	0	1 (1.1)	1 (0.5)
膿痂疹	1 (1.1)	0	0	0
感染	0	1 (1.1)	0	1 (0.5)
インフルエンザ	1 (1.1)	1 (1.1)	2 (2.2)	3 (1.6)
カポジ水痘様発疹	0	3 (3.3)	1 (1.1)	4 (2.2)
伝染性軟属腫	0	0	1 (1.1)	1 (0.5)
細菌性爪床感染	1 (1.1)	0	0	0
上咽頭炎	14 (15.6)	12 (13.2)	14 (15.4)	26 (14.3)
口腔ヘルペス	0	1 (1.1)	2 (2.2)	3 (1.6)
細菌性外耳炎	1 (1.1)	0	0	0
中耳炎	0	0	1 (1.1)	1 (0.5)
爪囲炎	0	0	1 (1.1)	1 (0.5)

Note: For subjects who do not enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug and no more than 30 days after the last dose of study drug.
For subjects who enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug in DB Period and before the first dose of study drug in BE Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=90) n (%)	Active UPA 15 mg QD (N=91) n (%)	Active UPA 30 mg QD (N=91) n (%)	Active UPA Total (N=182) n (%)
歯周炎	1 (1.1)	0	0	0
咽頭炎	1 (1.1)	0	1 (1.1)	1 (0.5)
細菌性咽頭炎	0	0	1 (1.1)	1 (0.5)
副鼻腔炎	0	0	1 (1.1)	1 (0.5)
皮下組織膿瘍	0	1 (1.1)	0	1 (0.5)
股部白癬	1 (1.1)	0	1 (1.1)	1 (0.5)
足部白癬	2 (2.2)	0	1 (1.1)	1 (0.5)
扁桃炎	0	1 (1.1)	2 (2.2)	3 (1.6)
上気道感染	0	3 (3.3)	1 (1.1)	4 (2.2)
ウイルス性上気道感染	0	0	1 (1.1)	1 (0.5)
傷害、中毒および処置合併症	1 (1.1)	4 (4.4)	2 (2.2)	6 (3.3)
節足動物咬傷	0	0	2 (2.2)	2 (1.1)
剥離骨折	0	1 (1.1)	0	1 (0.5)
足骨折	0	1 (1.1)	0	1 (0.5)
四肢損傷	0	1 (1.1)	0	1 (0.5)
皮膚擦過傷	1 (1.1)	0	0	0
皮膚創傷	0	1 (1.1)	0	1 (0.5)
臨床検査	3 (3.3)	4 (4.4)	5 (5.5)	9 (4.9)
アラニンアミノトランスフェラーゼ増加	0	1 (1.1)	1 (1.1)	2 (1.1)
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (1.1)	1 (1.1)	2 (1.1)

Note: For subjects who do not enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug and no more than 30 days after the last dose of study drug.
For subjects who enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug in DB Period and before the first dose of study drug in BE Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=90) n (%)	Active UPA 15 mg QD (N=91) n (%)	Active UPA 30 mg QD (N=91) n (%)	Active UPA Total (N=182) n (%)
血中クレアチンホスホキナーゼ増加	0	1 (1.1)	2 (2.2)	3 (1.6)
血中トリグリセリド増加	1 (1.1)	0	0	0
尿中血陽性	1 (1.1)	0	0	0
好中球数減少	0	1 (1.1)	1 (1.1)	2 (1.1)
尿中蛋白陽性	1 (1.1)	0	0	0
尿中ウロビリノーゲン増加	2 (2.2)	1 (1.1)	0	1 (0.5)
白血球数減少	0	0	2 (2.2)	2 (1.1)
筋骨格系および結合組織障害	1 (1.1)	3 (3.3)	6 (6.6)	9 (4.9)
関節痛	0	0	5 (5.5)	5 (2.7)
背部痛	0	1 (1.1)	0	1 (0.5)
椎間板突出	1 (1.1)	0	0	0
関節腫脹	0	0	1 (1.1)	1 (0.5)
筋肉痛	0	1 (1.1)	0	1 (0.5)
四肢痛	0	1 (1.1)	0	1 (0.5)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	2 (2.2)	0	2 (1.1)
平滑筋腫	0	1 (1.1)	0	1 (0.5)
皮膚乳頭腫	0	1 (1.1)	0	1 (0.5)
神経系障害	4 (4.4)	3 (3.3)	2 (2.2)	5 (2.7)
小脳出血	0	1 (1.1)	0	1 (0.5)
浮動性めまい	1 (1.1)	0	1 (1.1)	1 (0.5)

Note: For subjects who do not enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug and no more than 30 days after the last dose of study drug.
For subjects who enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug in DB Period and before the first dose of study drug in BE Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=90) n (%)	Active UPA 15 mg QD (N=91) n (%)	Active UPA 30 mg QD (N=91) n (%)	Active UPA Total (N=182) n (%)
ジスキネジア	1 (1.1)	0	0	0
頭痛	2 (2.2)	1 (1.1)	1 (1.1)	2 (1.1)
感覚鈍麻	0	1 (1.1)	0	1 (0.5)
傾眠	0	0	1 (1.1)	1 (0.5)
精神障害	1 (1.1)	1 (1.1)	0	1 (0.5)
うつ病	0	1 (1.1)	0	1 (0.5)
睡眠障害	1 (1.1)	0	0	0
呼吸器、胸郭および縦隔障害	1 (1.1)	1 (1.1)	4 (4.4)	5 (2.7)
喘息	1 (1.1)	0	2 (2.2)	2 (1.1)
咳嗽	0	0	1 (1.1)	1 (0.5)
鼻出血	0	0	1 (1.1)	1 (0.5)
口腔咽頭痛	0	1 (1.1)	0	1 (0.5)
皮膚および皮下組織障害	14 (15.6)	18 (19.8)	20 (22.0)	38 (20.9)
ざ瘡	5 (5.6)	12 (13.2)	18 (19.8)	30 (16.5)
脱毛症	0	1 (1.1)	0	1 (0.5)
水疱	0	1 (1.1)	0	1 (0.5)
アトピー性皮膚炎	3 (3.3)	3 (3.3)	0	3 (1.6)
接触皮膚炎	1 (1.1)	1 (1.1)	0	1 (0.5)
異汗性湿疹	1 (1.1)	0	0	0
紅斑	0	1 (1.1)	0	1 (0.5)

Note: For subjects who do not enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug and no more than 30 days after the last dose of study drug.
For subjects who enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug in DB Period and before the first dose of study drug in BE Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=90) n (%)	Active UPA 15 mg QD (N=91) n (%)	Active UPA 30 mg QD (N=91) n (%)	Active UPA Total (N=182) n (%)
過角化	1 (1.1)	0	0	0
汗疹	0	0	1 (1.1)	1 (0.5)
光線過敏性反応	1 (1.1)	0	0	0
脂漏性皮膚炎	0	1 (1.1)	0	1 (0.5)
日光皮膚炎	0	2 (2.2)	0	2 (1.1)
毛細血管拡張症	1 (1.1)	0	0	0
蕁麻疹	2 (2.2)	0	1 (1.1)	1 (0.5)
血管障害	1 (1.1)	0	0	0
低血圧	1 (1.1)	0	0	0

Note: For subjects who do not enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug and no more than 30 days after the last dose of study drug.
For subjects who enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug in DB Period and before the first dose of study drug in BE Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W24 Table 14.3__1.5.1.1

表 2. 二重盲検投与期で有害事象を発現した被験者数及び発現割合：MedDRA 器官別大分類及び基本語別（二重盲検投与期の安全性解析対象集団，青少年）

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=9) n (%)	Active UPA 15 mg QD (N=10) n (%)	Active UPA 30 mg QD (N=10) n (%)	Active UPA Total (N=20) n (%)
Any adverse event	6 (66.7)	9 (90.0)	8 (80.0)	17 (85.0)
眼障害	0	1 (10.0)	0	1 (5.0)
アレルギー性結膜炎	0	1 (10.0)	0	1 (5.0)
胃腸障害	0	0	1 (10.0)	1 (5.0)
腹部不快感	0	0	1 (10.0)	1 (5.0)
一般・全身障害および投与部位の状態	0	1 (10.0)	1 (10.0)	2 (10.0)
倦怠感	0	1 (10.0)	0	1 (5.0)
発熱	0	1 (10.0)	1 (10.0)	2 (10.0)
感染症および寄生虫症	4 (44.4)	6 (60.0)	5 (50.0)	11 (55.0)
気管支炎	0	0	1 (10.0)	1 (5.0)
感染性腸炎	0	0	1 (10.0)	1 (5.0)
胃腸炎	1 (11.1)	0	0	0
インフルエンザ	0	1 (10.0)	1 (10.0)	2 (10.0)
カポジ水痘様発疹	0	1 (10.0)	0	1 (5.0)
伝染性軟属腫	0	0	1 (10.0)	1 (5.0)
上咽頭炎	3 (33.3)	1 (10.0)	1 (10.0)	2 (10.0)
中耳炎	0	0	1 (10.0)	1 (5.0)
咽頭炎	0	0	1 (10.0)	1 (5.0)
副鼻腔炎	0	0	1 (10.0)	1 (5.0)
上気道感染	0	3 (30.0)	1 (10.0)	4 (20.0)

Note: For subjects who do not enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug and no more than 30 days after the last dose of study drug.
For subjects who enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug in DB Period and before the first dose of study drug in BE Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=9) n (%)	Active UPA 15 mg QD (N=10) n (%)	Active UPA 30 mg QD (N=10) n (%)	Active UPA Total (N=20) n (%)
ウイルス性上気道感染	0	0	1 (10.0)	1 (5.0)
傷害、中毒および処置合併症	0	1 (10.0)	1 (10.0)	2 (10.0)
節足動物咬傷	0	0	1 (10.0)	1 (5.0)
剥離骨折	0	1 (10.0)	0	1 (5.0)
臨床検査	0	1 (10.0)	0	1 (5.0)
血中クレアチンホスホキナーゼ増加	0	1 (10.0)	0	1 (5.0)
呼吸器、胸郭および縦隔障害	0	0	1 (10.0)	1 (5.0)
喘息	0	0	1 (10.0)	1 (5.0)
皮膚および皮下組織障害	3 (33.3)	4 (40.0)	3 (30.0)	7 (35.0)
ざ瘡	1 (11.1)	3 (30.0)	3 (30.0)	6 (30.0)
接触皮膚炎	0	1 (10.0)	0	1 (5.0)
紅斑	0	1 (10.0)	0	1 (5.0)
光線過敏性反応	1 (11.1)	0	0	0
蕁麻疹	1 (11.1)	0	0	0
血管障害	1 (11.1)	0	0	0
低血圧	1 (11.1)	0	0	0

Note: For subjects who do not enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug and no more than 30 days after the last dose of study drug.
For subjects who enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug in DB Period and before the first dose of study drug in BE Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W24 Table 14.3__1.5.1.2

表 3. 二重盲検投与期で有害事象を発現した被験者数及び発現割合：MedDRA 器官別大分類及び基本語別（二重盲検投与期の安全性解析対象集団，成人）

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=81) n (%)	Active UPA 15 mg QD (N=81) n (%)	Active UPA 30 mg QD (N=81) n (%)	Active UPA Total (N=162) n (%)
Any adverse event	32 (39.5)	42 (51.9)	50 (61.7)	92 (56.8)
血液およびリンパ系障害	1 (1.2)	1 (1.2)	4 (4.9)	5 (3.1)
貧血	0	0	1 (1.2)	1 (0.6)
リンパ節痛	1 (1.2)	0	0	0
リンパ節症	0	1 (1.2)	0	1 (0.6)
好中球減少症	0	0	3 (3.7)	3 (1.9)
心臓障害	0	1 (1.2)	0	1 (0.6)
動悸	0	1 (1.2)	0	1 (0.6)
耳および迷路障害	1 (1.2)	0	0	0
耳痛	1 (1.2)	0	0	0
眼障害	1 (1.2)	0	1 (1.2)	1 (0.6)
アトピー性白内障	1 (1.2)	0	0	0
アレルギー性結膜炎	0	0	1 (1.2)	1 (0.6)
胃腸障害	3 (3.7)	5 (6.2)	6 (7.4)	11 (6.8)
腹部不快感	0	0	2 (2.5)	2 (1.2)
腹部膨満	0	0	1 (1.2)	1 (0.6)
上腹部痛	0	2 (2.5)	0	2 (1.2)
便秘	1 (1.2)	0	0	0
下痢	1 (1.2)	1 (1.2)	2 (2.5)	3 (1.9)
食中毒	0	1 (1.2)	0	1 (0.6)

Note: For subjects who do not enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug and no more than 30 days after the last dose of study drug.
For subjects who enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug in DB Period and before the first dose of study drug in BE Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=81) n (%)	Active UPA 15 mg QD (N=81) n (%)	Active UPA 30 mg QD (N=81) n (%)	Active UPA Total (N=162) n (%)
血便排泄	0	1 (1.2)	0	1 (0.6)
粘液便	0	1 (1.2)	0	1 (0.6)
悪心	1 (1.2)	0	0	0
口内炎	0	0	2 (2.5)	2 (1.2)
一般・全身障害および投与部位の状態	1 (1.2)	4 (4.9)	6 (7.4)	10 (6.2)
胸痛	0	0	1 (1.2)	1 (0.6)
疲労	0	1 (1.2)	0	1 (0.6)
倦怠感	0	0	2 (2.5)	2 (1.2)
末梢性浮腫	0	0	1 (1.2)	1 (0.6)
発熱	1 (1.2)	3 (3.7)	2 (2.5)	5 (3.1)
肝胆道系障害	1 (1.2)	0	0	0
胆石症	1 (1.2)	0	0	0
感染症および寄生虫症	21 (25.9)	23 (28.4)	28 (34.6)	51 (31.5)
気管支炎	1 (1.2)	0	1 (1.2)	1 (0.6)
よう	0	0	1 (1.2)	1 (0.6)
蜂巣炎	1 (1.2)	1 (1.2)	0	1 (0.6)
結膜炎	0	1 (1.2)	1 (1.2)	2 (1.2)
膀胱炎	0	0	1 (1.2)	1 (0.6)
丹毒	0	1 (1.2)	0	1 (0.6)
毛包炎	2 (2.5)	3 (3.7)	2 (2.5)	5 (3.1)

Note: For subjects who do not enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug and no more than 30 days after the last dose of study drug.
For subjects who enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug in DB Period and before the first dose of study drug in BE Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=81) n (%)	Active UPA 15 mg QD (N=81) n (%)	Active UPA 30 mg QD (N=81) n (%)	Active UPA Total (N=162) n (%)
せつ	2 (2.5)	2 (2.5)	0	2 (1.2)
胃腸炎	0	0	1 (1.2)	1 (0.6)
ウイルス性胃腸炎	0	0	1 (1.2)	1 (0.6)
歯肉炎	0	0	1 (1.2)	1 (0.6)
単純ヘルペス	2 (2.5)	2 (2.5)	2 (2.5)	4 (2.5)
ヘルペスウイルス感染	0	1 (1.2)	0	1 (0.6)
帯状疱疹	0	0	4 (4.9)	4 (2.5)
麦粒腫	0	0	1 (1.2)	1 (0.6)
膿痂疹	1 (1.2)	0	0	0
感染	0	1 (1.2)	0	1 (0.6)
インフルエンザ	1 (1.2)	0	1 (1.2)	1 (0.6)
カポジ水痘様発疹	0	2 (2.5)	1 (1.2)	3 (1.9)
細菌性爪床感染	1 (1.2)	0	0	0
上咽頭炎	11 (13.6)	11 (13.6)	13 (16.0)	24 (14.8)
口腔ヘルペス	0	1 (1.2)	2 (2.5)	3 (1.9)
細菌性外耳炎	1 (1.2)	0	0	0
爪囲炎	0	0	1 (1.2)	1 (0.6)
歯周炎	1 (1.2)	0	0	0
咽頭炎	1 (1.2)	0	0	0
細菌性咽頭炎	0	0	1 (1.2)	1 (0.6)

Note: For subjects who do not enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug and no more than 30 days after the last dose of study drug.
For subjects who enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug in DB Period and before the first dose of study drug in BE Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=81) n (%)	Active UPA 15 mg QD (N=81) n (%)	Active UPA 30 mg QD (N=81) n (%)	Active UPA Total (N=162) n (%)
皮下組織膿瘍	0	1 (1.2)	0	1 (0.6)
股部白癬	1 (1.2)	0	1 (1.2)	1 (0.6)
足部白癬	2 (2.5)	0	1 (1.2)	1 (0.6)
扁桃炎	0	1 (1.2)	2 (2.5)	3 (1.9)
傷害、中毒および処置合併症	1 (1.2)	3 (3.7)	1 (1.2)	4 (2.5)
節足動物咬傷	0	0	1 (1.2)	1 (0.6)
足骨折	0	1 (1.2)	0	1 (0.6)
四肢損傷	0	1 (1.2)	0	1 (0.6)
皮膚擦過傷	1 (1.2)	0	0	0
皮膚創傷	0	1 (1.2)	0	1 (0.6)
臨床検査	3 (3.7)	3 (3.7)	5 (6.2)	8 (4.9)
アラニンアミノトランスフェラーゼ増加	0	1 (1.2)	1 (1.2)	2 (1.2)
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (1.2)	1 (1.2)	2 (1.2)
血中クレアチンホスホキナーゼ増加	0	0	2 (2.5)	2 (1.2)
血中トリグリセリド増加	1 (1.2)	0	0	0
尿中血陽性	1 (1.2)	0	0	0
好中球数減少	0	1 (1.2)	1 (1.2)	2 (1.2)
尿中蛋白陽性	1 (1.2)	0	0	0
尿中ウロビリノーゲン増加	2 (2.5)	1 (1.2)	0	1 (0.6)
白血球数減少	0	0	2 (2.5)	2 (1.2)

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For subjects who enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug in DB Period and before the first dose of study drug in BE Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=81) n (%)	Active UPA 15 mg QD (N=81) n (%)	Active UPA 30 mg QD (N=81) n (%)	Active UPA Total (N=162) n (%)
筋骨格系および結合組織障害	1 (1.2)	3 (3.7)	6 (7.4)	9 (5.6)
関節痛	0	0	5 (6.2)	5 (3.1)
背部痛	0	1 (1.2)	0	1 (0.6)
椎間板突出	1 (1.2)	0	0	0
関節腫脹	0	0	1 (1.2)	1 (0.6)
筋肉痛	0	1 (1.2)	0	1 (0.6)
四肢痛	0	1 (1.2)	0	1 (0.6)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	2 (2.5)	0	2 (1.2)
平滑筋腫	0	1 (1.2)	0	1 (0.6)
皮膚乳頭腫	0	1 (1.2)	0	1 (0.6)
神経系障害	4 (4.9)	3 (3.7)	2 (2.5)	5 (3.1)
小脳出血	0	1 (1.2)	0	1 (0.6)
浮動性めまい	1 (1.2)	0	1 (1.2)	1 (0.6)
ジスキネジア	1 (1.2)	0	0	0
頭痛	2 (2.5)	1 (1.2)	1 (1.2)	2 (1.2)
感覚鈍麻	0	1 (1.2)	0	1 (0.6)
傾眠	0	0	1 (1.2)	1 (0.6)
精神障害	1 (1.2)	1 (1.2)	0	1 (0.6)
うつ病	0	1 (1.2)	0	1 (0.6)
睡眠障害	1 (1.2)	0	0	0

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For subjects who enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug in DB Period and before the first dose of study drug in BE Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=81) n (%)	Active UPA 15 mg QD (N=81) n (%)	Active UPA 30 mg QD (N=81) n (%)	Active UPA Total (N=162) n (%)
呼吸器、胸郭および縦隔障害	1 (1.2)	1 (1.2)	3 (3.7)	4 (2.5)
喘息	1 (1.2)	0	1 (1.2)	1 (0.6)
咳嗽	0	0	1 (1.2)	1 (0.6)
鼻出血	0	0	1 (1.2)	1 (0.6)
口腔咽頭痛	0	1 (1.2)	0	1 (0.6)
皮膚および皮下組織障害	11 (13.6)	14 (17.3)	17 (21.0)	31 (19.1)
ざ瘡	4 (4.9)	9 (11.1)	15 (18.5)	24 (14.8)
脱毛症	0	1 (1.2)	0	1 (0.6)
水疱	0	1 (1.2)	0	1 (0.6)
アトピー性皮膚炎	3 (3.7)	3 (3.7)	0	3 (1.9)
接触皮膚炎	1 (1.2)	0	0	0
異汗性湿疹	1 (1.2)	0	0	0
過角化	1 (1.2)	0	0	0
汗疹	0	0	1 (1.2)	1 (0.6)
脂漏性皮膚炎	0	1 (1.2)	0	1 (0.6)
日光皮膚炎	0	2 (2.5)	0	2 (1.2)
毛細血管拡張症	1 (1.2)	0	0	0
蕁麻疹	1 (1.2)	0	1 (1.2)	1 (0.6)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W24 Table 14.3__1.5.1.3

表 4. ウパダシチニブ投与期間中で有害事象を発現した被験者数及び発現割合：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団）

	Active		
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=133) n (%)	UPA 30 mg QD (N=136) n (%)	UPA Total (N=269) n (%)
Any adverse event	80 (60.2)	95 (69.9)	175 (65.1)
血液およびリンパ系障害	1 (0.8)	7 (5.1)	8 (3.0)
貧血	0	3 (2.2)	3 (1.1)
リンパ節症	1 (0.8)	0	1 (0.4)
好中球減少症	0	4 (2.9)	4 (1.5)
心臓障害	1 (0.8)	0	1 (0.4)
動悸	1 (0.8)	0	1 (0.4)
耳および迷路障害	1 (0.8)	1 (0.7)	2 (0.7)
耳鳴	1 (0.8)	0	1 (0.4)
頭位性回転性めまい	0	1 (0.7)	1 (0.4)
眼障害	4 (3.0)	3 (2.2)	7 (2.6)
アトピー性白内障	1 (0.8)	0	1 (0.4)
結膜充血	1 (0.8)	0	1 (0.4)
アレルギー性結膜炎	2 (1.5)	1 (0.7)	3 (1.1)
ドライアイ	0	1 (0.7)	1 (0.4)
夜盲	0	1 (0.7)	1 (0.4)
胃腸障害	6 (4.5)	11 (8.1)	17 (6.3)
腹部不快感	0	3 (2.2)	3 (1.1)
腹部膨満	0	1 (0.7)	1 (0.4)
上腹部痛	2 (1.5)	0	2 (0.7)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
慢性胃炎	0	1 (0.7)	1 (0.4)
便秘	0	1 (0.7)	1 (0.4)
齲歯	1 (0.8)	0	1 (0.4)
下痢	1 (0.8)	4 (2.9)	5 (1.9)
食中毒	1 (0.8)	0	1 (0.4)
血便排泄	1 (0.8)	0	1 (0.4)
胃酸過多	0	1 (0.7)	1 (0.4)
粘液便	1 (0.8)	0	1 (0.4)
口内炎	0	2 (1.5)	2 (0.7)
一般・全身障害および投与部位の状態	8 (6.0)	10 (7.4)	18 (6.7)
胸痛	0	1 (0.7)	1 (0.4)
疲労	1 (0.8)	0	1 (0.4)
倦怠感	1 (0.8)	2 (1.5)	3 (1.1)
末梢性浮腫	1 (0.8)	1 (0.7)	2 (0.7)
発熱	6 (4.5)	6 (4.4)	12 (4.5)
感染症および寄生虫症	54 (40.6)	60 (44.1)	114 (42.4)
気管支炎	0	3 (2.2)	3 (1.1)
よう	0	1 (0.7)	1 (0.4)
蜂巣炎	2 (1.5)	0	2 (0.7)
結膜炎	2 (1.5)	3 (2.2)	5 (1.9)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
膀胱炎	1 (0.8)	1 (0.7)	2 (0.7)
爪の皮膚糸状菌症	0	1 (0.7)	1 (0.4)
感染性腸炎	0	1 (0.7)	1 (0.4)
丹毒	1 (0.8)	0	1 (0.4)
毛包炎	5 (3.8)	4 (2.9)	9 (3.3)
せつ	5 (3.8)	2 (1.5)	7 (2.6)
胃腸炎	0	1 (0.7)	1 (0.4)
ウイルス性胃腸炎	0	1 (0.7)	1 (0.4)
陰部ヘルペス	1 (0.8)	0	1 (0.4)
歯肉炎	1 (0.8)	1 (0.7)	2 (0.7)
手足口病	0	1 (0.7)	1 (0.4)
単純ヘルペス	6 (4.5)	3 (2.2)	9 (3.3)
ヘルペスウイルス感染	1 (0.8)	0	1 (0.4)
帯状疱疹	5 (3.8)	11 (8.1)	16 (5.9)
播種性帯状疱疹	1 (0.8)	0	1 (0.4)
麦粒腫	1 (0.8)	2 (1.5)	3 (1.1)
膿痂疹	1 (0.8)	0	1 (0.4)
感染	1 (0.8)	1 (0.7)	2 (0.7)
インフルエンザ	1 (0.8)	3 (2.2)	4 (1.5)
カポジ水痘様発疹	4 (3.0)	2 (1.5)	6 (2.2)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
伝染性軟属腫	0	1 (0.7)	1 (0.4)
上咽頭炎	24 (18.0)	28 (20.6)	52 (19.3)
口腔ヘルペス	2 (1.5)	4 (2.9)	6 (2.2)
外耳炎	0	2 (1.5)	2 (0.7)
中耳炎	0	1 (0.7)	1 (0.4)
爪囲炎	0	1 (0.7)	1 (0.4)
咽頭炎	1 (0.8)	1 (0.7)	2 (0.7)
細菌性咽頭炎	0	1 (0.7)	1 (0.4)
ニューモシスチス・イロベチイ肺炎	1 (0.8)	0	1 (0.4)
副鼻腔炎	0	1 (0.7)	1 (0.4)
皮膚感染	1 (0.8)	0	1 (0.4)
皮下組織膿瘍	1 (0.8)	0	1 (0.4)
股部白癬	0	1 (0.7)	1 (0.4)
足部白癬	0	3 (2.2)	3 (1.1)
癜風	1 (0.8)	0	1 (0.4)
扁桃炎	3 (2.3)	2 (1.5)	5 (1.9)
上気道感染	3 (2.3)	1 (0.7)	4 (1.5)
尿路感染	1 (0.8)	0	1 (0.4)
ウイルス性上気道感染	0	1 (0.7)	1 (0.4)
傷害、中毒および処置合併症	6 (4.5)	8 (5.9)	14 (5.2)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
節足動物咬傷	0	3 (2.2)	3 (1.1)
節足動物刺傷	1 (0.8)	0	1 (0.4)
剥離骨折	1 (0.8)	0	1 (0.4)
骨挫傷	0	1 (0.7)	1 (0.4)
大腿骨骨折	0	1 (0.7)	1 (0.4)
足骨折	1 (0.8)	0	1 (0.4)
手骨折	1 (0.8)	0	1 (0.4)
熱射病	0	1 (0.7)	1 (0.4)
靭帯捻挫	0	1 (0.7)	1 (0.4)
四肢損傷	1 (0.8)	0	1 (0.4)
皮膚擦過傷	0	1 (0.7)	1 (0.4)
皮膚創傷	1 (0.8)	0	1 (0.4)
臨床検査	14 (10.5)	10 (7.4)	24 (8.9)
アラニンアミノトランスフェラーゼ増加	3 (2.3)	3 (2.2)	6 (2.2)
アスパラギン酸アミノトランスフェラーゼ増加	2 (1.5)	2 (1.5)	4 (1.5)
血中クレアチンホスホキナーゼ増加	2 (1.5)	4 (2.9)	6 (2.2)
血中トリグリセリド増加	2 (1.5)	0	2 (0.7)
ヘモグロビン減少	1 (0.8)	1 (0.7)	2 (0.7)
肝酵素上昇	1 (0.8)	0	1 (0.4)
リンパ球形態異常	0	1 (0.7)	1 (0.4)

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Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
骨髄球存在	0	1 (0.7)	1 (0.4)
好中球数減少	1 (0.8)	2 (1.5)	3 (1.1)
尿中蛋白陽性	1 (0.8)	0	1 (0.4)
赤血球数減少	1 (0.8)	0	1 (0.4)
尿中ウロビリノーゲン増加	1 (0.8)	0	1 (0.4)
体重減少	1 (0.8)	0	1 (0.4)
白血球数減少	0	2 (1.5)	2 (0.7)
筋骨格系および結合組織障害	5 (3.8)	8 (5.9)	13 (4.8)
関節痛	0	6 (4.4)	6 (2.2)
背部痛	1 (0.8)	1 (0.7)	2 (0.7)
椎間板突出	1 (0.8)	0	1 (0.4)
関節腫脹	0	1 (0.7)	1 (0.4)
筋肉痛	1 (0.8)	2 (1.5)	3 (1.1)
四肢痛	1 (0.8)	0	1 (0.4)
滑液嚢腫	1 (0.8)	0	1 (0.4)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	6 (4.5)	1 (0.7)	7 (2.6)
平滑筋腫	1 (0.8)	0	1 (0.4)
皮膚乳頭腫	5 (3.8)	1 (0.7)	6 (2.2)
神経系障害	4 (3.0)	7 (5.1)	11 (4.1)
小脳出血	1 (0.8)	0	1 (0.4)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
浮動性めまい	0	1 (0.7)	1 (0.4)
頭痛	2 (1.5)	3 (2.2)	5 (1.9)
感覚鈍麻	1 (0.8)	0	1 (0.4)
ヘルペス後神経痛	0	1 (0.7)	1 (0.4)
傾眠	0	3 (2.2)	3 (1.1)
精神障害	4 (3.0)	1 (0.7)	5 (1.9)
抑うつ気分	1 (0.8)	0	1 (0.4)
うつ病	1 (0.8)	0	1 (0.4)
不眠症	1 (0.8)	0	1 (0.4)
落ち着きのなさ	0	1 (0.7)	1 (0.4)
身体症状症	1 (0.8)	0	1 (0.4)
呼吸器、胸郭および縦隔障害	8 (6.0)	8 (5.9)	16 (5.9)
喘息	2 (1.5)	3 (2.2)	5 (1.9)
慢性気管支炎	0	1 (0.7)	1 (0.4)
咳嗽	1 (0.8)	1 (0.7)	2 (0.7)
鼻出血	0	1 (0.7)	1 (0.4)
口腔咽頭痛	4 (3.0)	3 (2.2)	7 (2.6)
上気道の炎症	1 (0.8)	0	1 (0.4)
皮膚および皮下組織障害	29 (21.8)	45 (33.1)	74 (27.5)
ざ瘡	20 (15.0)	38 (27.9)	58 (21.6)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
脱毛症	1 (0.8)	0	1 (0.4)
水疱	1 (0.8)	1 (0.7)	2 (0.7)
アトピー性皮膚炎	5 (3.8)	1 (0.7)	6 (2.2)
接触皮膚炎	1 (0.8)	1 (0.7)	2 (0.7)
紅斑	1 (0.8)	0	1 (0.4)
過角化	1 (0.8)	0	1 (0.4)
汗疹	1 (0.8)	2 (1.5)	3 (1.1)
口囲皮膚炎	1 (0.8)	0	1 (0.4)
小水疱性皮疹	0	1 (0.7)	1 (0.4)
脂漏性皮膚炎	1 (0.8)	0	1 (0.4)
皮膚亀裂	0	1 (0.7)	1 (0.4)
日光皮膚炎	2 (1.5)	0	2 (0.7)
蕁麻疹	1 (0.8)	2 (1.5)	3 (1.1)
接触蕁麻疹	0	1 (0.7)	1 (0.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W24 Table 14.3__1.5.2.1

表 5. ウパダシチニブ投与期間中に有害事象を発現した被験者数及び発現割合：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団，青少年）

	Active		
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=14) n (%)	UPA 30 mg QD (N=14) n (%)	UPA Total (N=28) n (%)
Any adverse event	9 (64.3)	11 (78.6)	20 (71.4)
眼障害	1 (7.1)	0	1 (3.6)
アレルギー性結膜炎	1 (7.1)	0	1 (3.6)
胃腸障害	0	1 (7.1)	1 (3.6)
腹部不快感	0	1 (7.1)	1 (3.6)
一般・全身障害および投与部位の状態	1 (7.1)	1 (7.1)	2 (7.1)
倦怠感	1 (7.1)	0	1 (3.6)
発熱	1 (7.1)	1 (7.1)	2 (7.1)
感染症および寄生虫症	7 (50.0)	9 (64.3)	16 (57.1)
気管支炎	0	1 (7.1)	1 (3.6)
結膜炎	0	1 (7.1)	1 (3.6)
膀胱炎	1 (7.1)	0	1 (3.6)
感染性腸炎	0	1 (7.1)	1 (3.6)
毛包炎	0	1 (7.1)	1 (3.6)
手足口病	0	1 (7.1)	1 (3.6)
膿痂疹	1 (7.1)	0	1 (3.6)
インフルエンザ	1 (7.1)	1 (7.1)	2 (7.1)
カポジ水痘様発疹	1 (7.1)	0	1 (3.6)
伝染性軟属腫	0	1 (7.1)	1 (3.6)
上咽頭炎	2 (14.3)	5 (35.7)	7 (25.0)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=14) n (%)	Active UPA 30 mg QD (N=14) n (%)	Active UPA Total (N=28) n (%)
中耳炎	0	1 (7.1)	1 (3.6)
咽頭炎	0	1 (7.1)	1 (3.6)
副鼻腔炎	0	1 (7.1)	1 (3.6)
上気道感染	3 (21.4)	1 (7.1)	4 (14.3)
ウイルス性上気道感染	0	1 (7.1)	1 (3.6)
傷害、中毒および処置合併症	1 (7.1)	2 (14.3)	3 (10.7)
節足動物咬傷	0	1 (7.1)	1 (3.6)
剥離骨折	1 (7.1)	0	1 (3.6)
靭帯捻挫	0	1 (7.1)	1 (3.6)
臨床検査	2 (14.3)	1 (7.1)	3 (10.7)
血中クレアチンホスホキナーゼ増加	1 (7.1)	0	1 (3.6)
リンパ球形態異常	0	1 (7.1)	1 (3.6)
骨髄球存在	0	1 (7.1)	1 (3.6)
尿中蛋白陽性	1 (7.1)	0	1 (3.6)
神経系障害	0	1 (7.1)	1 (3.6)
頭痛	0	1 (7.1)	1 (3.6)
呼吸器、胸郭および縦隔障害	3 (21.4)	2 (14.3)	5 (17.9)
喘息	1 (7.1)	1 (7.1)	2 (7.1)
咳嗽	1 (7.1)	0	1 (3.6)
口腔咽頭痛	1 (7.1)	1 (7.1)	2 (7.1)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=14) n (%)	Active UPA 30 mg QD (N=14) n (%)	Active UPA Total (N=28) n (%)
皮膚および皮下組織障害	6 (42.9)	5 (35.7)	11 (39.3)
ざ瘡	4 (28.6)	5 (35.7)	9 (32.1)
アトピー性皮膚炎	1 (7.1)	0	1 (3.6)
接触皮膚炎	1 (7.1)	0	1 (3.6)
紅斑	1 (7.1)	0	1 (3.6)
小水疱性皮疹	0	1 (7.1)	1 (3.6)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W24 Table 14.3__1.5.2.2

表 6. ウパダシチニブ投与期間中に有害事象を発現した被験者数及び発現割合：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団，成人）

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) n (%)	Active UPA 30 mg QD (N=122) n (%)	Active UPA Total (N=241) n (%)
Any adverse event	71 (59.7)	84 (68.9)	155 (64.3)
血液およびリンパ系障害	1 (0.8)	7 (5.7)	8 (3.3)
貧血	0	3 (2.5)	3 (1.2)
リンパ節症	1 (0.8)	0	1 (0.4)
好中球減少症	0	4 (3.3)	4 (1.7)
心臓障害	1 (0.8)	0	1 (0.4)
動悸	1 (0.8)	0	1 (0.4)
耳および迷路障害	1 (0.8)	1 (0.8)	2 (0.8)
耳鳴	1 (0.8)	0	1 (0.4)
頭位性回転性めまい	0	1 (0.8)	1 (0.4)
眼障害	3 (2.5)	3 (2.5)	6 (2.5)
アトピー性白内障	1 (0.8)	0	1 (0.4)
結膜充血	1 (0.8)	0	1 (0.4)
アレルギー性結膜炎	1 (0.8)	1 (0.8)	2 (0.8)
ドライアイ	0	1 (0.8)	1 (0.4)
夜盲	0	1 (0.8)	1 (0.4)
胃腸障害	6 (5.0)	10 (8.2)	16 (6.6)
腹部不快感	0	2 (1.6)	2 (0.8)
腹部膨満	0	1 (0.8)	1 (0.4)
上腹部痛	2 (1.7)	0	2 (0.8)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) n (%)	Active UPA 30 mg QD (N=122) n (%)	Active UPA Total (N=241) n (%)
慢性胃炎	0	1 (0.8)	1 (0.4)
便秘	0	1 (0.8)	1 (0.4)
齲歯	1 (0.8)	0	1 (0.4)
下痢	1 (0.8)	4 (3.3)	5 (2.1)
食中毒	1 (0.8)	0	1 (0.4)
血便排泄	1 (0.8)	0	1 (0.4)
胃酸過多	0	1 (0.8)	1 (0.4)
粘液便	1 (0.8)	0	1 (0.4)
口内炎	0	2 (1.6)	2 (0.8)
一般・全身障害および投与部位の状態	7 (5.9)	9 (7.4)	16 (6.6)
胸痛	0	1 (0.8)	1 (0.4)
疲労	1 (0.8)	0	1 (0.4)
倦怠感	0	2 (1.6)	2 (0.8)
末梢性浮腫	1 (0.8)	1 (0.8)	2 (0.8)
発熱	5 (4.2)	5 (4.1)	10 (4.1)
感染症および寄生虫症	47 (39.5)	51 (41.8)	98 (40.7)
気管支炎	0	2 (1.6)	2 (0.8)
よう	0	1 (0.8)	1 (0.4)
蜂巣炎	2 (1.7)	0	2 (0.8)
結膜炎	2 (1.7)	2 (1.6)	4 (1.7)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) n (%)	Active UPA 30 mg QD (N=122) n (%)	Active UPA Total (N=241) n (%)
膀胱炎	0	1 (0.8)	1 (0.4)
爪の皮膚糸状菌症	0	1 (0.8)	1 (0.4)
丹毒	1 (0.8)	0	1 (0.4)
毛包炎	5 (4.2)	3 (2.5)	8 (3.3)
せつ	5 (4.2)	2 (1.6)	7 (2.9)
胃腸炎	0	1 (0.8)	1 (0.4)
ウイルス性胃腸炎	0	1 (0.8)	1 (0.4)
陰部ヘルペス	1 (0.8)	0	1 (0.4)
歯肉炎	1 (0.8)	1 (0.8)	2 (0.8)
単純ヘルペス	6 (5.0)	3 (2.5)	9 (3.7)
ヘルペスウイルス感染	1 (0.8)	0	1 (0.4)
帯状疱疹	5 (4.2)	11 (9.0)	16 (6.6)
播種性帯状疱疹	1 (0.8)	0	1 (0.4)
麦粒腫	1 (0.8)	2 (1.6)	3 (1.2)
感染	1 (0.8)	1 (0.8)	2 (0.8)
インフルエンザ	0	2 (1.6)	2 (0.8)
カポジ水痘様発疹	3 (2.5)	2 (1.6)	5 (2.1)
上咽頭炎	22 (18.5)	23 (18.9)	45 (18.7)
口腔ヘルペス	2 (1.7)	4 (3.3)	6 (2.5)
外耳炎	0	2 (1.6)	2 (0.8)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) n (%)	Active UPA 30 mg QD (N=122) n (%)	Active UPA Total (N=241) n (%)
爪囲炎	0	1 (0.8)	1 (0.4)
咽頭炎	1 (0.8)	0	1 (0.4)
細菌性咽頭炎	0	1 (0.8)	1 (0.4)
ニューモシスチス・イロベチイ肺炎	1 (0.8)	0	1 (0.4)
皮膚感染	1 (0.8)	0	1 (0.4)
皮下組織膿瘍	1 (0.8)	0	1 (0.4)
股部白癬	0	1 (0.8)	1 (0.4)
足部白癬	0	3 (2.5)	3 (1.2)
癜風	1 (0.8)	0	1 (0.4)
扁桃炎	3 (2.5)	2 (1.6)	5 (2.1)
尿路感染	1 (0.8)	0	1 (0.4)
傷害、中毒および処置合併症	5 (4.2)	6 (4.9)	11 (4.6)
節足動物咬傷	0	2 (1.6)	2 (0.8)
節足動物刺傷	1 (0.8)	0	1 (0.4)
骨挫傷	0	1 (0.8)	1 (0.4)
大腿骨骨折	0	1 (0.8)	1 (0.4)
足骨折	1 (0.8)	0	1 (0.4)
手骨折	1 (0.8)	0	1 (0.4)
熱射病	0	1 (0.8)	1 (0.4)
四肢損傷	1 (0.8)	0	1 (0.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) n (%)	Active UPA 30 mg QD (N=122) n (%)	Active UPA Total (N=241) n (%)
皮膚擦過傷	0	1 (0.8)	1 (0.4)
皮膚創傷	1 (0.8)	0	1 (0.4)
臨床検査	12 (10.1)	9 (7.4)	21 (8.7)
アラニンアミノトランスフェラーゼ増加	3 (2.5)	3 (2.5)	6 (2.5)
アスパラギン酸アミノトランスフェラーゼ増加	2 (1.7)	2 (1.6)	4 (1.7)
血中クレアチンホスホキナーゼ増加	1 (0.8)	4 (3.3)	5 (2.1)
血中トリグリセリド増加	2 (1.7)	0	2 (0.8)
ヘモグロビン減少	1 (0.8)	1 (0.8)	2 (0.8)
肝酵素上昇	1 (0.8)	0	1 (0.4)
好中球数減少	1 (0.8)	2 (1.6)	3 (1.2)
赤血球数減少	1 (0.8)	0	1 (0.4)
尿中ウロビリノーゲン増加	1 (0.8)	0	1 (0.4)
体重減少	1 (0.8)	0	1 (0.4)
白血球数減少	0	2 (1.6)	2 (0.8)
筋骨格系および結合組織障害	5 (4.2)	8 (6.6)	13 (5.4)
関節痛	0	6 (4.9)	6 (2.5)
背部痛	1 (0.8)	1 (0.8)	2 (0.8)
椎間板突出	1 (0.8)	0	1 (0.4)
関節腫脹	0	1 (0.8)	1 (0.4)
筋肉痛	1 (0.8)	2 (1.6)	3 (1.2)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) n (%)	Active UPA 30 mg QD (N=122) n (%)	Active UPA Total (N=241) n (%)
四肢痛	1 (0.8)	0	1 (0.4)
滑液嚢腫	1 (0.8)	0	1 (0.4)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	6 (5.0)	1 (0.8)	7 (2.9)
平滑筋腫	1 (0.8)	0	1 (0.4)
皮膚乳頭腫	5 (4.2)	1 (0.8)	6 (2.5)
神経系障害	4 (3.4)	6 (4.9)	10 (4.1)
小脳出血	1 (0.8)	0	1 (0.4)
浮動性めまい	0	1 (0.8)	1 (0.4)
頭痛	2 (1.7)	2 (1.6)	4 (1.7)
感覚鈍麻	1 (0.8)	0	1 (0.4)
ヘルペス後神経痛	0	1 (0.8)	1 (0.4)
傾眠	0	3 (2.5)	3 (1.2)
精神障害	4 (3.4)	1 (0.8)	5 (2.1)
抑うつ気分	1 (0.8)	0	1 (0.4)
うつ病	1 (0.8)	0	1 (0.4)
不眠症	1 (0.8)	0	1 (0.4)
落ち着きのなさ	0	1 (0.8)	1 (0.4)
身体症状症	1 (0.8)	0	1 (0.4)
呼吸器、胸郭および縦隔障害	5 (4.2)	6 (4.9)	11 (4.6)
喘息	1 (0.8)	2 (1.6)	3 (1.2)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) n (%)	Active UPA 30 mg QD (N=122) n (%)	Active UPA Total (N=241) n (%)
慢性気管支炎	0	1 (0.8)	1 (0.4)
咳嗽	0	1 (0.8)	1 (0.4)
鼻出血	0	1 (0.8)	1 (0.4)
口腔咽頭痛	3 (2.5)	2 (1.6)	5 (2.1)
上気道の炎症	1 (0.8)	0	1 (0.4)
皮膚および皮下組織障害	23 (19.3)	40 (32.8)	63 (26.1)
ざ瘡	16 (13.4)	33 (27.0)	49 (20.3)
脱毛症	1 (0.8)	0	1 (0.4)
水疱	1 (0.8)	1 (0.8)	2 (0.8)
アトピー性皮膚炎	4 (3.4)	1 (0.8)	5 (2.1)
接触皮膚炎	0	1 (0.8)	1 (0.4)
過角化	1 (0.8)	0	1 (0.4)
汗疹	1 (0.8)	2 (1.6)	3 (1.2)
口囲皮膚炎	1 (0.8)	0	1 (0.4)
脂漏性皮膚炎	1 (0.8)	0	1 (0.4)
皮膚亀裂	0	1 (0.8)	1 (0.4)
日光皮膚炎	2 (1.7)	0	2 (0.8)
蕁麻疹	1 (0.8)	2 (1.6)	3 (1.2)
接触蕁麻疹	0	1 (0.8)	1 (0.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W24 Table 14.3__1.5.2.3

表 7. ウパダシチニブ投与期間中の有害事象の 100 人年あたりの発現率：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団）

	Active		
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=133) (PYS=82.8) Events (E/100PY)	UPA 30 mg QD (N=136) (PYS=81.5) Events (E/100PY)	UPA Total (N=269) (PYS=164.2) Events (E/100PY)
Any adverse event	208 (251.3)	245 (300.7)	453 (275.8)
血液およびリンパ系障害	1 (1.2)	8 (9.8)	9 (5.5)
貧血	0	4 (4.9)	4 (2.4)
リンパ節症	1 (1.2)	0	1 (0.6)
好中球減少症	0	4 (4.9)	4 (2.4)
心臓障害	1 (1.2)	0	1 (0.6)
動悸	1 (1.2)	0	1 (0.6)
耳および迷路障害	1 (1.2)	1 (1.2)	2 (1.2)
耳鳴	1 (1.2)	0	1 (0.6)
頭位性回転性めまい	0	1 (1.2)	1 (0.6)
眼障害	5 (6.0)	3 (3.7)	8 (4.9)
アトピー性白内障	1 (1.2)	0	1 (0.6)
結膜充血	1 (1.2)	0	1 (0.6)
アレルギー性結膜炎	3 (3.6)	1 (1.2)	4 (2.4)
ドライアイ	0	1 (1.2)	1 (0.6)
夜盲	0	1 (1.2)	1 (0.6)
胃腸障害	7 (8.5)	14 (17.2)	21 (12.8)
腹部不快感	0	3 (3.7)	3 (1.8)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=82.8) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=81.5) Events (E/100PY)	Active UPA Total (N=269) (PYS=164.2) Events (E/100PY)
腹部膨満	0	1 (1.2)	1 (0.6)
上腹部痛	2 (2.4)	0	2 (1.2)
慢性胃炎	0	1 (1.2)	1 (0.6)
便秘	0	1 (1.2)	1 (0.6)
齲歯	1 (1.2)	0	1 (0.6)
下痢	1 (1.2)	4 (4.9)	5 (3.0)
食中毒	1 (1.2)	0	1 (0.6)
血便排泄	1 (1.2)	0	1 (0.6)
胃酸過多	0	1 (1.2)	1 (0.6)
粘液便	1 (1.2)	0	1 (0.6)
口内炎	0	3 (3.7)	3 (1.8)
一般・全身障害および投与部位の状態	10 (12.1)	10 (12.3)	20 (12.2)
胸痛	0	1 (1.2)	1 (0.6)
疲労	1 (1.2)	0	1 (0.6)
倦怠感	1 (1.2)	2 (2.5)	3 (1.8)
末梢性浮腫	1 (1.2)	1 (1.2)	2 (1.2)
発熱	7 (8.5)	6 (7.4)	13 (7.9)
感染症および寄生虫症	89 (107.5)	104 (127.7)	193 (117.5)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=82.8) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=81.5) Events (E/100PY)	Active UPA Total (N=269) (PYS=164.2) Events (E/100PY)
気管支炎	0	3 (3.7)	3 (1.8)
よう	0	1 (1.2)	1 (0.6)
蜂巣炎	2 (2.4)	0	2 (1.2)
結膜炎	2 (2.4)	3 (3.7)	5 (3.0)
膀胱炎	1 (1.2)	1 (1.2)	2 (1.2)
爪の皮膚糸状菌症	0	1 (1.2)	1 (0.6)
感染性腸炎	0	1 (1.2)	1 (0.6)
丹毒	1 (1.2)	0	1 (0.6)
毛包炎	6 (7.2)	4 (4.9)	10 (6.1)
せつ	5 (6.0)	2 (2.5)	7 (4.3)
胃腸炎	0	1 (1.2)	1 (0.6)
ウイルス性胃腸炎	0	1 (1.2)	1 (0.6)
陰部ヘルペス	1 (1.2)	0	1 (0.6)
歯肉炎	1 (1.2)	1 (1.2)	2 (1.2)
手足口病	0	1 (1.2)	1 (0.6)
単純ヘルペス	7 (8.5)	5 (6.1)	12 (7.3)
ヘルペスウイルス感染	1 (1.2)	0	1 (0.6)
帯状疱疹	5 (6.0)	11 (13.5)	16 (9.7)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=82.8) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=81.5) Events (E/100PY)	Active UPA Total (N=269) (PYS=164.2) Events (E/100PY)
播種性帯状疱疹	1 (1.2)	0	1 (0.6)
麦粒腫	1 (1.2)	2 (2.5)	3 (1.8)
膿痂疹	1 (1.2)	0	1 (0.6)
感染	1 (1.2)	1 (1.2)	2 (1.2)
インフルエンザ	1 (1.2)	3 (3.7)	4 (2.4)
カポジ水痘様発疹	4 (4.8)	2 (2.5)	6 (3.7)
伝染性軟属腫	0	1 (1.2)	1 (0.6)
上咽頭炎	30 (36.2)	38 (46.6)	68 (41.4)
口腔ヘルペス	3 (3.6)	6 (7.4)	9 (5.5)
外耳炎	0	2 (2.5)	2 (1.2)
中耳炎	0	1 (1.2)	1 (0.6)
爪囲炎	0	1 (1.2)	1 (0.6)
咽頭炎	1 (1.2)	1 (1.2)	2 (1.2)
細菌性咽頭炎	0	1 (1.2)	1 (0.6)
ニューモシスチス・イロベチイ肺炎	1 (1.2)	0	1 (0.6)
副鼻腔炎	0	1 (1.2)	1 (0.6)
皮膚感染	1 (1.2)	0	1 (0.6)
皮下組織膿瘍	1 (1.2)	0	1 (0.6)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=82.8) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=81.5) Events (E/100PY)	Active UPA Total (N=269) (PYS=164.2) Events (E/100PY)
股部白癬	0	1 (1.2)	1 (0.6)
足部白癬	0	3 (3.7)	3 (1.8)
癜風	1 (1.2)	0	1 (0.6)
扁桃炎	6 (7.2)	2 (2.5)	8 (4.9)
上気道感染	3 (3.6)	1 (1.2)	4 (2.4)
尿路感染	1 (1.2)	0	1 (0.6)
ウイルス性上気道感染	0	1 (1.2)	1 (0.6)
傷害、中毒および処置合併症	6 (7.2)	8 (9.8)	14 (8.5)
節足動物咬傷	0	3 (3.7)	3 (1.8)
節足動物刺傷	1 (1.2)	0	1 (0.6)
剥離骨折	1 (1.2)	0	1 (0.6)
骨挫傷	0	1 (1.2)	1 (0.6)
大腿骨骨折	0	1 (1.2)	1 (0.6)
足骨折	1 (1.2)	0	1 (0.6)
手骨折	1 (1.2)	0	1 (0.6)
熱射病	0	1 (1.2)	1 (0.6)
靭帯捻挫	0	1 (1.2)	1 (0.6)
四肢損傷	1 (1.2)	0	1 (0.6)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=82.8) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=81.5) Events (E/100PY)	Active UPA Total (N=269) (PYS=164.2) Events (E/100PY)
皮膚擦過傷	0	1 (1.2)	1 (0.6)
皮膚創傷	1 (1.2)	0	1 (0.6)
臨床検査	18 (21.7)	17 (20.9)	35 (21.3)
アラニンアミノトランスフェラーゼ増加	4 (4.8)	4 (4.9)	8 (4.9)
アスパラギン酸アミノトランスフェラーゼ増加	2 (2.4)	2 (2.5)	4 (2.4)
血中クレアチンホスホキナーゼ増加	2 (2.4)	4 (4.9)	6 (3.7)
血中トリグリセリド増加	2 (2.4)	0	2 (1.2)
ヘモグロビン減少	2 (2.4)	1 (1.2)	3 (1.8)
肝酵素上昇	1 (1.2)	0	1 (0.6)
リンパ球形態異常	0	1 (1.2)	1 (0.6)
骨髄球存在	0	1 (1.2)	1 (0.6)
好中球数減少	1 (1.2)	2 (2.5)	3 (1.8)
尿中蛋白陽性	1 (1.2)	0	1 (0.6)
赤血球数減少	1 (1.2)	0	1 (0.6)
尿中ウロビリノーゲン増加	1 (1.2)	0	1 (0.6)
体重減少	1 (1.2)	0	1 (0.6)
白血球数減少	0	2 (2.5)	2 (1.2)
筋骨格系および結合組織障害	5 (6.0)	12 (14.7)	17 (10.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=82.8) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=81.5) Events (E/100PY)	Active UPA Total (N=269) (PYS=164.2) Events (E/100PY)
関節痛	0	8 (9.8)	8 (4.9)
背部痛	1 (1.2)	1 (1.2)	2 (1.2)
椎間板突出	1 (1.2)	0	1 (0.6)
関節腫脹	0	1 (1.2)	1 (0.6)
筋肉痛	1 (1.2)	2 (2.5)	3 (1.8)
四肢痛	1 (1.2)	0	1 (0.6)
滑液嚢腫	1 (1.2)	0	1 (0.6)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	6 (7.2)	1 (1.2)	7 (4.3)
平滑筋腫	1 (1.2)	0	1 (0.6)
皮膚乳頭腫	5 (6.0)	1 (1.2)	6 (3.7)
神経系障害	6 (7.2)	8 (9.8)	14 (8.5)
小脳出血	1 (1.2)	0	1 (0.6)
浮動性めまい	0	1 (1.2)	1 (0.6)
頭痛	4 (4.8)	3 (3.7)	7 (4.3)
感覚鈍麻	1 (1.2)	0	1 (0.6)
ヘルペス後神経痛	0	1 (1.2)	1 (0.6)
傾眠	0	3 (3.7)	3 (1.8)
精神障害	4 (4.8)	1 (1.2)	5 (3.0)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=82.8) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=81.5) Events (E/100PY)	Active UPA Total (N=269) (PYS=164.2) Events (E/100PY)
抑うつ気分	1 (1.2)	0	1 (0.6)
うつ病	1 (1.2)	0	1 (0.6)
不眠症	1 (1.2)	0	1 (0.6)
落ち着きのなさ	0	1 (1.2)	1 (0.6)
身体症状症	1 (1.2)	0	1 (0.6)
呼吸器、胸郭および縦隔障害	8 (9.7)	9 (11.0)	17 (10.4)
喘息	2 (2.4)	3 (3.7)	5 (3.0)
慢性気管支炎	0	1 (1.2)	1 (0.6)
咳嗽	1 (1.2)	1 (1.2)	2 (1.2)
鼻出血	0	1 (1.2)	1 (0.6)
口腔咽頭痛	4 (4.8)	3 (3.7)	7 (4.3)
上気道の炎症	1 (1.2)	0	1 (0.6)
皮膚および皮下組織障害	41 (49.5)	49 (60.1)	90 (54.8)
ざ瘡	24 (29.0)	39 (47.9)	63 (38.4)
脱毛症	1 (1.2)	0	1 (0.6)
水疱	1 (1.2)	1 (1.2)	2 (1.2)
アトピー性皮膚炎	5 (6.0)	1 (1.2)	6 (3.7)
接触皮膚炎	1 (1.2)	1 (1.2)	2 (1.2)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=82.8) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=81.5) Events (E/100PY)	Active UPA Total (N=269) (PYS=164.2) Events (E/100PY)
紅斑	1 (1.2)	0	1 (0.6)
過角化	1 (1.2)	0	1 (0.6)
汗疹	1 (1.2)	2 (2.5)	3 (1.8)
口囲皮膚炎	1 (1.2)	0	1 (0.6)
小水疱性皮疹	0	1 (1.2)	1 (0.6)
脂漏性皮膚炎	1 (1.2)	0	1 (0.6)
皮膚亀裂	0	1 (1.2)	1 (0.6)
日光皮膚炎	2 (2.4)	0	2 (1.2)
蕁麻疹	2 (2.4)	2 (2.5)	4 (2.4)
接触蕁麻疹	0	1 (1.2)	1 (0.6)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W24 Table 14.3__1.6.2.1

表 8. ウパダシチニブ投与期間中の有害事象の 100 人年あたりの発現率：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団，青少年）

	Active		
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=14) (PYS=10.0) Events (E/100PY)	UPA 30 mg QD (N=14) (PYS=8.6) Events (E/100PY)	UPA Total (N=28) (PYS=18.6) Events (E/100PY)
Any adverse event	27 (271.2)	33 (382.2)	60 (322.7)
眼障害	2 (20.1)	0	2 (10.8)
アレルギー性結膜炎	2 (20.1)	0	2 (10.8)
胃腸障害	0	1 (11.6)	1 (5.4)
腹部不快感	0	1 (11.6)	1 (5.4)
一般・全身障害および投与部位の状態	2 (20.1)	1 (11.6)	3 (16.1)
倦怠感	1 (10.0)	0	1 (5.4)
発熱	1 (10.0)	1 (11.6)	2 (10.8)
感染症および寄生虫症	10 (100.4)	18 (208.4)	28 (150.6)
気管支炎	0	1 (11.6)	1 (5.4)
結膜炎	0	1 (11.6)	1 (5.4)
膀胱炎	1 (10.0)	0	1 (5.4)
感染性腸炎	0	1 (11.6)	1 (5.4)
毛包炎	0	1 (11.6)	1 (5.4)
手足口病	0	1 (11.6)	1 (5.4)
膿痂疹	1 (10.0)	0	1 (5.4)
インフルエンザ	1 (10.0)	1 (11.6)	2 (10.8)
カポジ水痘様発疹	1 (10.0)	0	1 (5.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=14) (PYS=10.0) Events (E/100PY)	Active UPA 30 mg QD (N=14) (PYS=8.6) Events (E/100PY)	Active UPA Total (N=28) (PYS=18.6) Events (E/100PY)
伝染性軟属腫	0	1 (11.6)	1 (5.4)
上咽頭炎	3 (30.1)	6 (69.5)	9 (48.4)
中耳炎	0	1 (11.6)	1 (5.4)
咽頭炎	0	1 (11.6)	1 (5.4)
副鼻腔炎	0	1 (11.6)	1 (5.4)
上気道感染	3 (30.1)	1 (11.6)	4 (21.5)
ウイルス性上気道感染	0	1 (11.6)	1 (5.4)
傷害、中毒および処置合併症	1 (10.0)	2 (23.2)	3 (16.1)
節足動物咬傷	0	1 (11.6)	1 (5.4)
剥離骨折	1 (10.0)	0	1 (5.4)
靭帯捻挫	0	1 (11.6)	1 (5.4)
臨床検査	2 (20.1)	2 (23.2)	4 (21.5)
血中クレアチンホスホキナーゼ増加	1 (10.0)	0	1 (5.4)
リンパ球形態異常	0	1 (11.6)	1 (5.4)
骨髄球存在	0	1 (11.6)	1 (5.4)
尿中蛋白陽性	1 (10.0)	0	1 (5.4)
神経系障害	0	1 (11.6)	1 (5.4)
頭痛	0	1 (11.6)	1 (5.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=14) (PYS=10.0) Events (E/100PY)	Active UPA 30 mg QD (N=14) (PYS=8.6) Events (E/100PY)	Active UPA Total (N=28) (PYS=18.6) Events (E/100PY)
呼吸器、胸郭および縦隔障害	3 (30.1)	2 (23.2)	5 (26.9)
喘息	1 (10.0)	1 (11.6)	2 (10.8)
咳嗽	1 (10.0)	0	1 (5.4)
口腔咽頭痛	1 (10.0)	1 (11.6)	2 (10.8)
皮膚および皮下組織障害	7 (70.3)	6 (69.5)	13 (69.9)
ざ瘡	4 (40.2)	5 (57.9)	9 (48.4)
アトピー性皮膚炎	1 (10.0)	0	1 (5.4)
接触皮膚炎	1 (10.0)	0	1 (5.4)
紅斑	1 (10.0)	0	1 (5.4)
小水疱性皮疹	0	1 (11.6)	1 (5.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W24 Table 14.3__1.6.2.2

表 9. ウパダシチニブ投与期間中の有害事象の 100 人年あたりの発現率：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団, 成人）

	Active		
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=119) (PYS=72.8) Events (E/100PY)	UPA 30 mg QD (N=122) (PYS=72.8) Events (E/100PY)	UPA Total (N=241) (PYS=145.6) Events (E/100PY)
Any adverse event	181 (248.6)	212 (291.1)	393 (269.8)
血液およびリンパ系障害	1 (1.4)	8 (11.0)	9 (6.2)
貧血	0	4 (5.5)	4 (2.7)
リンパ節症	1 (1.4)	0	1 (0.7)
好中球減少症	0	4 (5.5)	4 (2.7)
心臓障害	1 (1.4)	0	1 (0.7)
動悸	1 (1.4)	0	1 (0.7)
耳および迷路障害	1 (1.4)	1 (1.4)	2 (1.4)
耳鳴	1 (1.4)	0	1 (0.7)
頭位性回転性めまい	0	1 (1.4)	1 (0.7)
眼障害	3 (4.1)	3 (4.1)	6 (4.1)
アトピー性白内障	1 (1.4)	0	1 (0.7)
結膜充血	1 (1.4)	0	1 (0.7)
アレルギー性結膜炎	1 (1.4)	1 (1.4)	2 (1.4)
ドライアイ	0	1 (1.4)	1 (0.7)
夜盲	0	1 (1.4)	1 (0.7)
胃腸障害	7 (9.6)	13 (17.8)	20 (13.7)
腹部不快感	0	2 (2.7)	2 (1.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) (PYS=72.8) Events (E/100PY)	Active UPA 30 mg QD (N=122) (PYS=72.8) Events (E/100PY)	Active UPA Total (N=241) (PYS=145.6) Events (E/100PY)
腹部膨満	0	1 (1.4)	1 (0.7)
上腹部痛	2 (2.7)	0	2 (1.4)
慢性胃炎	0	1 (1.4)	1 (0.7)
便秘	0	1 (1.4)	1 (0.7)
齲歯	1 (1.4)	0	1 (0.7)
下痢	1 (1.4)	4 (5.5)	5 (3.4)
食中毒	1 (1.4)	0	1 (0.7)
血便排泄	1 (1.4)	0	1 (0.7)
胃酸過多	0	1 (1.4)	1 (0.7)
粘液便	1 (1.4)	0	1 (0.7)
口内炎	0	3 (4.1)	3 (2.1)
一般・全身障害および投与部位の状態	8 (11.0)	9 (12.4)	17 (11.7)
胸痛	0	1 (1.4)	1 (0.7)
疲労	1 (1.4)	0	1 (0.7)
倦怠感	0	2 (2.7)	2 (1.4)
末梢性浮腫	1 (1.4)	1 (1.4)	2 (1.4)
発熱	6 (8.2)	5 (6.9)	11 (7.6)
感染症および寄生虫症	79 (108.5)	86 (118.1)	165 (113.3)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) (PYS=72.8) Events (E/100PY)	Active UPA 30 mg QD (N=122) (PYS=72.8) Events (E/100PY)	Active UPA Total (N=241) (PYS=145.6) Events (E/100PY)
気管支炎	0	2 (2.7)	2 (1.4)
よう	0	1 (1.4)	1 (0.7)
蜂巣炎	2 (2.7)	0	2 (1.4)
結膜炎	2 (2.7)	2 (2.7)	4 (2.7)
膀胱炎	0	1 (1.4)	1 (0.7)
爪の皮膚糸状菌症	0	1 (1.4)	1 (0.7)
丹毒	1 (1.4)	0	1 (0.7)
毛包炎	6 (8.2)	3 (4.1)	9 (6.2)
せつ	5 (6.9)	2 (2.7)	7 (4.8)
胃腸炎	0	1 (1.4)	1 (0.7)
ウイルス性胃腸炎	0	1 (1.4)	1 (0.7)
陰部ヘルペス	1 (1.4)	0	1 (0.7)
歯肉炎	1 (1.4)	1 (1.4)	2 (1.4)
単純ヘルペス	7 (9.6)	5 (6.9)	12 (8.2)
ヘルペスウイルス感染	1 (1.4)	0	1 (0.7)
帯状疱疹	5 (6.9)	11 (15.1)	16 (11.0)
播種性帯状疱疹	1 (1.4)	0	1 (0.7)
麦粒腫	1 (1.4)	2 (2.7)	3 (2.1)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) (PYS=72.8) Events (E/100PY)	Active UPA 30 mg QD (N=122) (PYS=72.8) Events (E/100PY)	Active UPA Total (N=241) (PYS=145.6) Events (E/100PY)
感染	1 (1.4)	1 (1.4)	2 (1.4)
インフルエンザ	0	2 (2.7)	2 (1.4)
カポジ水痘様発疹	3 (4.1)	2 (2.7)	5 (3.4)
上咽頭炎	27 (37.1)	32 (43.9)	59 (40.5)
口腔ヘルペス	3 (4.1)	6 (8.2)	9 (6.2)
外耳炎	0	2 (2.7)	2 (1.4)
爪囲炎	0	1 (1.4)	1 (0.7)
咽頭炎	1 (1.4)	0	1 (0.7)
細菌性咽頭炎	0	1 (1.4)	1 (0.7)
ニューモシスチス・イロベチイ肺炎	1 (1.4)	0	1 (0.7)
皮膚感染	1 (1.4)	0	1 (0.7)
皮下組織膿瘍	1 (1.4)	0	1 (0.7)
股部白癬	0	1 (1.4)	1 (0.7)
足部白癬	0	3 (4.1)	3 (2.1)
癜風	1 (1.4)	0	1 (0.7)
扁桃炎	6 (8.2)	2 (2.7)	8 (5.5)
尿路感染	1 (1.4)	0	1 (0.7)
傷害、中毒および処置合併症	5 (6.9)	6 (8.2)	11 (7.6)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) (PYS=72.8) Events (E/100PY)	Active UPA 30 mg QD (N=122) (PYS=72.8) Events (E/100PY)	Active UPA Total (N=241) (PYS=145.6) Events (E/100PY)
節足動物咬傷	0	2 (2.7)	2 (1.4)
節足動物刺傷	1 (1.4)	0	1 (0.7)
骨挫傷	0	1 (1.4)	1 (0.7)
大腿骨骨折	0	1 (1.4)	1 (0.7)
足骨折	1 (1.4)	0	1 (0.7)
手骨折	1 (1.4)	0	1 (0.7)
熱射病	0	1 (1.4)	1 (0.7)
四肢損傷	1 (1.4)	0	1 (0.7)
皮膚擦過傷	0	1 (1.4)	1 (0.7)
皮膚創傷	1 (1.4)	0	1 (0.7)
臨床検査	16 (22.0)	15 (20.6)	31 (21.3)
アラニンアミノトランスフェラーゼ増加	4 (5.5)	4 (5.5)	8 (5.5)
アスパラギン酸アミノトランスフェラーゼ増加	2 (2.7)	2 (2.7)	4 (2.7)
血中クレアチンホスホキナーゼ増加	1 (1.4)	4 (5.5)	5 (3.4)
血中トリグリセリド増加	2 (2.7)	0	2 (1.4)
ヘモグロビン減少	2 (2.7)	1 (1.4)	3 (2.1)
肝酵素上昇	1 (1.4)	0	1 (0.7)
好中球数減少	1 (1.4)	2 (2.7)	3 (2.1)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) (PYS=72.8) Events (E/100PY)	Active UPA 30 mg QD (N=122) (PYS=72.8) Events (E/100PY)	Active UPA Total (N=241) (PYS=145.6) Events (E/100PY)
赤血球数減少	1 (1.4)	0	1 (0.7)
尿中ウロビリノーゲン増加	1 (1.4)	0	1 (0.7)
体重減少	1 (1.4)	0	1 (0.7)
白血球数減少	0	2 (2.7)	2 (1.4)
筋骨格系および結合組織障害	5 (6.9)	12 (16.5)	17 (11.7)
関節痛	0	8 (11.0)	8 (5.5)
背部痛	1 (1.4)	1 (1.4)	2 (1.4)
椎間板突出	1 (1.4)	0	1 (0.7)
関節腫脹	0	1 (1.4)	1 (0.7)
筋肉痛	1 (1.4)	2 (2.7)	3 (2.1)
四肢痛	1 (1.4)	0	1 (0.7)
滑液嚢腫	1 (1.4)	0	1 (0.7)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	6 (8.2)	1 (1.4)	7 (4.8)
平滑筋腫	1 (1.4)	0	1 (0.7)
皮膚乳頭腫	5 (6.9)	1 (1.4)	6 (4.1)
神経系障害	6 (8.2)	7 (9.6)	13 (8.9)
小脳出血	1 (1.4)	0	1 (0.7)
浮動性めまい	0	1 (1.4)	1 (0.7)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=119) (PYS=72.8) Events (E/100PY)	UPA 30 mg QD (N=122) (PYS=72.8) Events (E/100PY)	UPA Total (N=241) (PYS=145.6) Events (E/100PY)
	Active		
頭痛	4 (5.5)	2 (2.7)	6 (4.1)
感覚鈍麻	1 (1.4)	0	1 (0.7)
ヘルペス後神経痛	0	1 (1.4)	1 (0.7)
傾眠	0	3 (4.1)	3 (2.1)
精神障害	4 (5.5)	1 (1.4)	5 (3.4)
抑うつ気分	1 (1.4)	0	1 (0.7)
うつ病	1 (1.4)	0	1 (0.7)
不眠症	1 (1.4)	0	1 (0.7)
落ち着きのなさ	0	1 (1.4)	1 (0.7)
身体症状症	1 (1.4)	0	1 (0.7)
呼吸器、胸郭および縦隔障害	5 (6.9)	7 (9.6)	12 (8.2)
喘息	1 (1.4)	2 (2.7)	3 (2.1)
慢性気管支炎	0	1 (1.4)	1 (0.7)
咳嗽	0	1 (1.4)	1 (0.7)
鼻出血	0	1 (1.4)	1 (0.7)
口腔咽頭痛	3 (4.1)	2 (2.7)	5 (3.4)
上気道の炎症	1 (1.4)	0	1 (0.7)
皮膚および皮下組織障害	34 (46.7)	43 (59.0)	77 (52.9)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) (PYS=72.8) Events (E/100PY)	Active UPA 30 mg QD (N=122) (PYS=72.8) Events (E/100PY)	Active UPA Total (N=241) (PYS=145.6) Events (E/100PY)
ざ瘡	20 (27.5)	34 (46.7)	54 (37.1)
脱毛症	1 (1.4)	0	1 (0.7)
水疱	1 (1.4)	1 (1.4)	2 (1.4)
アトピー性皮膚炎	4 (5.5)	1 (1.4)	5 (3.4)
接触皮膚炎	0	1 (1.4)	1 (0.7)
過角化	1 (1.4)	0	1 (0.7)
汗疹	1 (1.4)	2 (2.7)	3 (2.1)
口囲皮膚炎	1 (1.4)	0	1 (0.7)
脂漏性皮膚炎	1 (1.4)	0	1 (0.7)
皮膚亀裂	0	1 (1.4)	1 (0.7)
日光皮膚炎	2 (2.7)	0	2 (1.4)
蕁麻疹	2 (2.7)	2 (2.7)	4 (2.7)
接触蕁麻疹	0	1 (1.4)	1 (0.7)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W24 Table 14.3__1.6.2.3

表 10. 二重盲検投与期で治験薬と関連ありの有害事象を発現した被験者数及び発現割合：MedDRA 器官別大分類及び基本語別（二重盲検投与期の安全性解析対象集団）

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=90) n (%)	Active UPA 15 mg QD (N=91) n (%)	Active UPA 30 mg QD (N=91) n (%)	Active UPA Total (N=182) n (%)
Any adverse event	11 (12.2)	12 (13.2)	24 (26.4)	36 (19.8)
血液およびリンパ系障害	0	1 (1.1)	4 (4.4)	5 (2.7)
貧血	0	0	1 (1.1)	1 (0.5)
リンパ節症	0	1 (1.1)	0	1 (0.5)
好中球減少症	0	0	3 (3.3)	3 (1.6)
眼障害	0	0	1 (1.1)	1 (0.5)
アレルギー性結膜炎	0	0	1 (1.1)	1 (0.5)
胃腸障害	2 (2.2)	2 (2.2)	3 (3.3)	5 (2.7)
腹部不快感	0	0	1 (1.1)	1 (0.5)
腹部膨満	0	0	1 (1.1)	1 (0.5)
便秘	1 (1.1)	0	0	0
下痢	1 (1.1)	1 (1.1)	1 (1.1)	2 (1.1)
粘液便	0	1 (1.1)	0	1 (0.5)
口内炎	0	0	1 (1.1)	1 (0.5)
一般・全身障害および投与部位の状態	0	2 (2.2)	3 (3.3)	5 (2.7)
倦怠感	0	1 (1.1)	2 (2.2)	3 (1.6)
末梢性浮腫	0	0	1 (1.1)	1 (0.5)
発熱	0	1 (1.1)	0	1 (0.5)
感染症および寄生虫症	3 (3.3)	6 (6.6)	11 (12.1)	17 (9.3)
よう	0	0	1 (1.1)	1 (0.5)

Note: For subjects who do not enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug and no more than 30 days after the last dose of study drug.
For subjects who enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug in DB Period and before the first dose of study drug in BE Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=90) n (%)	Active UPA 15 mg QD (N=91) n (%)	Active UPA 30 mg QD (N=91) n (%)	Active UPA Total (N=182) n (%)
蜂巣炎	1 (1.1)	0	0	0
丹毒	0	1 (1.1)	0	1 (0.5)
毛包炎	1 (1.1)	1 (1.1)	0	1 (0.5)
せつ	0	2 (2.2)	0	2 (1.1)
ウイルス性胃腸炎	0	0	1 (1.1)	1 (0.5)
単純ヘルペス	1 (1.1)	0	1 (1.1)	1 (0.5)
ヘルペスウイルス感染	0	1 (1.1)	0	1 (0.5)
帯状疱疹	0	0	4 (4.4)	4 (2.2)
カポジ水痘様発疹	0	2 (2.2)	0	2 (1.1)
伝染性軟属腫	0	0	1 (1.1)	1 (0.5)
上咽頭炎	1 (1.1)	0	2 (2.2)	2 (1.1)
口腔ヘルペス	0	0	1 (1.1)	1 (0.5)
中耳炎	0	0	1 (1.1)	1 (0.5)
扁桃炎	0	1 (1.1)	0	1 (0.5)
臨床検査	2 (2.2)	2 (2.2)	1 (1.1)	3 (1.6)
尿中血陽性	1 (1.1)	0	0	0
好中球数減少	0	1 (1.1)	0	1 (0.5)
尿中蛋白陽性	1 (1.1)	0	0	0
尿中ウロビリノーゲン増加	2 (2.2)	1 (1.1)	0	1 (0.5)
白血球数減少	0	0	1 (1.1)	1 (0.5)

Note: For subjects who do not enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug and no more than 30 days after the last dose of study drug.
For subjects who enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug in DB Period and before the first dose of study drug in BE Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=90) n (%)	Active UPA 15 mg QD (N=91) n (%)	Active UPA 30 mg QD (N=91) n (%)	Active UPA Total (N=182) n (%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	1 (1.1)	0	1 (0.5)
皮膚乳頭腫	0	1 (1.1)	0	1 (0.5)
神経系障害	2 (2.2)	1 (1.1)	1 (1.1)	2 (1.1)
小脳出血	0	1 (1.1)	0	1 (0.5)
ジスキネジア	1 (1.1)	0	0	0
頭痛	1 (1.1)	0	0	0
傾眠	0	0	1 (1.1)	1 (0.5)
皮膚および皮下組織障害	4 (4.4)	4 (4.4)	7 (7.7)	11 (6.0)
ざ瘡	3 (3.3)	2 (2.2)	7 (7.7)	9 (4.9)
脱毛症	0	1 (1.1)	0	1 (0.5)
アトピー性皮膚炎	1 (1.1)	1 (1.1)	0	1 (0.5)
血管障害	1 (1.1)	0	0	0
低血圧	1 (1.1)	0	0	0

Note: For subjects who do not enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug and no more than 30 days after the last dose of study drug.
For subjects who enter BE Period, TEAEs are defined as any event with an onset or worsening date on or after the first dose of study drug in DB Period and before the first dose of study drug in BE Period.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W24 Table 14.3__1.9.1

表 11. ウパダシチニブ投与期間中に治験薬と関連ありの有害事象を発現した被験者数及び発現割合：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団）

	Active		
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=133) n (%)	UPA 30 mg QD (N=136) n (%)	UPA Total (N=269) n (%)
Any adverse event	29 (21.8)	43 (31.6)	72 (26.8)
血液およびリンパ系障害	1 (0.8)	6 (4.4)	7 (2.6)
貧血	0	2 (1.5)	2 (0.7)
リンパ節症	1 (0.8)	0	1 (0.4)
好中球減少症	0	4 (2.9)	4 (1.5)
眼障害	0	1 (0.7)	1 (0.4)
アレルギー性結膜炎	0	1 (0.7)	1 (0.4)
胃腸障害	2 (1.5)	5 (3.7)	7 (2.6)
腹部不快感	0	1 (0.7)	1 (0.4)
腹部膨満	0	1 (0.7)	1 (0.4)
便秘	0	1 (0.7)	1 (0.4)
下痢	1 (0.8)	2 (1.5)	3 (1.1)
粘液便	1 (0.8)	0	1 (0.4)
口内炎	0	1 (0.7)	1 (0.4)
一般・全身障害および投与部位の状態	2 (1.5)	3 (2.2)	5 (1.9)
倦怠感	1 (0.8)	2 (1.5)	3 (1.1)
末梢性浮腫	0	1 (0.7)	1 (0.4)
発熱	1 (0.8)	0	1 (0.4)
感染症および寄生虫症	19 (14.3)	22 (16.2)	41 (15.2)
よう	0	1 (0.7)	1 (0.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
結膜炎	0	2 (1.5)	2 (0.7)
膀胱炎	1 (0.8)	0	1 (0.4)
丹毒	1 (0.8)	0	1 (0.4)
毛包炎	3 (2.3)	0	3 (1.1)
せつ	3 (2.3)	2 (1.5)	5 (1.9)
ウイルス性胃腸炎	0	1 (0.7)	1 (0.4)
歯肉炎	1 (0.8)	0	1 (0.4)
単純ヘルペス	2 (1.5)	2 (1.5)	4 (1.5)
ヘルペスウイルス感染	1 (0.8)	0	1 (0.4)
帯状疱疹	4 (3.0)	10 (7.4)	14 (5.2)
播種性帯状疱疹	1 (0.8)	0	1 (0.4)
麦粒腫	1 (0.8)	1 (0.7)	2 (0.7)
膿痂疹	1 (0.8)	0	1 (0.4)
感染	0	1 (0.7)	1 (0.4)
カポジ水痘様発疹	3 (2.3)	1 (0.7)	4 (1.5)
伝染性軟属腫	0	1 (0.7)	1 (0.4)
上咽頭炎	1 (0.8)	2 (1.5)	3 (1.1)
口腔ヘルペス	1 (0.8)	2 (1.5)	3 (1.1)
中耳炎	0	1 (0.7)	1 (0.4)
ニューモシスチス・イロベチイ肺炎	1 (0.8)	0	1 (0.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
足部白癬	0	1 (0.7)	1 (0.4)
扁桃炎	2 (1.5)	0	2 (0.7)
尿路感染	1 (0.8)	0	1 (0.4)
傷害、中毒および処置合併症	0	1 (0.7)	1 (0.4)
熱射病	0	1 (0.7)	1 (0.4)
臨床検査	7 (5.3)	4 (2.9)	11 (4.1)
アラニンアミノトランスフェラーゼ増加	1 (0.8)	1 (0.7)	2 (0.7)
アスパラギン酸アミノトランスフェラーゼ増加	1 (0.8)	1 (0.7)	2 (0.7)
ヘモグロビン減少	1 (0.8)	1 (0.7)	2 (0.7)
肝酵素上昇	1 (0.8)	0	1 (0.4)
リンパ球形態異常	0	1 (0.7)	1 (0.4)
骨髄球存在	0	1 (0.7)	1 (0.4)
好中球数減少	1 (0.8)	1 (0.7)	2 (0.7)
尿中蛋白陽性	1 (0.8)	0	1 (0.4)
赤血球数減少	1 (0.8)	0	1 (0.4)
尿中ウロビリノーゲン増加	1 (0.8)	0	1 (0.4)
白血球数減少	0	1 (0.7)	1 (0.4)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1 (0.8)	0	1 (0.4)
皮膚乳頭腫	1 (0.8)	0	1 (0.4)
神経系障害	1 (0.8)	3 (2.2)	4 (1.5)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
小脳出血	1 (0.8)	0	1 (0.4)
ヘルペス後神経痛	0	1 (0.7)	1 (0.4)
傾眠	0	2 (1.5)	2 (0.7)
精神障害	0	1 (0.7)	1 (0.4)
落ち着きのなさ	0	1 (0.7)	1 (0.4)
呼吸器、胸郭および縦隔障害	1 (0.8)	1 (0.7)	2 (0.7)
喘息	1 (0.8)	1 (0.7)	2 (0.7)
皮膚および皮下組織障害	8 (6.0)	17 (12.5)	25 (9.3)
ざ瘡	5 (3.8)	17 (12.5)	22 (8.2)
脱毛症	1 (0.8)	0	1 (0.4)
アトピー性皮膚炎	2 (1.5)	0	2 (0.7)
蕁麻疹	1 (0.8)	0	1 (0.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W24 Table 14.3__1.9.2

表 12. ウパダシチニブ投与期間中の治験薬と関連ありの有害事象の 100 人年あたりの発現率：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団）

	Active		
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=133) (PYS=82.8) Events (E/100PY)	UPA 30 mg QD (N=136) (PYS=81.5) Events (E/100PY)	UPA Total (N=269) (PYS=164.2) Events (E/100PY)
Any adverse event	59 (71.3)	78 (95.7)	137 (83.4)
血液およびリンパ系障害	1 (1.2)	7 (8.6)	8 (4.9)
貧血	0	3 (3.7)	3 (1.8)
リンパ節症	1 (1.2)	0	1 (0.6)
好中球減少症	0	4 (4.9)	4 (2.4)
眼障害	0	1 (1.2)	1 (0.6)
アレルギー性結膜炎	0	1 (1.2)	1 (0.6)
胃腸障害	2 (2.4)	7 (8.6)	9 (5.5)
腹部不快感	0	1 (1.2)	1 (0.6)
腹部膨満	0	1 (1.2)	1 (0.6)
便秘	0	1 (1.2)	1 (0.6)
下痢	1 (1.2)	2 (2.5)	3 (1.8)
粘液便	1 (1.2)	0	1 (0.6)
口内炎	0	2 (2.5)	2 (1.2)
一般・全身障害および投与部位の状態	3 (3.6)	3 (3.7)	6 (3.7)
倦怠感	1 (1.2)	2 (2.5)	3 (1.8)
末梢性浮腫	0	1 (1.2)	1 (0.6)
発熱	2 (2.4)	0	2 (1.2)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=82.8) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=81.5) Events (E/100PY)	Active UPA Total (N=269) (PYS=164.2) Events (E/100PY)
感染症および寄生虫症	31 (37.5)	30 (36.8)	61 (37.1)
よう	0	1 (1.2)	1 (0.6)
結膜炎	0	2 (2.5)	2 (1.2)
膀胱炎	1 (1.2)	0	1 (0.6)
丹毒	1 (1.2)	0	1 (0.6)
毛包炎	3 (3.6)	0	3 (1.8)
せつ	3 (3.6)	2 (2.5)	5 (3.0)
ウイルス性胃腸炎	0	1 (1.2)	1 (0.6)
歯肉炎	1 (1.2)	0	1 (0.6)
単純ヘルペス	3 (3.6)	3 (3.7)	6 (3.7)
ヘルペスウイルス感染	1 (1.2)	0	1 (0.6)
帯状疱疹	4 (4.8)	10 (12.3)	14 (8.5)
播種性帯状疱疹	1 (1.2)	0	1 (0.6)
麦粒腫	1 (1.2)	1 (1.2)	2 (1.2)
膿痂疹	1 (1.2)	0	1 (0.6)
感染	0	1 (1.2)	1 (0.6)
カポジ水痘様発疹	3 (3.6)	1 (1.2)	4 (2.4)
伝染性軟属腫	0	1 (1.2)	1 (0.6)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=82.8) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=81.5) Events (E/100PY)	Active UPA Total (N=269) (PYS=164.2) Events (E/100PY)
上咽頭炎	1 (1.2)	2 (2.5)	3 (1.8)
口腔ヘルペス	1 (1.2)	3 (3.7)	4 (2.4)
中耳炎	0	1 (1.2)	1 (0.6)
ニューモシスチス・イロベチイ肺炎	1 (1.2)	0	1 (0.6)
足部白癬	0	1 (1.2)	1 (0.6)
扁桃炎	4 (4.8)	0	4 (2.4)
尿路感染	1 (1.2)	0	1 (0.6)
傷害、中毒および処置合併症	0	1 (1.2)	1 (0.6)
熱射病	0	1 (1.2)	1 (0.6)
臨床検査	9 (10.9)	7 (8.6)	16 (9.7)
アラニンアミノトランスフェラーゼ増加	1 (1.2)	1 (1.2)	2 (1.2)
アスパラギン酸アミノトランスフェラーゼ増加	1 (1.2)	1 (1.2)	2 (1.2)
ヘモグロビン減少	2 (2.4)	1 (1.2)	3 (1.8)
肝酵素上昇	1 (1.2)	0	1 (0.6)
リンパ球形態異常	0	1 (1.2)	1 (0.6)
骨髄球存在	0	1 (1.2)	1 (0.6)
好中球数減少	1 (1.2)	1 (1.2)	2 (1.2)
尿中蛋白陽性	1 (1.2)	0	1 (0.6)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=82.8) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=81.5) Events (E/100PY)	Active UPA Total (N=269) (PYS=164.2) Events (E/100PY)
赤血球数減少	1 (1.2)	0	1 (0.6)
尿中ウロビリノーゲン増加	1 (1.2)	0	1 (0.6)
白血球数減少	0	1 (1.2)	1 (0.6)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1 (1.2)	0	1 (0.6)
皮膚乳頭腫	1 (1.2)	0	1 (0.6)
神経系障害	1 (1.2)	3 (3.7)	4 (2.4)
小脳出血	1 (1.2)	0	1 (0.6)
ヘルペス後神経痛	0	1 (1.2)	1 (0.6)
傾眠	0	2 (2.5)	2 (1.2)
精神障害	0	1 (1.2)	1 (0.6)
落ち着きのなさ	0	1 (1.2)	1 (0.6)
呼吸器、胸郭および縦隔障害	1 (1.2)	1 (1.2)	2 (1.2)
喘息	1 (1.2)	1 (1.2)	2 (1.2)
皮膚および皮下組織障害	10 (12.1)	17 (20.9)	27 (16.4)
ざ瘡	6 (7.2)	17 (20.9)	23 (14.0)
脱毛症	1 (1.2)	0	1 (0.6)
アトピー性皮膚炎	2 (2.4)	0	2 (1.2)
蕁麻疹	1 (1.2)	0	1 (0.6)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W24 Table 14.3__1.9.3

重篤な有害事象の叙述

Subject [redacted] ([redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
ニューモシスチス・イロベチイ肺炎	X	X		X

Treatment Group	Age at Study Start	Sex	Race
P1:Placebo /P2:Upa 15 mg QD	5[redacted]	MALE	ASIAN

Medical History	Onset Year
ATOPIC DERMATITIS	19[redacted]
ASTHMA	19[redacted]
RHINITIS ALLERGIC	19[redacted]
DEPRESSION	20[redacted]
INSOMNIA	20[redacted]
PHLEGMONE	20[redacted]
POST INFLAMMATORY PIGMENTATION	20[redacted]
ALCOHOLIC HEPATITIS	20[redacted]
HYPOTHYROIDISM	20[redacted]
AST HIGH	20[redacted]
ESSENTIAL HYPERTENSION	20[redacted]
LONG QT SYNDROME	20[redacted]
ALLERGIC RHINITIS	NOT REPORTED
ASTHMA	NOT REPORTED
GALLSTONES	NOT REPORTED
SPLEOMEGALY	NOT REPORTED

Prior Procedures	Procedure Year
Not reported.	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	20 CIGARETTE	17	20[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose	Last Dose	Duration

				Date/Day	Date/Day	(Days)
P1:PLACEBO		ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 112	112
P2:ABT-494	15 MG	ORAL	QD	[redacted]20[redacted] / 113	[redacted]20[redacted] / 183	71

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BETAMETHASONE	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted]
EPINASTINE	20 mg	QD	Y-M: 20[redacted]
STELAMIN	1 OTHER: TABLETS	PRN	Y-M: 20[redacted]
TACROLIMUS	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted]
BETAMETHASONE	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted]
EPINASTINE	20 mg	QD	Y-M: 20[redacted]
HYDROXYZINE	25 mg	QD	Y-M: 20[redacted]
STELAMIN	1 OTHER: TABLETS	PRN	Y-M: 20[redacted]
TACROLIMUS	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted]
FEXOFENADINE	60 mg	BID	Y-M: 20[redacted]
VALISONE-G	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted]
CINAL	1 OTHER: TABLETS	TID	Y-M: 20[redacted]
TACROLIMUS	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted]
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted] / -342
LEVOTHYROXINE	12.5 ug	QD	Y-M: 20[redacted] / -342
VENLAFAXINE	150 mg	QD	Y-M: 20[redacted] / -342
SUVOREXANT	20 mg	QD	Y-M: 20[redacted] / -283
HYDROXYZINE	25 mg	QD	Y-M: 20[redacted] / -181
HEPARINOID	PROPER DOSE OTHER: APPLICATION	PRN	Y-M: 20[redacted] / -97
WHITE SOFT PARAFFIN	PROPER DOSE OTHER: APPLICATION	BID	Y-M: 20[redacted] / -63
AMLODIPINE	2.5 mg	QD	Y-M: 20[redacted] / -51
AMLODIPINE	5 mg	QD	Y-M: 20[redacted] / -36
TRAZODONE	25 mg	QD	Y-M: 20[redacted] / -20

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
EPINASTINE	20 mg	QD	Y-M: 20[redacted]	NOT REPORTED
FEXOFENADINE	60 mg	BID	Y-M: 20[redacted]	NOT REPORTED
CINAL	1 OTHER: TABLETS	TID	Y-M: 20[redacted]	Y-M: 20[redacted] /

LEVOTHYROXINE	12.5 ug	QD	Y-M: 20[redacted]-[redacted] / 188 -	NOT REPORTED
VENLAFAXINE	150 mg	QD	Y-M: 20[redacted]-[redacted] / 342 -	NOT REPORTED
SUVOREXANT	20 mg	QD	Y-M: 20[redacted]-[redacted] / 342 -	NOT REPORTED
HYDROXYZINE	25 mg	QD	Y-M: 20[redacted]-[redacted] / 283 -	NOT REPORTED
HEPARINOID	PROPER DOSE OTHER: APPLICATION	PRN	Y-M: 20[redacted]-[redacted] / 181 -	NOT REPORTED
TRAZODONE	25 mg	QD	Y-M: 20[redacted]-[redacted] / 97 -	NOT REPORTED
CANDESAR A	1 OTHER: TABLETS	QD	Y-M: 20[redacted]-[redacted] / 20 9	NOT REPORTED
ALPRAZOLAM	0.4 mg	PRN	Y-M: 20[redacted]-[redacted] / 15	NOT REPORTED
HERBAL PREPARATION	3 OTHER: TABLET	TID	Y-M: 20[redacted]-[redacted] / 183	Y-M: 20[redacted]-[redacted] / 183
AMBROXOL	15 mg	TID	Y-M: 20[redacted]-[redacted] / 184	Y-M: 20[redacted]-[redacted] / 187
CEFDITOREN	100 mg	TID	Y-M: 20[redacted]-[redacted] / 184	Y-M: 20[redacted]-[redacted] / 187
DIMEMORFAN	20 mg	TID	Y-M: 20[redacted]-[redacted] / 184	Y-M: 20[redacted]-[redacted] / 187
IBUPROFEN	200 mg	TID	Y-M: 20[redacted]-[redacted] / 184	Y-M: 20[redacted]-[redacted] / 187
CEFTRIAXONE	1 g	QD	Y-M: 20[redacted]-[redacted] / 188	Y-M: 20[redacted]-[redacted] / 188
ESZOPICLONE	1 mg	QD	Y-M: 20[redacted]-[redacted] / 188	Y-M: 20[redacted]-[redacted] / 188
MINOCYCLINE	100 mg	QD	Y-M: 20[redacted]-[redacted] / 188	Y-M: 20[redacted]-[redacted] / 188
LOXOPROFEN	60 mg	QD	Y-M: 20[redacted]-[redacted] / 188	Y-M: 20[redacted]-[redacted] / 189
ASCORBIC ACID	1 OTHER: PACKAGE	TID	Y-M: 20[redacted]-[redacted] / 189	Y-M: 20[redacted]-[redacted] / 189
METHYLPREDNISOLONE	500 mg	QD	Y-M: 20[redacted]-[redacted] / 189	Y-M: 20[redacted]-[redacted] / 191
CEFTRIAXONE	1 g	BID	Y-M: 20[redacted]-[redacted] / 189	Y-M: 20[redacted]-[redacted] / 192
MINOCYCLINE	100 mg	BID	Y-M: 20[redacted]-[redacted] / 189	Y-M: 20[redacted]-[redacted] / 192
BACTRIM	3 OTHER: TABLET	TID	Y-M: 20[redacted]-[redacted] / 189	Y-M: 20[redacted]-[redacted] / 197
REBAMIPIDE	100 mg	TID	Y-M: 20[redacted]-[redacted] / 189	Y-M: 20[redacted]-[redacted] / 201
FAMOTIDINE	10 mg	BID	Y-M: 20[redacted]-[redacted] / 189	Y-M: 20[redacted]-[redacted] / 204
ASCORBIC ACID	1 OTHER: PACKAGE	TID	Y-M: 20[redacted]-[redacted] / 190	Y-M: 20[redacted]-[redacted] / 218
PREDNISOLONE	30 mg	BID	Y-M: 20[redacted]-[redacted] / 192	Y-M: 20[redacted]-[redacted] / 194

PREDNISOLONE	15 mg	QD	Y-M: 20[redacted]-[redacted] / 195	Y-M: 20[redacted]-[redacted] / 197
LOXOPROFEN	60 mg	QD	Y-M: 20[redacted]-[redacted] / 197	Y-M: 20[redacted]-[redacted] / 199
BACTRIM	3 OTHER: TABLET	QD	Y-M: 20[redacted]-[redacted] / 198	Y-M: 20[redacted]-[redacted] / 198
MOXIFLOXACIN	400 mg	QD	Y-M: 20[redacted]-[redacted] / 198	Y-M: 20[redacted]-[redacted] / 201
PREDNISOLONE	15 mg	QD	Y-M: 20[redacted]-[redacted] / 198	Y-M: 20[redacted]-[redacted] / 201
FLUOCINONIDE	PROPER DOSE OTHER: APPLICATION	QD	Y-M: 20[redacted]-[redacted] / 211	NOT REPORTED
TACROLIMUS	PROPER DOSE OTHER: APPLICATION	QD	Y-M: 20[redacted]-[redacted] / 211	NOT REPORTED
WHITE SOFT PARAFFIN	PROPER DOSE OTHER: APPLICATION	QD	Y-M: 20[redacted]-[redacted] / 211	NOT REPORTED

Event #1: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Event of Interest - Serious Infections, Event of Interest - Opportunistic Infection excluding Tuberculosis and Herpes Zosters

Event Description	PNEUMOCYSTIS PNEUMONIA
Preferred term	ニューモシスチス・イロベチイ肺炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 188 (5 DAYS AFTER LAST TREATMENT)
Age at AE Onset	5[redacted]
Laboratory Testing	[redacted]20[redacted] (RX DAY 174): Chloride: 102 [98 - 108] MMOL/L; [redacted]20[redacted] (RX DAY 188): Alanine Aminotransferase: 53 [5 - 35] U/L; Albumin: 38 [38 - 52] G/L; Alkaline Phosphatase: 235 [100 - 360] U/L; Aspartate Aminotransferase: 64 [10 - 35] U/L; Basophils: 0.018 [0 - 0.22] 10^9/L; Basophils/Leukocytes: 0.3 [0 - 2] %; Bilirubin: 32 [3 - 19] UMOL/L; Blood Urea Nitrogen: 4.2 [2.9 - 8.2] MMOL/L; Calcium: 2.2 [2.07 - 2.59] MMOL/L; Chloride: 99 [98 - 108] MMOL/L; Cholesterol: 4.37 [3.36 - 5.69] MMOL/L; Creatine Kinase: 109 [60 - 270] U/L; Creatinine: 83 [53 - 106] UMOL/L; Eosinophils: 0.048 [0 - 0.43] 10^9/L; Eosinophils/Leukocytes: 0.8 [0 - 5] %; Erythrocytes: 2.7 [4.3 - 5.5] 10^12/L; Glucose: 6.7 [3.9 - 6.1] MMOL/L; Glucose: NEGATIVE [NOT REPORTED - NOT REPORTED] N/A; Hematocrit: 0.27 [0.4 - 0.5] FRACTION OF 1; Hemoglobin: 91 [135 - 170] G/L; Leukocytes: 6 [4 - 8.5] 10^9/L; Lymphocytes: 1.122 [0.96 - 4.75] 10^9/L; Lymphocytes/Leukocytes: 18.7 [18 - 52] %; Monocytes: 1.074 [0.1 - 0.97] 10^9/L; Monocytes/Leukocytes: 17.9 [3 - 9] %; NPTST001-A/G: 0.97 [1.2 - 2.1] RATIO; NPTST004-AMYLASE: 67 [35 - 125] U/L; NPTST005-ANA: LESS THAN 40 [0 - 39.999] TIMES; NPTST006-ANA(CYTOPLASMIC): NOT DETECTED [NOT REPORTED - NOT REPORTED] TIMES; NPTST007-ANA(DISCRETE SP.): NOT DETECTED [NOT REPORTED - NOT REPORTED] TIMES; NPTST008-ANA(HEMOGENEOUS): NOT DETECTED [NOT REPORTED - NOT REPORTED] TIMES; NPTST009-ANA(NUCLEOLAR): NOT DETECTED [NOT REPORTED - NOT REPORTED] TIMES; NPTST010-ANA(OTHER CHROMOSOME TYPE 1): NOT DETECTED [NOT REPORTED - NOT REPORTED] TIMES; NPTST011-ANA(OTHER CHROMOSOME TYPE2): NOTO DETECTED [NOT REPORTED - NOT REPORTED] TIMES; NPTST012-ANA(SPECKLED): NOT DETECTED [NOT REPORTED - NOT REPORTED] TIMES; NPTST014-APTT(ACTIVITY): 78 [70 - 130] %; NPTST015-APTT(CONTROL): 28.7 [NOT REPORTED - NOT REPORTED] sec; NPTST016-APTT(SEC): 32.1 [NOT REPORTED - NOT REPORTED] sec; NPTST017-ATYPICAL LYMPHOCYTE: 0 [0 - 0] %; NPTST020-BETA-D-GLUCAN: 200 [0 - 20] PG/ML; NPTST021-BLOOD GAS(BE): 1 [-2 - 2] MMOL/L; NPTST022-BLOOD GAS(BODY TEMPERATURE): 37.0 [NOT REPORTED - NOT REPORTED] DEGREE; NPTST023-BLOOD GAS(HCO3): 24.7 [21 - 29] MMOL/L; NPTST024-BLOOD GAS(HEMOGLOBIN): 9.1 [NOT REPORTED - NOT REPORTED] g/dL; NPTST025-BLOOD GAS(O2CT): 12.1 [18 - 22] ML/DL; NPTST026-BLOOD GAS(O2SAT): 93.9 [92 - 96] %; NPTST027-BLOOD GAS(PCO2): 35.5 [32 - 46] MMHG; NPTST028-BLOOD GAS(PH): 7.46 [7.38 -

7.46] N/A; NPTST029-BLOOD GAS(PO2): 65 [74 - 108] MMHG; NPTST030-BNP: 20.5 [0 - 18.4] PG/ML; NPTST033-CHOLINESTERASE: 95 [200 - 470] U/L; NPTST035-CMV IGG(EIA): 20.6 [0 - 2] N/A; NPTST037-CMV IGM(INDEX): 1.09 [0 - 0.8] N/A; NPTST040-CRP: 12.68 [0 - 0.3] MG/DL; NPTST042-D-DIMER QUANTITATIVE: 800 [0 - 1000] NG/ML; NPTST043-DIRECT BILIRUBIN: 1.1 [0 - 0.4] MG/DL; NPTST046-EGFR: 67.16 [NOT REPORTED - NOT REPORTED] mL/min/1.73m2; NPTST047-ERYTHROBLAST: 0 [0 - 0] N/A; NPTST048-FIBRINOGEN: 604 [200 - 400] MG/DL; NPTST050-GAMMA-GTP: 787 [0 - 80] U/L; NPTST051-HBS ANTIGEN(SEMIQUANTITATIVE): LESS THAN 8 [0 - 7.999] N/A; NPTST052-HCV ANTIBODY(DETERMINATION): NEGATIVE [NOT REPORTED - NOT REPORTED] N/A; NPTST053-HCV ANTIBODY(IDX): 0.1 [0 - 0.99] N/A; NPTST056-IGA: 598 [110 - 410] MG/DL; NPTST057-IGE(IGE NON-SPECIFIC): 11500 [0 - 173] IU/ML; NPTST058-IGG: 1346 [870 - 1700] MG/DL; NPTST059-IGM: 59 [33 - 190] MG/DL; NPTST060-KL-6: 320 [0 - 500] U/ML; NPTST062-LDH: 333 [110 - 240] U/L; NPTST063-MCH: 33.6 [27 - 35] PG; NPTST064-MCHC: 34 [31 - 36] G/DL; NPTST065-MCV: 99 [83 - 98] FL; NPTST066-METAMYELOCYTE: 0 [0 - 0] %; NPTST070-MYELOBLAST: 0 [0 - 0] %; NPTST071-MYELOCYTE: 0 [0 - 0] %; NPTST075-PERIPHERAL: NOT DETECTED [NOT REPORTED - NOT REPORTED] TIMES; NPTST076-PROCALCITONIN: LESS THAN 0.5~2 [NOT REPORTED - NOT REPORTED] ng/dL; NPTST077-PROMYELOCYTE: 0 [0 - 0] %; NPTST079-PT TIME(ACTIVITY): 54 [70 - 130] %; NPTST080-PT TIME(CONTROL): 11.5 [NOT REPORTED - NOT REPORTED] sec; NPTST081-PT TIME(INR): 1.34 [NOT REPORTED - NOT REPORTED] N/A; NPTST082-PT TIME(SEC): 15.4 [NOT REPORTED - NOT REPORTED] sec; NPTST087-PULMONARY SURFACTANT PROTEIN D: 27 [0 - 110] NG/ML; NPTST089-RF(QUANTITATIVE): 13 [0 - 15] IU/ML; NPTST090-RPR: NEGATIVE [NOT REPORTED - NOT REPORTED] N/A; NPTST093-TPHA: NEGATIVE [NOT REPORTED - NOT REPORTED] N/A; NPTST096-URIN PROTEIN: +/- [NOT REPORTED - NOT REPORTED] N/A; NPTST097-URINARY OCCULT BLOOD: NEGATIVE [NOT REPORTED - NOT REPORTED] N/A; NPTST099-URINARY SEDIMENT(BACTERIA): 1+ [NOT REPORTED - NOT REPORTED] N/A; NPTST100-URINARY SEDIMENT(GLITTER CELL): 1+ [NOT REPORTED - NOT REPORTED] N/A; NPTST101-URINARY SEDIMENT(HYALINE CAST): 1 [NOT REPORTED - NOT REPORTED] /2-5 VISUAL FIELDS; NPTST102-URINARY SEDIMENT(MUCUS): 1+ [NOT REPORTED - NOT REPORTED] N/A; NPTST103-URINARY SEDIMENT(RED BLOOD CELL: BELOW 1 [NOT REPORTED - NOT REPORTED] /10 VISUAL FIELD; NPTST104-URINARY SEDIMENT(SQUAMOUS CELL): 1~4 [NOT REPORTED - NOT REPORTED] /VF; NPTST106-URINARY SEDIMENT(URINARY TRACRT: BELOW 1 [NOT REPORTED - NOT REPORTED] /10 VISUAL FIELD; NPTST108-URINARY SEDIMENT(WHITE BLOOD CE: 20~29 [NOT REPORTED - NOT REPORTED] /VF; NPTST109-URINE BILIRUBIN: NEGATIVE [NOT REPORTED - NOT REPORTED] N/A; NPTST110-URINE KETON BODY: NEGATIVE [NOT REPORTED - NOT REPORTED] N/A; NPTST115-UROBILINOGEN: 2+ [NOT REPORTED - NOT REPORTED] N/A; Neutrophils: 3.738 [2.4 - 7.56] 10^9/L; Neutrophils/Leukocytes: 62.3 [40 - 79] %; Platelets: 135 [130 - 350] 10^9/L; Potassium: 3.8 [3.5 - 5] MMOL/L; Protein: 77 [65 - 82] G/L; Sodium: 135 [137 - 147] MMOL/L; Triglycerides: 1.25 [0.34 - 1.7] MMOL/L; Urate: 345.01 [214.14 - 416.39] UMOL/L; [redacted]20[redacted] (RX DAY 191): Alanine Aminotransferase: 54 [5 - 35] U/L; Albumin: 33 [38 - 52] G/L; Aspartate Aminotransferase: 68 [10 - 35] U/L; Basophils: 0.014 [0 - 0.22] 10^9/L; Basophils/Leukocytes: 0.1 [0 - 2] %; Bilirubin: 10 [3 - 19] UMOL/L; Blood Urea Nitrogen: 6 [2.9 - 8.2] MMOL/L; Calcium: 2.1 [2.07 - 2.59] MMOL/L; Chloride: 108 [98 - 108] MMOL/L; Creatine Kinase: 62 [60 - 270] U/L; Creatinine: 57 [53 - 106] UMOL/L; Eosinophils: 0 [0 - 0.43] 10^9/L; Eosinophils/Leukocytes: 0 [0 - 5] %; Erythrocytes: 2.4 [4.3 - 5.5] 10^12/L; Glucose: 8.3 [3.9 - 6.1] MMOL/L; Hematocrit: 0.24 [0.4 - 0.5] FRACTION OF 1; Hemoglobin: 82 [135 - 170] G/L; Leukocytes: 14.4 [4 - 8.5] 10^9/L; Lymphocytes: 5.573 [0.96 - 4.75] 10^9/L; Lymphocytes/Leukocytes: 38.7 [18 - 52] %; Monocytes: 1.022 [0.1 - 0.97] 10^9/L; Monocytes/Leukocytes: 7.1 [3 - 9] %; NPTST001-A/G: 0.94 [1.2 - 2.1] RATIO; NPTST017-ATYPICAL LYMPHOCYTE: 0 [0 - 0] %; NPTST033-CHOLINESTERASE: 75 [200 - 470] U/L; NPTST040-CRP: 5.82 [0 - 0.3] MG/DL; NPTST046-EGFR: 100.55 [NOT REPORTED - NOT REPORTED] mL/min/1.73m2; NPTST047-ERYTHROBLAST: 0 [0 - 0] N/A; NPTST050-GAMMA-GTP: 530 [0 - 80] U/L; NPTST061-LD: 342 [110 - 240] U/L; NPTST063-MCH: 33.6 [27 - 35] PG; NPTST064-MCHC: 34.2 [31 - 36] G/DL; NPTST065-MCV: 98 [83 - 98] FL; NPTST066-METAMYELOCYTE: 0 [0 - 0] %; NPTST070-MYELOBLAST: 0 [0 - 0] %; NPTST071-MYELOCYTE: 0 [0 - 0] %; NPTST077-PROMYELOCYTE: 0 [0 - 0] %; Neutrophils: 7.79 [2.4 - 7.56] 10^9/L; Neutrophils/Leukocytes: 54.1 [40 - 79] %; Platelets: 136 [130 - 350] 10^9/L; Potassium: 3.9 [3.5 - 5] MMOL/L; Protein: 68 [65 - 82] G/L; Sodium: 139 [137 - 147] MMOL/L; Urate: 208.2 [214.14 -

416.39] UMOL/L; [redacted]20[redacted] (RX DAY 196): Alanine Aminotransferase: 120 [5 - 35] U/L; Albumin: 39 [38 - 52] G/L; Alkaline Phosphatase: 256 [100 - 360] U/L; Aspartate Aminotransferase: 67 [10 - 35] U/L; Basophils: 0.062 [0 - 0.22] 10^9/L; Basophils/Leukocytes: 0.5 [0 - 2] %; Bilirubin: 14 [3 - 19] UMOL/L; Blood Urea Nitrogen: 6.3 [2.9 - 8.2] MMOL/L; Calcium: 2.32 [2.07 - 2.59] MMOL/L; Chloride: 105 [98 - 108] MMOL/L; Creatine Kinase: 32 [60 - 270] U/L; Creatinine: 92 [53 - 106] UMOL/L; Eosinophils: 0.185 [0 - 0.43] 10^9/L; Eosinophils/Leukocytes: 1.5 [0 - 5] %; Erythrocytes: 3.1 [4.3 - 5.5] 10^12/L; Glucose: 4.1 [3.9 - 6.1] MMOL/L; Hematocrit: 0.3 [0.4 - 0.5] FRACTION OF 1; Hemoglobin: 102 [135 - 170] G/L; Leukocytes: 12.3 [4 - 8.5] 10^9/L; Lymphocytes: 3.936 [0.96 - 4.75] 10^9/L; Lymphocytes/Leukocytes: 32 [18 - 52] %; Monocytes: 0.763 [0.1 - 0.97] 10^9/L; Monocytes/Leukocytes: 6.2 [3 - 9] %; NPTST001-A/G: 1.08 [1.2 - 2.1] RATIO; NPTST017-ATYPICAL LYMPHOCYTE: 0 [0 - 0] %; NPTST033-CHOLINESTERASE: 93 [200 - 470] U/L; NPTST040-CRP: 0.33 [0 - 0.3] MG/DL; NPTST046-EGFR: 60.13 [NOT REPORTED - NOT REPORTED] mL/min/1.73m2; NPTST047-ERYTHROBLAST: 0 [0 - 0] N/A; NPTST050-GAMMA-GTP: 502 [0 - 80] U/L; NPTST061-LD: 316 [110 - 240] U/L; NPTST063-MCH: 33.4 [27 - 35] PG; NPTST064-MCHC: 33.9 [31 - 36] G/DL; NPTST065-MCV: 99 [83 - 98] FL; NPTST066-METAMYELOCYTE: 0 [0 - 0] %; NPTST070-MYELOBLAST: 0 [0 - 0] %; NPTST071-MYELOCYTE: 0 [0 - 0] %; NPTST077-PROMYELOCYTE: 0 [0 - 0] %; Neutrophils: 7.355 [2.4 - 7.56] 10^9/L; Neutrophils/Leukocytes: 59.8 [40 - 79] %; Platelets: 177 [130 - 350] 10^9/L; Potassium: 4.5 [3.5 - 5] MMOL/L; Protein: 75 [65 - 82] G/L; Sodium: 135 [137 - 147] MMOL/L; Urate: 339.06 [214.14 - 416.39] UMOL/L; [redacted]20[redacted] (RX DAY 198): Alanine Aminotransferase: 73 [5 - 35] U/L; Albumin: 38 [38 - 52] G/L; Alkaline Phosphatase: 283 [100 - 360] U/L; Aspartate Aminotransferase: 29 [10 - 35] U/L; Basophils: 0.014 [0 - 0.22] 10^9/L; Basophils/Leukocytes: 0.1 [0 - 2] %; Bilirubin: 10 [3 - 19] UMOL/L; Blood Urea Nitrogen: 10.9 [2.9 - 8.2] MMOL/L; Calcium: 2.5 [2.07 - 2.59] MMOL/L; Chloride: 103 [98 - 108] MMOL/L; Creatine Kinase: 30 [60 - 270] U/L; Creatinine: 147 [53 - 106] UMOL/L; Eosinophils: 0.043 [0 - 0.43] 10^9/L; Eosinophils/Leukocytes: 0.3 [0 - 5] %; Erythrocytes: 3.1 [4.3 - 5.5] 10^12/L; Glucose: 4.4 [3.9 - 6.1] MMOL/L; Glucose: - [NOT REPORTED - NOT REPORTED] N/A; Hematocrit: 0.3 [0.4 - 0.5] FRACTION OF 1; Hemoglobin: 103 [135 - 170] G/L; Leukocytes: 14.3 [4 - 8.5] 10^9/L; Lymphocytes: 2.36 [0.96 - 4.75] 10^9/L; Lymphocytes/Leukocytes: 16.5 [18 - 52] %; Monocytes: 0.329 [0.1 - 0.97] 10^9/L; Monocytes/Leukocytes: 2.3 [3 - 9] %; NPTST001-A/G: 1.12 [1.2 - 2.1] RATIO; NPTST017-ATYPICAL LYMPHOCYTE: 0 [0 - 0] %; NPTST033-CHOLINESTERASE: 80 [200 - 470] U/L; NPTST040-CRP: 1.76 [0 - 0.3] MG/DL; NPTST046-EGFR: 36.05 [NOT REPORTED - NOT REPORTED] mL/min/1.73m2; NPTST047-ERYTHROBLAST: 0 [0 - 0] N/A; NPTST050-GAMMA-GTP: 390 [0 - 80] U/L; NPTST061-LD: 247 [110 - 240] U/L; NPTST063-MCH: 33.7 [27 - 35] PG; NPTST064-MCHC: 34.1 [31 - 36] G/DL; NPTST065-MCV: 99 [83 - 98] FL; NPTST066-METAMYELOCYTE: 0 [0 - 0] %; NPTST070-MYELOBLAST: 0 [0 - 0] %; NPTST071-MYELOCYTE: 0 [0 - 0] %; NPTST077-PROMYELOCYTE: 0 [0 - 0] %; NPTST096-URIN PROTEIN: +/- [NOT REPORTED - NOT REPORTED] N/A; NPTST097-URINARY OCCULT BLOOD: - [NOT REPORTED - NOT REPORTED] N/A; NPTST098-URINARY SEDIMANT(MUCUS): 1+ [NOT REPORTED - NOT REPORTED] N/A; NPTST099-URINARY SEDIMENT(BACTERIA): 2+ [NOT REPORTED - NOT REPORTED] N/A; NPTST101-URINARY SEDIMENT(HYALINE CAST): 1~4 [NOT REPORTED - NOT REPORTED] /VF; NPTST103-URINARY SEDIMENT(RED BLOOD CELL: BELOW 1 [NOT REPORTED - NOT REPORTED] /10 VISUAL FIELD; NPTST104-URINARY SEDIMENT(SQUAMOUS CELL): 1~4 [NOT REPORTED - NOT REPORTED] /VF; NPTST105-URINARY SEDIMENT(URIC ACID CRYS: 1+ [NOT REPORTED - NOT REPORTED] N/A; NPTST107-URINARY SEDIMENT(URINARY TRACT: 1 [NOT REPORTED - NOT REPORTED] /2-5 VISUAL FIELD; NPTST108-URINARY SEDIMENT(WHITE BLOOD CE: 1~4 [NOT REPORTED - NOT REPORTED] /VF; NPTST109-URINE BILIRUBIN: - [NOT REPORTED - NOT REPORTED] N/A; NPTST111-URINE KETONE BODY: - [NOT REPORTED - NOT REPORTED] N/A; NPTST114-URINRY SEDIMENT(TUBALAR EPITHEL: 1~4 [NOT REPORTED - NOT REPORTED] /VF; Neutrophils: 11.554 [2.4 - 7.56] 10^9/L; Neutrophils/Leukocytes: 80.8 [40 - 79] %; Platelets: 133 [130 - 350] 10^9/L; Potassium: 5.1 [3.5 - 5] MMOL/L; Protein: 72 [65 - 82] G/L; Sodium: 133 [137 - 147] MMOL/L; Urate: 345.01 [214.14 - 416.39] UMOL/L; Urobilinogen: +/- [NOT REPORTED - NOT REPORTED] N/A; [redacted]20[redacted] (RX DAY 201): Alanine Aminotransferase: 45 [5 - 35] U/L; Albumin: 35 [38 - 52] G/L; Alkaline Phosphatase: 288 [100 - 360] U/L; Aspartate Aminotransferase: 22 [10 - 35] U/L; Basophils: 0.061 [0 - 0.22] 10^9/L; Basophils/Leukocytes: 0.4 [0 - 2] %; Bilirubin: 9 [3 - 19] UMOL/L; Blood Urea Nitrogen: 5.9 [2.9 - 8.2] MMOL/L; Calcium: 2.42 [2.07 - 2.59] MMOL/L; Chloride: 106 [98 - 108] MMOL/L; Creatinine: 84 [53 - 106] UMOL/L; Eosinophils: 0.334 [0 - 0.43] 10^9/L; Eosinophils/Leukocytes: 2.2 [0

	- 5] %; Erythrocytes: 2.7 [4.3 - 5.5] 10^12/L; Glucose: 4 [3.9 - 6.1] MMOL/L; Hematocrit: 0.27 [0.4 - 0.5] FRACTION OF 1; Hemoglobin: 91 [135 - 170] G/L; Leukocytes: 15.2 [4 - 8.5] 10^9/L; Lymphocytes: 8.482 [0.96 - 4.75] 10^9/L; Lymphocytes/Leukocytes: 55.8 [18 - 52] %; Monocytes: 0.775 [0.1 - 0.97] 10^9/L; Monocytes/Leukocytes: 5.1 [3 - 9] %; NPTST001-A/G: 0.88 [1.2 - 2.1] RATIO; NPTST017-ATYPICAL LYMPHOCYTE: 0 [0 - 0] %; NPTST040-CRP: 1.55 [0 - 0.3] MG/DL; NPTST046-EGFR: 66.39 [NOT REPORTED - NOT REPORTED] mL/min/1.73m2; NPTST047-ERYTHROBLAST: 0 [0 - 0] %; NPTST050-GAMMA-GTP: 306 [0 - 80] U/L; NPTST061-LD: 240 [110 - 240] U/L; NPTST063-MCH: 33.2 [27 - 35] PG; NPTST064-MCHC: 33.3 [31 - 36] G/DL; NPTST065-MCV: 100 [83 - 98] FL; NPTST066-METAMYELOCYTE: 0 [0 - 0] %; NPTST070-MYELOBLAST: 0 [0 - 0] %; NPTST071-MYELOCYTE: 0 [0 - 0] %; NPTST077-PROMYELOCYTE: 0 [0 - 0] %; Neutrophils: 5.548 [2.4 - 7.56] 10^9/L; Neutrophils/Leukocytes: 36.5 [40 - 79] %; Platelets: 145 [130 - 350] 10^9/L; Potassium: 5 [3.5 - 5] MMOL/L; Protein: 75 [65 - 82] G/L; Sodium: 137 [137 - 147] MMOL/L; [redacted]20[redacted] (RX DAY 204): Alanine Aminotransferase: 52 [5 - 35] U/L; Albumin: 36 [38 - 52] G/L; Alkaline Phosphatase: 260 [100 - 360] U/L; Aspartate Aminotransferase: 26 [10 - 35] U/L; Basophils: 0.05 [0 - 0.22] 10^9/L; Basophils/Leukocytes: 0.6 [0 - 2] %; Bilirubin: 10 [3 - 19] UMOL/L; Blood Urea Nitrogen: 3.1 [2.9 - 8.2] MMOL/L; Calcium: 2.47 [2.07 - 2.59] MMOL/L; Creatinine: 62 [53 - 106] UMOL/L; Eosinophils: 0.299 [0 - 0.43] 10^9/L; Eosinophils/Leukocytes: 3.6 [0 - 5] %; Erythrocytes: 2.8 [4.3 - 5.5] 10^12/L; Glucose: 4.8 [3.9 - 6.1] MMOL/L; Hematocrit: 0.28 [0.4 - 0.5] FRACTION OF 1; Hemoglobin: 93 [135 - 170] G/L; Leukocytes: 8.3 [4 - 8.5] 10^9/L; Lymphocytes: 4.176 [0.96 - 4.75] 10^9/L; Lymphocytes/Leukocytes: 50.2 [18 - 52] %; Monocytes: 0.838 [0.1 - 0.97] 10^9/L; Monocytes/Leukocytes: 10.1 [3 - 9] %; NPTST001-A/G: 0.8 [1.2 - 2.1] RATIO; NPTST017-ATYPICAL LYMPHOCYTE: 0 [0 - 0] %; NPTST040-CRP: 0.51 [0 - 0.3] MG/DL; NPTST046-EGFR: 92.72 [NOT REPORTED - NOT REPORTED] mL/min/1.73m2; NPTST047-ERYTHROBLAST: 0 [0 - 0] N/A; NPTST050-GAMMA-GTP: 287 [0 - 80] U/L; NPTST061-LD: 211 [110 - 240] U/L; NPTST063-MCH: 32.9 [27 - 35] PG; NPTST064-MCHC: 33.5 [31 - 36] G/DL; NPTST065-MCV: 98 [83 - 98] FL; NPTST066-METAMYELOCYTE: 0 [0 - 0] %; NPTST070-MYELOBLAST: 0 [0 - 0] %; NPTST071-MYELOCYTE: 0 [0 - 0] %; NPTST077-PROMYELOCYTE: 0 [0 - 0] %; Neutrophils: 2.974 [2.4 - 7.56] 10^9/L; Neutrophils/Leukocytes: 35.5 [40 - 79] %; Platelets: 104 [130 - 350] 10^9/L; Potassium: 4.6 [3.5 - 5] MMOL/L; Protein: 81 [65 - 82] G/L; Sodium: 137 [137 - 147] MMOL/L
Microbiology	[redacted]20[redacted] (RX DAY 188): BLOOD NPTST019-BETA-D GLUCAN: POSITIVE-BETA-D GLUCAN 200; BLOOD NPTST034-CMV IGG(DETERMINATION): POSITIVE-CMV IGG(EIA)20.6; BLOOD NPTST036-CMV IGM(DETERMINATION): -+/-; BLOOD NPTST038-CMV PP65: NEGATIVE; BLOOD NPTST069-MYCOPLASMAL ANTIGEN: NEGATIVE; URINE NPTST112-URINE LEGIONELLA ANTIGEN: NEGATIVE; URINE NPTST113-URINE PNEUMOCOCCAL: NEGATIVE
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 188): CT: THE CONCENTRATION RISE AREA SUCH AS FROSTED GLASS WAS OBSERVED OVER LUNG UPPER. THERE IS A MILD THICKENING IN INTERLOBULAR SEPTA. IT'S LIKE A INTERSTITIAL CHANGE. SAME FINDINGS AS DRUG INDUCED LUNG INJURY. IN THE LOWER LOBE, BRONCHOPNEUMONIA LIKE BY SHADING AROUND THE BRONCHI. PNEUMOCYSTIS PNEUMONIA (PCP) WAS SUSPECTED FROM DRUG INDUCED LUNG INJURY AND PNEUMONIA CYTOMEGALOVIRAL .
AE Stopped Rx Day	212 (29 DAYS AFTER LAST TREATMENT)
Duration of AE	25 DAYS
Severity	Severe
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, CONCOMITANT OR ADDITIONAL TRTMNT

GIVEN

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M17-377

本被験者は日本の 5[redacted] 歳男性であり，ウパダシチニブの治験で盲検化された治験薬，フルオシノロンアセトニド，プレドニゾロン及び TACROLIMUS が投与され，ニューモシスチス肺炎を発現した。被験者は元喫煙者（20 本／日，17 年間）かつ飲酒者（2 杯未満／日）であり，関連する病歴はアトピー性皮膚炎，喘息，アレルギー性鼻炎，甲状腺機能低下症及び本態性高血圧症であった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者はニューモシスチス肺炎を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，ニューモシスチス肺炎は消失した。

本事象の発現前，被験者は 20[redacted] 年 [redacted] 月 [redacted] 日から 20[redacted] 年 [redacted] 月 [redacted] 日まで続いた発熱を報告し，一般的な風邪（非重篤）と診断された。その後，治験薬の投与は中断された。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は発熱，倦怠感，咳嗽，頭痛，呼吸困難及び食欲不振のため入院した。同日の検査の結果，好中球数（絶対値）は 3738/μL，リンパ球数（絶対値）は 1122/μL であった。20[redacted] 年 [redacted] 月 [redacted] 日，気管支鏡検査が予定されていたが，5 L/分の酸素吸入が必要な状態となったため実施しなかった。20[redacted] 年 [redacted] 月 [redacted] 日，呼吸不全が継続しており，7 L/分の酸素吸入を必要とした。また，β-D-グルカン増加も認められ，ニューモシスチス肺炎と判断された。20[redacted] 年 [redacted] 月 [redacted] 日，酸素吸入は中止された。20[redacted] 年 [redacted] 月 [redacted] 日，発熱していたが他の症状はなく，Avelox の投与により改善した。20[redacted] 年 [redacted] 月 [redacted] 日，クレアチニン値上昇のため Bactramin の投与を中止した。20[redacted] 年 [redacted] 月 [redacted] 日，呼吸不全が消失していたため，退院した。20[redacted] 年 [redacted] 月 [redacted] 日の来院時には 36.9°C の微熱があったが，その他の症状はなく，被験者は回復したと判断された。

被験者は試験を中止した。

プレドニゾロン，ファモチジン，レバミピド，AVELOX，LOXOPROFEN SODIUM，CEFTRIAXONE NA，ミノサイクリン塩酸塩，SOL-MELCORT 及び BACTRAMIN が投与された。

The patient's past medications include:

ANFLAVATE LOTION for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

ANFLAVATE OINTMENT for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

CELESTANA for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted] [redacted] 20[redacted] - [redacted] 20[redacted])

EPINASTINE HYDROCHLORIDE for ATOPIC DERMATITIS ([redacted])

TACROLIMUS for ATOPIC DERMATITIS ([redacted])

HYDROXYZINE PAMOATE for ATOPIC DERMATITIS ([redacted])

RINDERON-VG for ATOPIC DERMATITIS ([redacted])

PROTOPIC for ATOPIC DERMATITIS ([redacted])

PROPETO for EMOLLIENT THERAPY ([redacted])

FLUOCINONIDE for ATOPIC DERMATITIS RESCUE THERAPY ([redacted])

AMBROXOL for COMMON COLD ([redacted])

ASTOMIN for COMMON COLD ([redacted])

CEFDITOREN PIVOXIL for COMMON COLD ([redacted])

IBUPROFEN for COMMON COLD ([redacted])

Causality for UPADACITINIB (Blinded)

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1) Pneumocystis pneumonia (10035661) (Pneumocystis jirovecii pneumonia (10073755)) [v.22.0] [10035661]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

Causality for FLUOCINOLONE ACETONIDE (Open Label)

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1) Pneumocystis pneumonia (10035661) (Pneumocystis jirovecii pneumonia (10073755)) [v.22.0] [10035661]

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

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

Dechallenge: Not Applicable

Causality for PREDNISOLONE (Open Label)

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1) Pneumocystis pneumonia (10035661) (Pneumocystis jirovecii pneumonia (10073755)) [v.22.0] [10035661]

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

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

Dechallenge: Not Applicable

Causality for TACROLIMUS (Open Label)

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1) Pneumocystis pneumonia (10035661) (Pneumocystis jirovecii pneumonia (10073755)) [v.22.0] [10035661]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of PNEUMOCYTIS PNEUMONIA

- Investigator: Not applicable

- AbbVie: Not applicable.

Alternative Etiology for FLUOCINOLONE ACETONIDE (Open Label)

Event of PNEUMOCYTIS PNEUMONIA

- Investigator: More likely related to Upadacitinib/Placebo.

- AbbVie: Weak temporal association. Last dose prior to event onset was approximately five and a half months prior to event onset.

Alternative Etiology for PREDNISOLONE (Open Label)

Event of PNEUMOCYTIS PNEUMONIA

- Investigator: More likely related to Upadacitinib/Placebo.

- AbbVie: Weak temporal association. Last dose prior to event onset was approximately five months prior to event onset.

Alternative Etiology for TACROLIMUS (Open Label)

Event of PNEUMOCYTIS PNEUMONIA

- Investigator: More likely related to Upadacitinib/Placebo.

- AbbVie: Weak temporal association. Last dose prior to event onset was approximately three months prior to event onset.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ANA(HEMOGENEOUS):** Not detected.

[redacted] **20[redacted] A/G RATIO:** 0.97 no unit (normal 1.20 to 2.10)

[redacted] **20[redacted] ALANINE AMINO TRANSFERASE:** 53 U/L (normal 5 to 35)

[redacted] **20[redacted] ALANINE AMINO TRANSFERASE:** 120 U/L (normal 5 to 35)

[redacted] **20[redacted] ALBUMIN:** 3.3 G/DL (normal 3.8 to 5.2)

[redacted] **20[redacted] ALKALINE PHOSPHATASE:** 98 U/L (normal 40 to 129)

[redacted] **20[redacted] ALKALINE PHOSPHATASE:** 235 U/L (normal 100 to 360)

[redacted] **20[redacted] ALKALINE PHOSPHATASE:** 256 U/L (normal 100 to 360)

[redacted] 20[redacted] **ALKALINE PHOSPHATASE:** 88 U/L (normal 40 to 129)

[redacted] 20[redacted] **ALT:** 28 U/L (normal 6 to 43)

[redacted] 20[redacted] **ALT:** 21 U/L (normal 6 to 43)

[redacted] 20[redacted] **ANA:** LESS THAN 40.

[redacted] 20[redacted] **ANA(CYTOPLASMIC):** Not detected.

[redacted] 20[redacted] **ANA(DISCRETE SP):** Not detected.

[redacted] 20[redacted] **ANA(NUCLEOLAR):** Not detected.

[redacted] 20[redacted] **ANA(OTHER CHROMOSOME TYPE 1):** Not detected.

[redacted] 20[redacted] **ANA(OTHER CHROMOSOME TYPE2):** Not detected.

[redacted] 20[redacted] **ANA(SPECKLED):** Not detected.

[redacted] 20[redacted] **APTT(ACTIVITY):** 78 % (normal 70 to 130)

[redacted] 20[redacted] **APTT(CONTROL):** 11.5 SEC

[redacted] 20[redacted] **APTT(SEC):** 32.1 SEC

[redacted] 20[redacted] **ASPARTATE AMINO TRANSFERASE:** 64 U/L (normal 10 to 35)

[redacted] 20[redacted] **ASPARTATE AMINO TRANSFERASE:** 7.5 U/L (normal 10 to 35)

[redacted] 20[redacted] **AST:** 87 U/L (normal 11 to 36)

[redacted] 20[redacted] **AST:** 44 U/L (normal 11 to 36)

[redacted] 20[redacted] **AST:** 28 U/L (normal 11 to 36)

[redacted] 20[redacted] **ATYPICAL LYMPHOCYTE:** 0 % (normal 0 to 0)

[redacted] 20[redacted] **BASOPHILS %:** 0.3 % (normal 0 to 2)

[redacted] 20[redacted] **BASOPHILS ABS:** 62 /UL (normal 0 to 0.3)

[redacted] 20[redacted] **BILIRUBIN:** 1.1 mg/dL (normal 0.0 to 0.4)

[redacted] 20[redacted] **BILIRUBIN:** 0.6 mg/dL (normal 0.2 to 1.1)

[redacted] 20[redacted] **BLOOD GAS(BE):** 1.0 MMOL/L (normal -2 to 2)

[redacted] 20[redacted] **BLOOD GAS(BODY TEMPERATURE):** 37.0 Degrees C

[redacted] 20[redacted] **BLOOD GAS(HCO3):** 24.7 MMOL/L (normal 21 to 29)

[redacted] 20[redacted] **BLOOD GAS(HEMOGLOBIN):** 9.1 G/DL

[redacted] 20[redacted] **BLOOD GAS(O2CT):** 12.1 ml/dl (normal 18 to 22)

[redacted] 20[redacted] **BLOOD GAS(O2SAT):** 93.9 % (normal 92 to 96)

[redacted] 20[redacted] **BLOOD GAS(PCO2):** 35.5 mmHg (normal 32 to 46)

[redacted] 20[redacted] **BLOOD GAS(PH):** 7.460 no unit (normal 7.38 to 7.46)

[redacted] 20[redacted] **BLOOD GAS(PO2):** 65.0 mmHg (normal 74 to 108)

[redacted] 20[redacted] **BLOOD UREA NITROGEN:** 11.7 mg/dL (normal 8 to 23)

[redacted] 20[redacted] **BNP:** 20.5 PG/ML (normal 0 to 18.4)

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

[redacted] 20[redacted] **BODY TEMPERATURE:** 38.8 Degrees C

[redacted] 20[redacted] **BODY TEMPERATURE:** 40 Degrees C

[redacted] 20[redacted] **BODY TEMPERATURE:** 36.9 Degrees C

[redacted] 20[redacted] **CALCIUM:** 8.8 mg/dL (normal 8.3 to 10.4)

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

[redacted] 20[redacted] **CHOLESTEROL:** 169 mg/dL (normal 130 to 220)

[redacted] 20[redacted] **CHOLINESTERASE:** 95 U/L (normal 200 to 470)

[redacted] 20[redacted] **CHOLINESTERASE:** 93 U/L (normal 200 to 470)

[redacted] 20[redacted] **CL:** 99 MEQ/L (normal 98 to 108)

[redacted] 20[redacted] **CMV IGG(DETERMINATION):** Positive.

[redacted] 20[redacted] **CMV IGG(EIA):** 20.6 no unit (normal 0 to 1.999)

[redacted] 20[redacted] **CMV IGM(DETERMINATION):** ±.

[redacted] 20[redacted] **CMV IGM(INDEX):** 1.09 no unit (normal 0 to 0.799)

[redacted] 20[redacted] **CMV PP65:** Negative.

[redacted] 20[redacted] **CREATINE KINASE:** 109 U/L (normal 60 to 270)

[redacted] 20[redacted] **CREATININE:** 0.65 mg/dL (normal 0.6 to 1.2)

[redacted] 20[redacted] **CRP:** 5.82 mg/dL (normal 0 to 0.3)

[redacted] **20[redacted] CRP:** 0.33 mg/dL (normal 0 to 0.3)

[redacted] **20[redacted] CRP QUANTITATIVE:** 12.68 mg/dL (normal 0 to 0.3)

[redacted] **20[redacted] CT:** THE CONCENTRATION RISE AREA SUCH AS FROSTED GLASS WAS OBSERVED OVER LUNG UPPER. THERE IS A MILD THICKENING IN INTERLOBULAR SEPTA. IT'S LIKE A INTERSTITIAL CHANGE. SAME FINDINGS AS DRUG INDUCED LUNG INJURY. IN THE LOWER LOBE, BRONCHOPNEUMONIA LIKE BY SHADING AROUND THE BRONCHI. PNEUMOCYSTIS PNEUMONIA (PCP) WAS SUSPECTED FROM DRUG INDUCED LUNG INJURY AND PNEUMONIA CYTOMEGALOVIRAL.

[redacted] **20[redacted] D-DIMER QUANTITATIVE:** 800 NG/ML (normal 0 to 1000)

[redacted] **20[redacted] EGFR:** 67.16 ML/MIN/1.73M*2

[redacted] **20[redacted] EGFR:** 100.55 ML/MIN/1.73M^2

[redacted] **20[redacted] EOSINOPHILS %:** 1.5 % (normal 0 to 5)

[redacted] **20[redacted] EOSINOPHILS ABS:** 48000 10^3/uL

[redacted] **20[redacted] EOSINOPHILS ABS:** 0

[redacted] **20[redacted] EOSINOPHILS ABS:** 185 /UL (normal 0 to 0.3)

[redacted] **20[redacted] ERYTHROBLAST:** 0 % (normal 0 to 0)

[redacted] **20[redacted] GLUCOSE:** 120 mg/dL (normal 70 to 110)

[redacted] **20[redacted] GLUCOSE:** 150 mg/dL (normal 70 to 110)

[redacted] **20[redacted] GLUCOSE:** 74 mg/dL (normal 70 to 110)

[redacted] **20[redacted] HBS ANTIGEN (SEMIQUANTITATIVE):** Less than 8. Normal value low: 0, Normal value high: 7.999.

[redacted] **20[redacted] HCV ANTIBODY(DETERMINATION):** Negative.

Unknown date HCV ANTIBODY(IDX): 0.1 no unit (normal 0 to 0.99)

[redacted] **20[redacted] HEMATOCRIT:** 24.0 % (normal 40 to 50)

[redacted] **20[redacted] HEMOGLOBIN:** 10.2 G/DL (normal 13.5 to 17)

[redacted] **20[redacted] IGA:** 598 mg/dL (normal 110 to 410)

[redacted] **20[redacted] IGE(IGE NON-SPECIFIC):** 11500 IU/mL (normal 0 to 173)

[redacted] **20[redacted] IGG:** 1346 mg/dL (normal 870 to 1700)

[redacted] **20[redacted] IGM:** 59 mg/dL (normal 33 to 190)

[redacted] 20[redacted] **KL-6:** 320 U/ML (normal 0 to 499.999)

[redacted] 20[redacted] **LD:** 316 U/L (normal 110 to 240)

[redacted] 20[redacted] **LDH:** 333 U/L (normal 110 to 240)

[redacted] 20[redacted] **LYMPHOCYTES %:** 32.0 % (normal 18 to 52)

[redacted] 20[redacted] **LYMPHOCYTES ABS:** 1122 10^3/uL

[redacted] 20[redacted] **LYMPHOCYTES ABS:** 5.573 10^3/uL

[redacted] 20[redacted] **LYMPHOCYTES ABS:** 3936 /UL (normal 0 to 0.3)

[redacted] 20[redacted] **MCH:** 33.6 PG (normal 27 to 35)

[redacted] 20[redacted] **MCHC:** 34.2 G/DL (normal 31 to 36)

[redacted] 20[redacted] **MCV:** 99 FL (normal 83 to 98)

[redacted] 20[redacted] **METAMYELOCYTE:** 0 % (normal0 to 0)

[redacted] 20[redacted] **MONOCYTES %:** 17.9 % (normal 3 to 9)

[redacted] 20[redacted] **MONOCYTES %:** 6.2 % (normal 3 to 9)

[redacted] 20[redacted] **MONOCYTES ABS:** 1074000 10^3/uL

[redacted] 20[redacted] **MONOCYTES ABS:** 1.022 10^3/uL

[redacted] 20[redacted] **MYCOPLASMAL ANTIGEN:** Negative.

[redacted] 20[redacted] **MYELOBLAST:** 0 % (normal 0 to 0)

[redacted] 20[redacted] **NEUTROPHILS %:** 62.3 % (normal 40 to 79)

[redacted] 20[redacted] **NEUTROPHILS ABS:** 3738 10^3/uL

[redacted] 20[redacted] **NEUTROPHILS ABS:** 7.79 10^3/uL

[redacted] 20[redacted] **NEUTROPHILS ABS:** 763 /UL

[redacted] 20[redacted] **NEUTROPHILS ABS:** 7355 /UL (normal 0 to 0.3)

[redacted] 20[redacted] **PLATELET COUNT:** 1350 10^3/uL (normal 130 to 350)

[redacted] 20[redacted] **PLATELET COUNT:** 136 10^3/uL (normal 130 to 350)

[redacted] 20[redacted] **PLATELET COUNT:** 177 10^3/uL (normal 13 to 35)

[redacted] 20[redacted] **POTASSIUM:** 3.8 MEQ/L (normal 3.5 to 5.0)

[redacted] 20[redacted] **PROCALCITONIN:** LESS THAN 0.5~2 NG/DL.

[redacted] 20[redacted] **RED BLOOD CELLS:** 2710 10^3/uL (normal 4300 to 5500)

[redacted] 20[redacted] **RED BLOOD CELLS:** 305 no units (normal 430 to 550)

[redacted] 20[redacted] **RPR:** Negative.

[redacted] 20[redacted] **SUGAR URINARY:** Negative.

[redacted] 20[redacted] **TOTAL BILIRUBIN:** 1.1 mg/dL (normal 0.2 to 1.2)

[redacted] 20[redacted] **TOTAL PROTEIN:** 7.7 G/DL (normal 6.5 to 8.2)

[redacted] 20[redacted] **TPHA:** Negative.

[redacted] 20[redacted] **UEIN LEGIONELLA ANTIGEN:** Negative.

[redacted] 20[redacted] **URINARY OCCULATE BLOOD:** Negative.

[redacted] 20[redacted] **URINARY SEDIMENT(BACTERIA):** 1+.

[redacted] 20[redacted] **URINARY SEDIMENT(GLITTER CELL):** 1+.

[redacted] 20[redacted] **URINARY SEDIMENT(HYALINE CAST):** 1.

[redacted] 20[redacted] **URINARY SEDIMENT(MUCUS):** 1+.

[redacted] 20[redacted] **URINARY SEDIMENT(RED BLOOD CELL):** Below 1.

[redacted] 20[redacted] **URINARY SEDIMENT(SQUAMOUS CELL):** 1-4.

[redacted] 20[redacted] **URINARY SEDIMENT(URINARY TRACRT CELL):** Below 1.

[redacted] 20[redacted] **URINARY SEDIMENT(WHITE BLOOD CELL):** 20-29.

[redacted] 20[redacted] **URINE BILIRUBIN:** Negative.

[redacted] 20[redacted] **URINE KETONE BODY:** Negative.

[redacted] 20[redacted] **URINE PNEUMOCOCCAL:** Negative.

[redacted] 20[redacted] **URINE PROTEIN:** ±.

[redacted] 20[redacted] **UROBILINOGEN:** 2+.

[redacted] 20[redacted] **WHITE BLOOD CELLS:** 6000 U/L (normal 4000 to 8500)

[redacted] 20[redacted] **WHITE BLOOD CELLS:** 123000 /UL (normal 4000 to 8500)

[redacted] 20[redacted] **Y-GTP:** 502 U/L (normal 0 to 80)

[redacted] **20[redacted] Y-GTP:** 530 U/L (normal 0 to 80)

[redacted] **20[redacted] B-D GLUCAN:** 200 PG/ML (normal 0 to 20)

Subject [redacted] ([redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
カポジ水痘様発疹				X
小脳出血	X	X		X

Treatment Group	Age at Study Start	Sex	Race
P1:Upa 15 mg QD	2[redacted]	MALE	ASIAN

Medical History	Onset Year
ATOPIC DERMATITIS	19[redacted]
FOOD ALLERGY(BUCKWHEAT)	20[redacted]
FOOD ALLERGY(CRUSTACEAN)	20[redacted]
FOOD ALLERGY(EGG)	20[redacted]
FOOD ALLERGY(WALNUT)	20[redacted]
ASTHAMA	20[redacted]
CATARACT	20[redacted]
ACNE COMEDONAL	20[redacted]
ASTHMA	NOT REPORTED
FOOD ALLERGY	NOT REPORTED

Prior Procedures	Procedure Year
PRIOR PROCEDURES: CATARACT SURGERY	20[redacted]

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

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
P1:ABT-494	15 MG	ORAL	QD	[redacted] / 1	[redacted] / 65	65

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BETAMETHASONE	1 OTHER: APPLICATION	QD	Y-M: [redacted] / -135
CLINDAMYCIN	1 OTHER: APPLICATION	QD	Y-M: [redacted] / -135
CLOBETASOL	1 OTHER: APPLICATION	QD	Y-M: [redacted] / -135
KETOCONAZOLE	1 OTHER: APPLICATION	QD	Y-M: [redacted] / -135
MINOCYCLINE	100 mg	QD	Y-M: [redacted] / -135
TACROLIMUS	1 OTHER: APPLICATION	QD	Y-M: [redacted] / -135
UREA	1 OTHER: APPLICATION	QD	Y-M: [redacted] / -135
ZINC	1 OTHER: APPLICATION	QD	Y-M: [redacted] / -135
CETIRIZINE	10 mg	QD	Y-M: [redacted] / -125
NADIFLOXACIN	1 OTHER: APPLICATION	BID	Y-M: [redacted] / -122
VALISONE-G	1 OTHER: APPLICATION	BID	Y-M: [redacted] / -122
BYAKKOKANINJINTO	3 g	BID	Y-M: [redacted] / -119
HERBAL PREPARATION	2.5 g	BID	Y-M: [redacted] / -119
RUPATADINE	10 mg	QD	Y-M: [redacted] / -119
CEFDINIR	100 mg	TID	Y-M: [redacted] / -103
ENTEROCOCCUS FAECALIS	1 mg	TID	Y-M: [redacted] / -103
HEPARINOID	1 OTHER: APPLICATION	QD	Y-M: [redacted] / -103
WHITE SOFT PARAFFIN	1 OTHER: APPLICATION	BID	Y-M: [redacted] / -7

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
CLINDAMYCIN	1 OTHER: APPLICATION	QD	Y-M: [redacted] / -135	NOT REPORTED
HEPARINOID	1 OTHER: APPLICATION	QD	Y-M: [redacted] / -103	NOT REPORTED
WHITE SOFT PARAFFIN	1 OTHER: APPLICATION	BID	Y-M: [redacted] / -7	NOT REPORTED
VALACICLOVIR	500 mg	BID	Y-M: [redacted] / 15	Y-M: [redacted] / 19
VALACICLOVIR	500 mg	BID	Y-M: [redacted] / 33	Y-M: [redacted] / 37
ATROPINE	0.5 mg	OTHER: ONCE	Y-M: [redacted] / 66	Y-M: [redacted] / 66
EPHEDRINE	28 mg	OTHER: ONCE	Y-M: [redacted] / 66	Y-M: [redacted] / 66
FLURBIPROFEN	50 mg	OTHER: ONCE	Y-M: [redacted] / 66	Y-M: [redacted] / 66
HYDROCORTISONE	1000 mg	OTHER: ONCE	Y-M: [redacted] / 66	Y-M: [redacted] / 66
MANNITOL	300 mL	OTHER: ONCE	Y-M: [redacted]	Y-M: [redacted] /

			/ 66	66
PHENYLEPHRINE	0.7 mg	OTHER: ONCE	Y-M: 20[redacted]	Y-M: 20[redacted] / 66
PROPOFOL	80 mg	OTHER: ONCE	Y-M: 20[redacted]	Y-M: 20[redacted] / 66
REMIFENTANIL	8 mg	OTHER: ONCE	Y-M: 20[redacted]	Y-M: 20[redacted] / 66
ROCURONIUM	50 mg	OTHER: ONCE	Y-M: 20[redacted]	Y-M: 20[redacted] / 66
SUGAMMADEX	200 mL	OTHER: ONCE	Y-M: 20[redacted]	Y-M: 20[redacted] / 66
CEFAZOLIN	1 g		Y-M: 20[redacted]	Y-M: 20[redacted] / 67
DEXMEDETOMIDINE	400 ug		Y-M: 20[redacted]	Y-M: 20[redacted] / 67
ACTIT	500 mL		Y-M: 20[redacted]	Y-M: 20[redacted] / 69
GLYCEOL	200 mL		Y-M: 20[redacted]	Y-M: 20[redacted] / 69
FAMOTIDINE	20 mg		Y-M: 20[redacted]	Y-M: 20[redacted] / 71
METOCLOPRAMIDE	10 mg		Y-M: 20[redacted]	Y-M: 20[redacted] / 75
HYDROXYZINE	25 mg		Y-M: 20[redacted]	Y-M: 20[redacted] / 70
AMINO ACIDS NOS W/ELECTROLYTES NOS/GLUCOSE/TH	500 mL		Y-M: 20[redacted]	Y-M: 20[redacted] / 79
ASCORBIC ACID	500 ug		Y-M: 20[redacted]	Y-M: 20[redacted] / 99
FLAVINE ADENINE DINUCLEOTIDE	10 mg		Y-M: 20[redacted]	Y-M: 20[redacted] / 99
HAITAMIN	30 mg		Y-M: 20[redacted]	Y-M: 20[redacted] / 99
THIAMINE	50 mg		Y-M: 20[redacted]	Y-M: 20[redacted] / 99
FAMOTIDINE	20 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 130
CEFTRIAXONE	2 g	OTHER: EVERY 12 HOURS	Y-M: 20[redacted]	Y-M: 20[redacted] / 93
VANCOMYCIN	1 g	OTHER: EVERY 12 HOURS	Y-M: 20[redacted]	Y-M: 20[redacted] / 104
MEROPENEM	2 g	OTHER: EVERY 8 HOURS	Y-M: 20[redacted]	Y-M: 20[redacted] / 130
ACTIT	500 mg	PRN	Y-M: 20[redacted]	Y-M: 20[redacted] / 101
ATROPINE	0.5 mg	OTHER: ONCE	Y-M: 20[redacted]	Y-M: 20[redacted] / 97
FLURBIPROFEN	50 mg	OTHER: ONCE	Y-M: 20[redacted]	Y-M: 20[redacted] / 97
HYDROCORTISONE	100 mg	OTHER: ONCE	Y-M: 20[redacted]	Y-M: 20[redacted] / 97
METOCLOPRAMIDE	10 mg	OTHER: ONCE	Y-M: 20[redacted]	Y-M: 20[redacted] / 97

PROPOFOL	120 ng	OTHER: ONCE	Y-M: 20[redacted] / 97	Y-M: 20[redacted] / 97
REMIFENTANIL	8 mg	OTHER: ONCE	Y-M: 20[redacted] / 97	Y-M: 20[redacted] / 97
ROCURONIUM	50 mg	OTHER: ONCE	Y-M: 20[redacted] / 97	Y-M: 20[redacted] / 97
SUGAMMADEX	200 mg	OTHER: ONCE	Y-M: 20[redacted] / 97	Y-M: 20[redacted] / 97
FAMOTIDINE	20 mg		Y-M: 20[redacted] / 97	Y-M: 20[redacted] / 98
IMMUNOGLOBULIN HUMAN NORMAL	2.5 g		Y-M: 20[redacted] / 97	Y-M: 20[redacted] / 99
METOCLOPRAMIDE	50 mL	OTHER: ONCE	Y-M: 20[redacted] / 100	Y-M: 20[redacted] / 100
ACTIT	500 mL		Y-M: 20[redacted] / 101	Y-M: 20[redacted] / 122
BETAHISTINE	1 OTHER: TAB	PRN	Y-M: 20[redacted] / 101	Y-M: 20[redacted] / 122
CLOSTRIDIUM BUTYRICUM	1 OTHER: TAB	PRN	Y-M: 20[redacted] / 101	Y-M: 20[redacted] / 122
ESZOPICLONE	1 mg	PRN	Y-M: 20[redacted] / 101	Y-M: 20[redacted] / 122
MEROPENEM	0.5 g		Y-M: 20[redacted] / 101	Y-M: 20[redacted] / 122
METOCLOPRAMIDE	10 mg		Y-M: 20[redacted] / 101	Y-M: 20[redacted] / 122
SODIUM CHLORIDE	100 mL		Y-M: 20[redacted] / 101	Y-M: 20[redacted] / 122
SODIUM CHLORIDE	50 mL		Y-M: 20[redacted] / 101	Y-M: 20[redacted] / 122
VANCOMYCIN	0.5 g		Y-M: 20[redacted] / 101	Y-M: 20[redacted] / 122
BETAHISTINE	1 OTHER: TAB	BID	Y-M: 20[redacted] / 104	Y-M: 20[redacted] / 122
VANCOMYCIN	1 g	OTHER: EVERY 8 HOURS	Y-M: 20[redacted] / 105	Y-M: 20[redacted] / 122
CLOSTRIDIUM BUTYRICUM	1 OTHER: TAB	TID	Y-M: 20[redacted] / 106	Y-M: 20[redacted] / 122
CLOSTRIDIUM BUTYRICUM			Y-M: 20[redacted] / 122	NOT REPORTED

Event #1: Event of Interest - Opportunistic Infection excluding Tuberculosis and Herpes Zosters

Event Description	KAPOSI'S VARICELLIFORM ERUPTION (AROUND THE FACE AND MOUTH)
Preferred term	カポジ水痘様発疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 31
Age at AE Onset	2[redacted]
Laboratory Testing	NOT APPLICABLE
Microbiology	NOT APPLICABLE
SAE Supplemental Procedure	NOT APPLICABLE
AE Stopped Rx Day	43
Duration of AE	13 DAYS
Severity	Moderate
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
Investigator Alternative Etiology	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	CONCOMITANT OR ADDITIONAL TRTMNT GIVEN

Event #2: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Event of Interest - Adjudicated Cardiovascular Events, Event of Interest - MACE

Event Description	CEREBELLAR HAEMORRHAGE
Preferred term	小脳出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 65
Age at AE Onset	2[redacted]
Laboratory Testing	NOT REPORTED
Microbiology	NOT REPORTED
SAE Supplemental Procedure	[redacted]20[redacted] (RX DAY 65): MRI,CT: CEREBELLAR HAEMORRHAGE CEREBRAL HAEMORRHAGE IN THE CENTER OF THE RIGHT CEREBELLUM; [redacted]20[redacted] (RX DAY 89): MRI:; [redacted]20[redacted] (RX DAY 91): CT:; [redacted]20[redacted] (RX DAY 94): CT:; [redacted]20[redacted] (RX DAY 96): CT:; [redacted]20[redacted] (RX DAY 97): CT:; [redacted]20[redacted] (RX DAY 98): CT:; [redacted]20[redacted] (RX DAY 101): CT:; [redacted]20[redacted] (RX DAY 104): CT:; [redacted]20[redacted] (RX DAY 107): CT:
AE Stopped Rx Day	123 (58 DAYS AFTER LAST TREATMENT)
Duration of AE	59 DAYS
Severity	Severe
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT, CONCOMITANT OR ADDITIONAL TRTMNT GIVEN

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M17-377

本被験者は日本の 2[redacted] 歳男性であり，ウパダシチニブの治験で盲検化された治験薬，プレドニゾロン及びトリアムシノロンアセトニドが投与され，小脳出血を発現した。被験者は非喫煙者かつ飲酒者（2 杯未満／日）であり，関連する病歴はアトピー性皮膚炎及び喘息であった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は小脳出血を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，小脳出血は消失した。

本事象の発現前，2[redacted]9 年 [redacted] 月 3 日から 20[redacted] 年 [redacted] 月 [redacted] 日まで発現していたヘルペス感染（非重篤）のため，治験薬，プレドニゾロン及びトリアムシノロンアセトニドの投与が中断された。また，20[redacted] 年 [redacted] 月 [redacted] 日から 20[redacted] 年 [redacted] 月 [redacted] 日まで，カポジ水痘様発疹（非重篤）を発現した。

20[redacted] 年 [redacted] 月 [redacted] 日，頭痛，嘔吐及び転倒のため入院した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は小脳出血と診断された。血腫は増大し，続いて意識レベルが低下した。開頭手術を受け，手術後に意識レベル，頭痛及び運動失調は改善した。

20[redacted] 年 [redacted] 月 [redacted] 日，微熱があり，右後頭下に自発痛及び圧痛があった。CT 検査の結果，筋肉下に体液貯留が認められ，穿刺により排膿が認められた。CEFXONE + VANCOMYCIN HYDROCHLORIDE が投与された。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は圧痛を自覚した。CT 検査の結果，膿瘍が認められ，穿刺が実施された。治療は MEROPENEM + VENILON I に変更された。20[redacted] 年 [redacted] 月 [redacted] 日，デブリードマンで洗浄した際，筋肉下及び皮下からの排膿が認められた。20[redacted] 年 [redacted] 月 [redacted] 日，ドレーンが抜去された。ドレーン抜去以降，感染はコントロールされた状態であった。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は MRI 検査を受けた。長期にわたる後遺症は認められず，20[redacted] 年 [redacted] 月 [redacted] 日に被験者は退院した。

治験責任医師の記述：被験者の病歴に頭部損傷はなく，本人の病歴及び家族歴に違法薬物の使用又は高血圧などの脳出血の交絡因子，若しくは動脈瘤もなかった。

塩酸メトクロプラミド，GLYCEOL，GASTER，MEROPENEM，VENILON I，ROPION，LUNESTA，MANNITOL，ファモチジン，CEFTRIAXONE 及びバンコマイシン塩酸塩が投与された。

The patient's past medications include:

ACETYLOL for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

ANFLAVATE for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

DERMOVATE for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

MINOMYCIN for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

NITRAZEN for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

PROTOPIC for ATOPIC DERMATITIS ([redacted])

RINDERON DP for ATOPIC DERMATITIS ([redacted])

ZINC OXIDE for ATOPIC DERMATITIS ([redacted])

CETIRIZINE for ATOPIC DERMATITIS ([redacted])

ACUATIM for ATOPIC DERMATITIS ([redacted])

RINDERON-VG for ATOPIC DERMATITIS ([redacted])

BYAKKOKANINJINTO for ATOPIC DERMATITIS ([redacted])

JIZUSOIPPO for ATOPIC DERMATITIS ([redacted])

RUPAFIN for ATOPIC DERMATITIS ([redacted])

BIOFERMIN R for ATOPIC DERMATITIS ([redacted])

CEFZON for ATOPIC DERMATITIS ([redacted])

Causality for UPADACITINIB (Blinded)

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1) Cerebellar haemorrhage (10008030) (Cerebellar haemorrhage (10008030)) [v.22.1] [10008030]

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

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

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Causality for PREDNISOLONE (Open Label)

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1) Cerebellar haemorrhage (10008030) (Cerebellar haemorrhage (10008030)) [v.22.1] [10008030]

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

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

Dechallenge: Not Applicable

Causality for TRIAMCINOLONE ACETONIDE (Open Label)

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1) Cerebellar haemorrhage (10008030) (Cerebellar haemorrhage (10008030)) [v.22.1] [10008030]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of CEREBELLAR HAEMORRHAGE

- Investigator: Not applicable

- AbbVie: Event's etiology is not consistent with study drug's mechanism of action. Additional risk factors include recent herpes infection and Kaposi's varicelliform eruption.

Alternative Etiology for PREDNISOLONE (Open Label)

Event of CEREBELLAR HAEMORRHAGE

- Investigator: Not reported

- AbbVie: Event's etiology is not consistent with study drug's mechanism of action. Additional risk factors include recent herpes infection and Kaposi's varicelliform eruption.

Alternative Etiology for TRIAMCINOLONE ACETONIDE (Open Label)

Event of CEREBELLAR HAEMORRHAGE

- Investigator: Not reported

- AbbVie: Event's etiology is not consistent with study drug's mechanism of action. Additional risk factors include recent herpes infection and Kaposi's varicelliform eruption.

Relevant Laboratory & Other Diagnostic Tests

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

[redacted] **20[redacted] CT:** Cerebellar haemorrha

[redacted] **20[redacted] CT:** Showed submuscular fluid retention, pustular retention with puncture.

[redacted] **20[redacted] CT:** Showed pustular puncture

[redacted] **20[redacted] MRI:** Cerebellar hemorrhage in the center of the right cerebullum

非重篤な有害事象

被験者は，顔面や口の周囲に広がるカポジ水痘様発疹を発現し，抗ウイルス薬が投与された。単純ヘルペスウイルス及びその他のウイルス検出の有無は不明である。本事象のため治験薬の投与は中断された。本事象は消失した。

Subject [redacted] ([redacted])

Reason for Narrative

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

Treatment Group	Age at Study Start	Sex	Race
P1:Upa 15 mg QD /P2:Upa 15 mg QD	2[redacted]	MALE	ASIAN

Medical History	Onset Year
ALLERGIC RHINITIS	19[redacted]
ASTHMA	19[redacted]
ATOPIC DERMATITIS	19[redacted]
FOOD ALLERGY	19[redacted]
CHICKEN POX	19[redacted]
ATTENTION DEFICIT HYPERACTIVITY DISORDER	20[redacted]
SOCIAL ANXIETY DISORDER	20[redacted]
INFLUENZA VIRAL INFECTION	20[redacted]
ALLERGIC RHINITIS	NOT REPORTED
ASTHMA	NOT REPORTED
FOOD ALLERGY	NOT REPORTED

Prior Procedures	Procedure Year
Not reported.	

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

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
P1:ABT-494	15 MG	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 109	109
P2:ABT-494	15 MG	ORAL	QD	[redacted]20[redacted] / 110		

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BCG Vaccine	NOT REPORTED	NOT REPORTED	Y-M: 19[redacted]
ARIPIPRAZOLE	3 mg	QD	Y-M: 20[redacted]
MEQUITAZINE	3 mg	BID	Y-M: 20[redacted]
OLOPATADINE	5 mg	BID	Y-M: 20[redacted]
STELAMIN	1 OTHER: TABLET	BID	Y-M: 20[redacted]
DIFLORASONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]
VALISONE-G	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]
BETAMETHASONE	1 OTHER: APPLICATION	TID	Y-M: 20[redacted]
CICLOSPORIN	50 mg	QD	Y-M: 20[redacted]
SUPLATAST TOSILATE	100 mg	TID	Y-M: 20[redacted]
TACROLIMUS	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]
CLOBETASOL	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]
OLOPATADINE	5 mg	BID	Y-M: 20[redacted]
LEVOCETIRIZINE	5 mg	QD	Y-M: 20[redacted]
BEPOTASTINE	10 mg	BID	Y-M: 20[redacted]
CLOBETASOL	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]
SALICYLIC ACID	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]
METHYLPHENIDATE	36 mg	QD	Y-M: 20[redacted]
CLOBETASOL	1 OTHER: APPLICATION	QD	Y-M: 20[redacted] / -332
DIFLORASONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -255
OLEA EUROPAEA	1 OTHER: APPLICATION	QD	Y-M: 20[redacted] / -199
OLOPATADINE	5 mg	BID	Y-M: 20[redacted] / -171
UNSEIIN	7.5 g	TID	Y-M: 20[redacted] / -128
DIFLORASONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -101
WHITE SOFT PARAFFIN	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -88
AUGMENTIN	1 OTHER: TABLETS	BID	Y-M: 20[redacted] / -49
DIFLORASONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -49

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
ARIPIPRAZOLE	3 mg	QD	Y-M: 20[redacted]	NOT REPORTED
BEPOTASTINE	10 mg	BID	Y-M: 20[redacted]	NOT REPORTED
METHYLPHENIDATE	36 mg	QD	Y-M: 20[redacted]	NOT REPORTED
OLOPATADINE	5 mg	BID	Y-M: 20[redacted] / -171	NOT REPORTED
FAMOTIDINE	20 mg	BID	Y-M: 20[redacted] / 6	NOT REPORTED
CLOBETASOL	1 OTHER: APPLICATION	QD	Y-M: 20[redacted] / 47	NOT REPORTED
WHITE SOFT PARAFFIN	1 OTHER: APPLICATION	QD	Y-M: 20[redacted] / 110	NOT REPORTED
PREDNISOLONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / 153	NOT REPORTED
WHITE SOFT PARAFFIN	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / 153	NOT REPORTED
ACICLOVIR	250 mg	TID	Y-M: 20[redacted] / 257	Y-M: 20[redacted] / 263
LOXOPROFEN	60 mg	PRN	Y-M: 20[redacted] / 257	Y-M: 20[redacted] / 264
BETAMETHASONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / 262	NOT REPORTED

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

Event Description	HERPES ZOSTER
Preferred term	帯状疱疹
AE Onset Date / Rx Day	[redacted] / 254
Age at AE Onset	[redacted]
Laboratory Testing	[redacted] (RX DAY 257): Leukocytes: 6.1 [3.5 - 9] 10^9/L; Lymphocytes/Leukocytes: 18 [30 - 45] %
Microbiology	NOT REPORTED
SAE Supplemental Procedure	NOT REPORTED
AE Stopped Rx Day	265
Duration of AE	12 DAYS
Severity	Severe
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, CONCOMITANT OR ADDITIONAL TRTMNT GIVEN

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M17-377

本被験者は日本の 2[redacted] 歳男性であり，ウパダシチニブの治験で盲検化された治験薬，プレドニゾロン及びフルオシノロンアセトニドが投与され，帯状疱疹を発現した。被験者は非喫煙者かつ飲酒者（2 杯未満／日）であり，関連する病歴はアレルギー性鼻炎，喘息，アトピー性皮膚炎，食物アレルギー，水痘及びインフルエンザウイルス感染であった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は帯状疱疹を発現した。

20[redacted] 年 [redacted] 月，本事象の発現前，被験者はプレドニゾロンによる併用療法を開始した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は自宅で発熱して体温 37°C となり，臀部のリンパ節腫脹が認められた。20[redacted] 年 [redacted] 月 [redacted] 日，右腹部から背部にかけて小水疱が発生した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は病院の皮膚科を受診した。

右腹部から背部にかけて，複数の小水疱集簇及び環状紅斑が認められた。また被験者は，昼夜を通して疼痛があると訴えた。帯状疱疹と診断され，被験者は入院した。免疫力が低下した可能性があり，点滴注入療法が必要であると判断された。右腹部から背部にかけて痂皮形成が始まった。20[redacted] 年 [redacted] 月 [redacted] 日，発疹が痂皮化して疼痛が改善し，被験者は退院した。

この帯状疱疹は病歴及び身体検査に基づいて診断されたものであり，症状は単一の皮膚分節に限局していた。

被験者には水痘の病歴があり，帯状疱疹の病歴又は帯状疱疹ワクチンの接種歴はなかった。

ACYCLOVIR 及び LOXONIN TABLET が投与された。

The patient's past medications include:

ZESULAN TABLETS for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

ALLELOCK TABLETS for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

EMPERACIN for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

DIFLAL for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

RINDERON-VG for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

ANTBATE LOTION for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

NEORAL for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

IPD CAPSULE for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

PROTOPIC for ATOPIC DERMATITIS ([redacted])

DERMOVATE SCALP LOTION for ATOPIC DERMATITIS ([redacted])

OLOPATADINE HYDRCHLORIDE OD for ATOPIC DERMATITIS ([redacted])

XYZAL for ATOPIC DERMATITIS ([redacted])

SALICYLIC ACID OINTMENT for ATOPIC DERMATITIS ([redacted])

COMCLO SHAMPOO for ATOPIC DERMATITIS ([redacted])

OLIVE OIL for ATOPIC DERMATITIS ([redacted])

UNSEIIN for ATOPIC DERMATITIS ([redacted])

Causality for UPADACITINIB (Blinded)

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1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.22.1] [10019974]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: No

Causality for PREDNISOLONE (Open Label)

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1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.22.1] [10019974]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

Causality for FLUOCINOLONE ACETONIDE (Open Label)

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1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.22.1] [10019974]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of HERPES ZOSTER

- Investigator: Not applicable

- AbbVie: Not applicable

Alternative Etiology for PREDNISOLONE (Open Label)

Event of HERPES ZOSTER

- Investigator: More likely related to ABT-494/Placebo

- AbbVie: Not applicable

Alternative Etiology for FLUOCINOLONE ACETONIDE (Open Label)

Event of HERPES ZOSTER

- Investigator: More likely due to ABT-494/Placebo

- AbbVie: Weak temporal association. Last dose was over 7 months prior to event onset.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BODY TEMPERATURE:** 37 Degrees C

Subject [redacted] ([redacted])

Reason for Narrative

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

Treatment Group	Age at Study Start	Sex	Race
P1:Placebo /P2:Upa 30 mg QD	5[redacted]	MALE	ASIAN

Medical History	Onset Year
ATOPIC DERMATITIS	19[redacted]
ALLERGIC RHINITIS	19[redacted]
CONJINCTIVITS ALLERGIC	19[redacted]
ASTHMA	20[redacted]
HYPER TENSION	20[redacted]
ALLERGIC RHINITIS	NOT REPORTED
ASTHMA	NOT REPORTED

Prior Procedures	Procedure Year
Not reported.	

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

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
P1:Placebo		ORAL	QD	[redacted] / 1	[redacted] / 110	110
P2:ABT-494	30 MG	ORAL	QD	[redacted] / 111		

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
SERETIDE	1 OTHER: INHALATION	BID	Y-M: [redacted]
AMLODIPINE	5 mg	QD	Y-M: [redacted]
BILASTINE	20 mg	QD	Y-M: [redacted]
DIFLORASONE	1 OTHER: APPLICATION	BID	Y-M: [redacted]
PREDNISOLONE	5 mg	TID	Y-M: [redacted]
BYAKKOKANINJINTO	3 g	TID	Y-M: [redacted]
ORENGEDOKUTO	2.5 mg	TID	Y-M: [redacted]
CICLOSPORIN	150 mg	QD	Y-M: [redacted]
OLOPATADINE	5 mg	TID	Y-M: [redacted]
PREDNISOLONE	1 OTHER: APPLICATION	QD	Y-M: [redacted]
TACROLIMUS	1 OTHER: APPLICATION	QD	Y-M: [redacted]
OLOPATADINE	5 mg	BID	Y-M: [redacted]
CICLOSPORIN	150 mg	OTHER: ONCE TWO DAYS	Y-M: [redacted]
HYDROXYZINE	10 mg	QD	Y-M: [redacted] / -296
CICLOSPORIN	150 mg	QD	Y-M: [redacted] / -135
DEXCHLORPHENIRAMINE	6 mg	QD	Y-M: [redacted] / -65
WHITE SOFT PARAFFIN	1 OTHER: APPLICATION	BID	Y-M: [redacted] / -33
CLOBETASOL	1 OTHER: APPLICATION	BID	Y-M: [redacted] / -21

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
SERETIDE	1 OTHER: INHALATION	BID	Y-M: [redacted]	NOT REPORTED
AMLODIPINE	5 mg	QD	Y-M: [redacted]	NOT REPORTED
OLOPATADINE	5 mg	BID	Y-M: [redacted]	NOT REPORTED
WHITE SOFT PARAFFIN	1 OTHER: APPLICATION	BID	Y-M: [redacted] / -33	NOT REPORTED
MOMETASONE	2 OTHER: SPRAY	QD	Y-M: [redacted] / 13	NOT REPORTED
OLOPATADINE	1 OTHER: APPLICATION	BID	Y-M: [redacted] / 13	NOT REPORTED
DEXCHLORPHENIRAMINE	6 mg	QD	Y-M: [redacted] / 111	NOT REPORTED
ACICLOVIR	1 OTHER: APPLICATION	QD	Y-M: [redacted] / 271	Y-M: [redacted] / 272
VALACICLOVIR	500 mg	TID	Y-M: [redacted] /	Y-M: [redacted] /

ACICLOVIR	250 mg	TID	Y-M: 20[redacted]-[redacted] / 271	Y-M: 20[redacted]-[redacted] / 272
AMOXICILLIN	250 mg	TID	Y-M: 20[redacted]-[redacted] / 272	Y-M: 20[redacted]-[redacted] / 274
AUGMENTIN	1 OTHER: TABLETS	TID	Y-M: 20[redacted]-[redacted] / 273	Y-M: 20[redacted]-[redacted] / 284
ACICLOVIR	1 OTHER: APPKICATION	QID	Y-M: 20[redacted]-[redacted] / 273	Y-M: 20[redacted]-[redacted] / 284
BETAMETHASONE	0.1 %	QID	Y-M: 20[redacted]-[redacted] / 273	Y-M: 20[redacted]-[redacted] / 285
LEVOFLOXACIN	0.5 %	QID	Y-M: 20[redacted]-[redacted] / 273	Y-M: 20[redacted]-[redacted] / 285
PARACETAMOL	400 mg	PRN	Y-M: 20[redacted]-[redacted] / 273	Y-M: 20[redacted]-[redacted] / 285
DIFLORASONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]-[redacted] / 275	NOT REPORTED
PREDNISOLONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]-[redacted] / 275	NOT REPORTED
GENTAMICIN	1 OTHER: APPLICATION	BID	Y-M: 20[redacted]-[redacted] / 279	Y-M: 20[redacted]-[redacted] / 285

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

Event Description	HERPES ZOSTER
Preferred term	帯状疱疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 266
Age at AE Onset	5[redacted]
Laboratory Testing	[redacted]20[redacted] (RX DAY 272): Leukocytes: 9.5 [3.5 - 9] 10^9/L; Lymphocytes/Leukocytes: 16 [30 - 45] %
Microbiology	NOT REPORTED
SAE Supplemental Procedure	NOT REPORTED
AE Stopped Rx Day	286 (1 DAY AFTER LAST TREATMENT)
Duration of AE	21 DAYS
Severity	Severe
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, CONCOMITANT OR ADDITIONAL TRTMNT GIVEN

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M17-377

本被験者は日本の 5[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，フルオシノロンアセトニド及びプレドニゾロンが投与され，帯状疱疹を発現した。被験者は非喫煙者かつ元飲酒者（2 杯未満／日）であり，関連する病歴はアトピー性皮膚炎及び帯状疱疹であった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は帯状疱疹を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，帯状疱疹は消失した。

本事象の発現前である 20[redacted] 年 [redacted] 月，単純ヘルペス（非重篤）が発現し，同月中に消失した。

20[redacted] 年 [redacted] 月 [redacted] 日，左眼瞼及び顔面が腫脹し，小水疱が出現した。20[redacted] 年 [redacted] 月 [redacted] 日，皮膚科で帯状疱疹と診断され，薬剤療法が開始された。20[redacted] 年 [redacted] 月 [redacted] 日，症状継続を理由に，被験者は入院した。被験者は夜間の発熱，疼痛，アトピー性皮膚炎によるそう痒及び左上眼瞼の二次感染（非重篤）を発現した。左上眼瞼の腫脹，水疱，びらん及び紅斑のため，入院期間は延長した。その後，上眼瞼には痂皮が形成され，浮腫は改善した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は退院した。

発症したのは単一の皮膚分節であった。眼科の診察で，角膜表面の異常や眼病変はないと確認された。被験者には帯状疱疹ワクチン接種歴及び水痘の病歴がなく，帯状疱疹の病歴があった。

COCARL，VALTREX，アセトアミノフェン及び ACYCLOVIR が投与された。

The patient's past medications include:

BILANOA for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

DIFLAL OINTMENT for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

PREDNISOLONE for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

BYAKKO KA NINJINTO for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

OREN GEDOKUTO for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

LIDMEX KOWA OINTMENT for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

NEORAL for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

OLOPATADINE HYDROCHLORIDE for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

PROTOPIC OINTMENT for CONJUCTIVITS ALLERGIC ([redacted] 20[redacted] - [redacted] 20[redacted])

ATARAX for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

NEOMALLERMIN-TR for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

DERMOVATE OINTMENT for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.22.1] [10019974]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Causality for FLUOCINOLONE ACETONIDE (Open Label)

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1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.22.1] [10019974]

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

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

Dechallenge: Not Applicable

Causality for PREDNISOLONE (Open Label)

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1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.22.1] [10019974]

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

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

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of HERPES ZOSTER

- Investigator: Not applicable

- AbbVie: Not applicable

Alternative Etiology for FLUOCINOLONE ACETONIDE (Open Label)

Event of HERPES ZOSTER

- Investigator: More likely related to ABT-494/Placebo

- AbbVie: Week temporal association, last dose received 6 months prior to event onset.

Alternative Etiology for PREDNISOLONE (Open Label)

Event of HERPES ZOSTER

- Investigator: More likely related to ABT-494/Placebo

- AbbVie: Week temporal association, last dose received 6 months prior to event onset.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BODY TEMPERATURE:** 38.5 F

[redacted] **20[redacted] BODY TEMPERATURE:** 37.4 F

[redacted] **20[redacted] LYMPHOCTYE PERCENTAGE:** 16 % (normal 30 to 45)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 9.5 X10**3/MCL (normal 3.5 to 9.0)

Subject [redacted] ([redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
単純ヘルペス	X			X

Treatment Group	Age at Study Start	Sex	Race
P1:Upa 30 mg QD /P2:Upa 30 mg QD	3[redacted]	MALE	ASIAN

Medical History	Onset Year
ASTHMA	20[redacted]
ATOPIC DERMATITIS	20[redacted]
HERPES SIMPLEX	20[redacted]
ASTHMA	NOT REPORTED

Prior Procedures	Procedure Year
Not reported.	

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

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
P1:ABT-494	30 MG	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 115	115
P2:ABT-494	30 MG	ORAL	QD	[redacted]20[redacted] / 116		

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
LORATADINE	10 mg	QD	Y: 20[redacted]
MEQUITAZINE	3 mg	PRN	Y: 20[redacted]
OLOPATADINE	5 mg	BID	Y: 20[redacted]
TACROLIMUS	1 OTHER: APPLICATION	QD	Y: 20[redacted]
CICLOSPORIN	100 mg	BID	Y-M: 20[redacted] / -298
DIFLUPREDNATE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -298
DIFLUPREDNATE	1 OTHER: APPLICATION	QD	Y-M: 20[redacted] / -298

FEXOFENADINE	120 mg	BID	Y-M: 20[redacted] / -298
HEPARINOID	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -298
CICLOSPORIN	75 mg	BID	Y-M: 20[redacted] / -291
CICLOSPORIN	100 mg	QD	Y-M: 20[redacted] / -277
FEXOFENADINE	60 mg	BID	Y-M: 20[redacted] / -277
CICLOSPORIN	75 mg	QD	Y-M: 20[redacted] / -256
CICLOSPORIN	100 mg	QD	Y-M: 20[redacted] / -244
DEXAMETHASONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -239
CICLOSPORIN	50 mg	QD	Y-M: 20[redacted] / -195
CICLOSPORIN	75 mg	QD	Y-M: 20[redacted] / -193
CICLOSPORIN	75 mg	QD	Y-M: 20[redacted] / -137
CICLOSPORIN	75 mg	QD	Y-M: 20[redacted] / -73
TACROLIMUS	1 OTHER: APPLICATION	QD	Y-M: 20[redacted] / -46
WHITE SOFT PARAFFIN	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -18

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
HEPARINOID	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -298	NOT REPORTED
FEXOFENADINE	60 mg	BID	Y-M: 20[redacted] / -277	NOT REPORTED
WHITE SOFT PARAFFIN	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -18	NOT REPORTED
VALACICLOVIR	500 mg	BID	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 31
VIDARABINE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 45
PENCICLOVIR	1000 mg	QD	Y-M: 20[redacted] / 32	Y-M: 20[redacted] / 33
ACICLOVIR	250 mg	QD	Y-M: 20[redacted] / 35	Y-M: 20[redacted] / 36
PARACETAMOL	500 mg	TID	Y-M: 20[redacted] / 35	Y-M: 20[redacted] / 36
LEVOFLOXACIN	500 mg	QD	Y-M: 20[redacted] / 35	Y-M: 20[redacted] / 39
GUAIAZULENE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / 36	Y-M: 20[redacted] / 42
PARACETAMOL	1000 mg	TID	Y-M: 20[redacted] / 36	Y-M: 20[redacted] / 42
ESZOPICLONE	2 mg	QD	Y-M: 20[redacted] / 37	Y-M: 20[redacted] / 41
ACICLOVIR	250 mg	TID	Y-M: 20[redacted] / 37	Y-M: 20[redacted] / 42
PREGABALIN	75 mg	QD	Y-M: 20[redacted] / 37	Y-M: 20[redacted] / 44
PREGABALIN	25 mg	QD	Y-M: 20[redacted] / 38	Y-M: 20[redacted] / 44
CEFDITOREN	100 mg	TID	Y-M: 20[redacted] / 45	Y-M: 20[redacted] / 55

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

Event Description	HERPES SIMPLEX AGGRAVATED
Preferred term	単純ヘルペス
AE Onset Date / Rx Day	[redacted]20[redacted] / 34
Age at AE Onset	3[redacted]
Laboratory Testing	[redacted]20[redacted] (RX DAY 35): Lymphocytes: 1.36 [0.96 - 4.75] 10^9/L; NPTST054-HERPES SIMPLEX TYPE 1 ANTIGEN: POSITIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED
Microbiology	[redacted]20[redacted] (RX DAY 35): WOUND NPTST095-TZANCK TEST: POSITIVE-GIANT VIRAL CELLS ARE DETECTED.
SAE Supplemental Procedure	NOT REPORTED

AE Stopped Rx Day	45
Duration of AE	12 DAYS
Severity	Severe
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
Investigator Alternative Etiology	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, CONCOMITANT OR ADDITIONAL TRTMNT GIVEN

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M17-377

本被験者は日本の 3[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬，プレドニゾロン，フルオシノロンアセトニド及び TACROLIMUS が投与され，単純ヘルペス増悪を発現した。被験者は非喫煙者かつ飲酒者（2 杯未満／日）であり，関連する病歴はアトピー性皮膚炎及び単純ヘルペスであった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は単純ヘルペス増悪を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，単純ヘルペス増悪は消失した。

本事象の発現前である 20[redacted] 年 [redacted] 月 [redacted] 日，単純ヘルペス（非重篤）と初めて診断され，Valaciclovir 及びビダラビン軟膏の投与が開始された。20[redacted] 年 [redacted] 月 [redacted] 日，Famvir の投与が開始された。プレドニゾロン外用薬の投与は中止された。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者が発熱した（体温の報告なし）。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は治験責任医師の診察を受けた。顔面全体の発赤及びそう痒とともに，右前額部及び左頬部の小さなびらん，紅斑及び小水疱が認められた。Tzanck 試験でウイルス性巨細胞が確認されたため，アシクロビルの点滴投与が開始された。体温は平熱であった。20[redacted] 年 [redacted] 月 [redacted] 日，症状の改善に乏しかったため，治験責任医師は被験者の入院が必要と判断した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者はヘルペスに対する加療のため入院した。20[redacted] 年 [redacted] 月 [redacted] 日，アシクロビルの点滴投与が完了し，被験者は退院した。退院後の 20[redacted] 年 [redacted] 月 [redacted] 日，顔面にあった小さなびらんの消失が診察で確認された。

被験者は本事象発現前に帯状疱疹の予防接種を受けていなかった。本事象は眼病変を伴わなかった。

LUNESTA, LYRICA, AZUNOL, CALONAL, FAMVIR, VALACICLOVIR, ビダラビン, アシクロビル及び LEVOFLOXACIN が投与された。

The patient's past medications include:

LORATADINE for ATOPIC DERMATITIS (20[redacted] - [redacted] 20[redacted])

MEQUITAZINE for ATOPIC DERMATITIS (20[redacted] - [redacted] 20[redacted])

OLOPATADINE HYDROCHLORIDE for ATOPIC DERMATITIS (20[redacted] - [redacted] 20[redacted])

PROTOPIC for ATOPIC DERMATITIS (20[redacted] - [redacted] 20[redacted])

FEXOFENADINE HCL for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

MYSER for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

NEORAL for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

METHADERM for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Herpes simplex aggravated (10048418) (Herpes simplex (10019948)) [v.22.1] [10048418]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Causality for PREDNISOLONE (Open Label)

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1) Herpes simplex aggravated (10048418) (Herpes simplex (10019948)) [v.22.1] [10048418]

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

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

Dechallenge: Not Applicable

Causality for FLUOCINOLONE ACETONIDE (Open Label)

---

1) Herpes simplex aggravated (10048418) (Herpes simplex (10019948)) [v.22.1] [10048418]

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

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

Dechallenge: Not Applicable

Causality for TACROLIMUS (Open Label)

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1) Herpes simplex aggravated (10048418) (Herpes simplex (10019948)) [v.22.1] [10048418]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of HERPES SIMPLEX AGGRAVATED

- Investigator: Not applicable

- AbbVie: Not applicable

Alternative Etiology for PREDNISOLONE (Open Label)

Event of HERPES SIMPLEX AGGRAVATED

- Investigator: More likely related to ABT-494/placebo

- AbbVie: Event more likely related to non-serious event of herpes simplex, which occurred prior to start of suspect drug.

Alternative Etiology for FLUOCINOLONE ACETONIDE (Open Label)

Event of HERPES SIMPLEX AGGRAVATED

- Investigator: More likely related to ABT-494/placebo

- AbbVie: Study drug is a low potency topical medication and unlikely to have significant local or systemic immunosupressive effects.

Alternative Etiology for TACROLIMUS (Open Label)

Event of HERPES SIMPLEX AGGRAVATED

- Investigator: More likely related to ABT-494/placebo

- AbbVie: N/A

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] HERPES SIMPLEX TYPE 1 ANTIGEN:** POSITIVE

[redacted] **20[redacted] TZANCK TEST:** positive: giant viral cells detected

Subject [redacted] ([redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
帯状疱疹	X			X
ヘルペス後神経痛				X

Treatment Group	Age at Study Start	Sex	Race
P1:Upa 30 mg QD /P2:Upa 30 mg QD	4[redacted]	MALE	ASIAN

Medical History	Onset Year
ATOPIC DERMATITIS	19[redacted]
CHICKENPOX	20[redacted]
SHINGLES	20[redacted]
ATOPIC DERMATITIS	20[redacted]

Prior Procedures	Procedure Year
Not reported.	

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

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
P1:ABT-494	30 MG	ORAL	QD	[redacted]20[redacted] / 1 0	[redacted]20[redacted] / 110	110
P2:ABT-494	30 MG	ORAL	QD	[redacted]20[redacted] / 111	[redacted]20[redacted] / 362	252

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BETAMETHASONE	0.05 %	BID	Y-M: 20[redacted]
HEPARINOID	0.3 %	QD	Y-M: 20[redacted]
PREDNISOLONE	0.3 %	BID	Y-M: 20[redacted]
DIFLUPREDNATE	0.05 %	QD	Y-M: 20[redacted]
TACROLIMUS	0.1 %	QD	Y-M: 20[redacted]
BILASTINE	20 mg	QD	Y-M: 20[redacted] / -331
CICLOSPORIN	50 mg	QD	Y-M: 20[redacted] / -296
BEPOTASTINE	20 mg	BID	Y-M: 20[redacted] / -212
WHITE SOFT PARAFFIN	500 mg	BID	Y-M: 20[redacted] / -9

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
HEPARINOID	0.3 %	QD	Y-M: 20[redacted]	NOT REPORTED
BILASTINE	20 mg	QD	Y-M: 20[redacted] / -331	NOT REPORTED
WHITE SOFT PARAFFIN	500 mg	BID	Y-M: 20[redacted] / -9	NOT REPORTED
ELECTROLYTES NOS	500 mL	QD	Y-M: 20[redacted] / 236	Y-M: 20[redacted] / 236
SODIUM CHLORIDE	500 mL	QD	Y-M: 20[redacted] / 236	Y-M: 20[redacted] / 236
FAMCICLOVIR	500 mg	TID	Y-M: 20[redacted] / 236	Y-M: 20[redacted] / 237
ACICLOVIR	250 mg	TID	Y-M: 20[redacted] / 236	Y-M: 20[redacted] / 243
GENTAMICIN	0.1 %	BID	Y-M: 20[redacted] / 236	Y-M: 20[redacted] / 279
PARACETAMOL	600 mg	TID	Y-M: 20[redacted] / 236	Y-M: 20[redacted] / 314
ACICLOVIR	3 %	TID	Y-M: 20[redacted] / 238	Y-M: 20[redacted] / 279
BROMFENAC	0.1 %	BID	Y-M: 20[redacted] / 238	Y-M: 20[redacted] / 279
LEVOFLOXACIN	0.5 %	TID	Y-M: 20[redacted] / 238	Y-M: 20[redacted] / 309
PARACETAMOL	600 mg	TID	Y-M: 20[redacted] / 315	NOT REPORTED

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

Event Description	HERPES ZOSTER
Preferred term	帯状疱疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 231
Age at AE Onset	4[redacted]
Laboratory Testing	[redacted]20[redacted] (RX DAY 236): NPTST116-VARICELLA-ZOSTER VIRU-SPECIFIC: POSITIVE [NOT REPORTED - NOT REPORTED] RATIO; NPTST117-VARICELLA-ZOSTER VIRUS-SPECIFIC: POSITIVE [NOT REPORTED - NOT REPORTED] RATIO
Microbiology	[redacted]20[redacted] (RX DAY 236): OTHER VESICULAR FLUID NPTST044-DIRECT FIUORESCENT ANTIBODY: POSITIVE-POSITIVE
SAE Supplemental Procedure	NOT REPORTED
AE Stopped Rx Day	315
Duration of AE	85 DAYS
Severity	Severe
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
Investigator	NOT REPORTED

Alternative Etiology	
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, CONCOMITANT OR ADDITIONAL TRTMNT GIVEN

Event #2: Event of Interest - Herpes Zoster

Event Description	POST HERPETIC NEURALGIA
Preferred term	ヘルペス後神経痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 315
Age at AE Onset	4[redacted]
Laboratory Testing	NOT APPLICABLE
Microbiology	NOT APPLICABLE
SAE Supplemental Procedure	NOT APPLICABLE
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	Moderate
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
Investigator Alternative Etiology	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	CONCOMITANT OR ADDITIONAL TRTMNT GIVEN

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M17-377

本被験者は日本の 4[redacted] 歳男性であり，ABT-494（ウパダシチニブ）の治験で盲検化された治験薬が投与され，帯状疱疹を発現した。被験者は非喫煙者かつ飲酒者（2 杯未満／日）であり，関連する病歴は水痘，帯状疱疹及びアトピー性皮膚炎であった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は帯状疱疹を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，帯状疱疹は消失した。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は右顔面痛を自覚した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は耳鼻咽喉科を受診した。20[redacted] 年 [redacted] 月 [redacted] 日，右顔面に水疱が認められた。被験者はその後，帯状疱疹と診断された。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は帯状疱疹のため皮膚科を受診した。Acyclovir の点滴投与のための入院を勧められたが，被験者は拒否した。点滴治療の後にめまい感が始まり，念のため，被験者はストレッチャーで皮膚科の診療室に戻された。その後，被験者は意識を消失し，救急科に搬送された。被験者は血圧が降下しており，熱射病（非重篤）と判断され静脈内補液を受けた。

被験者の血圧は正常に復し，同日退院した。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は帯状疱疹による発熱及び倦怠感のため睡眠障害を発現し，入院した。入院中，下痢及び歩き回り（いずれも非重篤）も発現した。被験者のリンパ球は改善し，20[redacted] 年 [redacted] 月 [redacted] 日に被験者は退院した。

被験者には水痘及び帯状疱疹の病歴があった。

被験者は本事象の発現前に帯状疱疹の予防接種を受けていなかった。

ZOVIRAX OPHTHALMIC OINTMENT，BRONUCK OPHTHALMIC SOLUTION，LEVOFLOXACIN OPHTHALMIC SOLUTION，ゲンタマイシン硫酸塩，COCARL，アシクロビル，YD SOLITA-T NO. 1，静注用生理食塩液及び FAMVIR が投与された。

The patient's past medications include:

BETAMETHASONE BUTYRATE PROPINATE for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

PREDNISOLONE VALERATE ACETATE for ATOPIC DERMATITIS ([redacted] [redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

DIFLUPREDNATE for ATOPIC DERMATITIS ([redacted] [redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

NEORAL for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

BEPOTASTINE BESILATE for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

PREDNISOLONE for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] [redacted] 20[redacted])

TRIAMCINOLONE ACETONIDE for ATOPIC DERMATITIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for UPADACITINIB (Blinded)

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1) Herpes zoster (10019974) (Herpes zoster (10019974)) [v.22.1] [10019974]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for UPADACITINIB (Blinded)

Event of HERPES ZOSTER

- Investigator: Not applicable

- AbbVie: Not applicable.

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] DIRECT FLUORESCENT ANTIBODY (WOUND): (Vesicular fluid) Positive

20[redacted] LYMPHOCYTES: After hospitalization: 1.33 (no units)

Unknown date LYMPHOCYTES: Before hospitalization: 1.47 (no units)

[redacted] 20[redacted] VARICELLA VIRUS TEST: (Blood) Positive

[redacted] 20[redacted] VARICELLA VIRUS TEST: (Vesicular fluid) Positive

非重篤な有害事象

被験者はヘルペス後神経痛を発現し，治療としてアセトアミノフェンが投与された。ヘルペス後神経痛の発現による治験薬の投与変更はなかった。ヘルペス後神経痛は未回復と判断された。

M17-377 試験（投与 52 週時）

治験の標題： 中等症から重症のアトピー性皮膚炎：日本の青少年及び成人被験者を対象としたステロイド外用薬併用下のウパダシチニブの評価	
治験実施施設： 日本，42 施設	
治験調整医師： [redacted], MD	
公表文献（参考資料）： なし	
試験期間（年数）： 最初の被験者の初回来院日：2018 年 10 月 27 日 最後の被験者の最終来院日：20[redacted] 年 [redacted] 月 [redacted] 日（投与 52 週時）	開発のフェーズ：III
目的： 全身療法の対象である中等症から重症の日本人の青少年及び成人アトピー性皮膚炎患者を対象に副腎皮質ステロイド外用薬併用下のウパダシチニブの安全性を評価する。 投与 24 週時までのデータは，24 週時総括報告書に示している。 本中間報告書のデータカットオフ日は，すべての被験者の投与 52 週時来院完了が予定されていた 20[redacted] 年 [redacted] 月 [redacted] 日とした。したがって，本報告書では投与 52 週時までに得られたデータを示している。	
被験者数（計画時と解析時）： 計画時：264 名，解析時：272 名	
診断と主要な組入れ基準： 選択基準は以下のとおりであった。 1）スクリーニング来院時に 12 歳以上 75 歳以下の成人男性及び女性，2）Hanifin & Rajka の診断基準に基づく慢性アトピー性皮膚炎であり，ベースラインの 3 年以上前に発症し，3）湿疹面積重症度指数（以下「EASI」）スコア 16 以上，バリデートされた治験責任医師による包括的評価–アトピー性皮膚炎（以下「vIGA-AD」）スコア 3 以上，アトピー性皮膚炎病変の体表面積（以下「BSA」）10%以上，及び毎日の最悪のかゆみの数値評価尺度（以下「NRS」）の週平均値 4 以上，の疾患活動性基準をすべて満たし，4）ベースライン前の少なくとも 7 日間，外用エモリエント（保湿剤）を 1 日 2 回使用している，5）副腎皮質ステロイド外用薬又はカルシニューリン阻害外用薬が効果不十分であったことを示す記録がある（ベースライン来院前 6 ヵ月以内），又はアトピー性皮膚炎に対するベースライン来院前 6 ヵ月以内の全身療法の記録がある。 主要な除外基準は以下のとおりであった。 1）ベースライン前の所定期間内にアトピー性皮膚炎の治療薬（［1］4 週以内のアトピー性皮膚炎に対する全身療法，［2］半減期［既知の場合］の 5 倍又は 12 週間，どちらか長い方の期間以内の生物学的製剤，［3］4 週以内の紫外線療法，レーザー療法，タンニングブース使用，又は疾患重症度に影響する若しくは疾患評価を妨げる可能性のある長時間の日光曝露，［4］4 週以内の経口又は非経口漢方薬，［5］2 週以内のマリファナ，［6］外用エモリエント［保湿剤］を除く 7 日以内の外用薬［副腎皮質ステロイド外用薬，カルシニューリン阻害外用薬，又はホスホジエステラーゼ 4 型阻害外用薬を含むがこれらに限定されない］）を使用している，2）被験者の安全性を確保するため，スクリーニング期間中に，以下の臨床検査値を認めた被験者を除外した：血清アスパラギン酸アミノトランスフェラーゼが基準値上限（以下「ULN」）の 2 倍超，血清アラニンアミノトランスフェラーゼが ULN の 2 倍超，推算糸球体濾過率が 40 mL/min/1.73 m^2 未満（成人は 4 変数を用いた Modification of Diet in Renal Disease 簡易式，青少年は Schwartz 式に基づく），総白血球数が 2500/μL 未満，好中球数（絶対値）が 1500/μL 未満，血小板数が 100000/μL 未満，リンパ球数（絶対値）が 800/μL 未満，及びヘモグロビン量が	

10 g/dL 未満。
治験方法： 本試験は全身療法の対象である中等症から重症の日本人の青少年及び成人アトピー性皮膚炎患者を対象として，副腎皮質ステロイド外用薬併用下でウパダシチニブを評価する第 III 相，ランダム化，二重盲検，多施設共同試験であった。アトピー性皮膚炎に対する外用薬が効果不十分であったことを示す記録がある（ベースライン来院前 6 ヵ月以内），又はアトピー性皮膚炎に対するベースライン来院前 6 ヵ月以内の全身療法の記録がある患者を適格とした。 本試験は，35 日間のスクリーニング期間，16 週間の二重盲検投与期，36 週間の盲検継続投与期（投与 16 週時～投与 52 週時），及び非盲検長期継続投与期（投与 52 週時～投与 160 週時，又は製造販売承認申請の完全な中止まで継続）から構成され，治験薬の最終投与から約 30 日後に追跡調査来院を行った。 本試験は，すべての被験者が投与 52 週時を完了した後は非盲検となった。 適格性基準を満たした被験者を，3 つの治験薬投与群（ウパダシチニブ 15 mg 群，ウパダシチニブ 30 mg 群又はプラセボ群）のいずれかに 1:1:1 の割合でランダム化し，副腎皮質ステロイド外用薬併用下で 1 日 1 回（以下「QD」）経口投与した。ベースライン疾患重症度（vIGA-AD：中等症 vs. 重症）及び年齢（18 歳未満 vs. 18～40 歳 vs. 40 歳超）による層別ランダム化を行った。 投与 16 週終了時に，プラセボ群の被験者を 1:1 の割合でウパダシチニブ 15 mg 群又は 30 mg 群に再度割り付け、経口投与（QD）した。ベースライン時にウパダシチニブ 15 mg 群又は 30 mg 群に割り付けられた被験者は，長期継続投与期でもそれまでの用量を投与 160 週時の来院まで継続することとした。 副腎皮質ステロイド外用薬の治験薬との併用投与は投与 16 週時までは必須とし，投与 16 週終了後の必要性は治験責任（担当）医師の判断に基づき決定することとした。また，投与 16 週後は，ストロングクラスの副腎皮質ステロイド外用薬による治療をレスキュー治療とみなさないこととした。 投与 4 週時～投与 24 週時の間の連続する 2 回の規定来院時に EASI スコアのベースラインからの 50%以上の低下（以下「EASI 50」）を達成していない被験者に対し，医学的に必要な場合（耐え難いアトピー性皮膚炎の症状をコントロールする必要がある），治験責任（担当）医師の判断でアトピー性皮膚炎に対するレスキュー治療を行うことができることとした。投与 24 週後は，規定来院又は規定外来院時に EASI 50 を達成していない被験者に対し，全身療法のレスキュー治療を行うことができることとした。 最後の被験者が投与 24 週時来院を完了した時点で中間解析を実施した。投与 24 週時の中間解析後は，実施医療機関及び被験者は引き続き投与 52 週時まで盲検性が維持された。 2 回目の中間解析は，試験継続中の最後の被験者が投与 52 週時来院を完了した時点で実施した。本解析には，投与 52 週時までの有効性データ及び 52 週時総括報告書の中間データベース固定までの安全性データが含まれている。 外部のデータモニタリング委員会（以下「DMC」）が試験期間を通して定期的に非盲検安全性データをレビューした。DMC の主要な責務は，本試験参加中の被験者の安全を保護することであった。
被験薬，用量 / 含量 / 濃度，投与法，ロット番号： ウパダシチニブ 15 mg フイルムコート錠（経口），バルクロット番号：[redacted]，[redacted]，[redacted] ウパダシチニブ 30 mg フイルムコート錠（経口），バルクロット番号：[redacted]，[redacted]，[redacted] 治療期間：二重盲検投与期：16 週間，盲検継続投与期及び非盲検長期継続投与期：最長で投与 160 週時まで
対照薬，用量 / 含量 / 濃度，投与法，ロット番号： ウパダシチニブに対応するプラセボ，バルクロット番号：[redacted]

評価基準：

安全性：

試験期間を通して，有害事象，バイタルサインの変動，身体検査，心電図，臨床検査及び製品苦情のデータを評価した。

有効性：

有効性の主要評価項目又は副次評価項目は規定していない。

探索的評価項目は以下のとおりであった。

- vIGA-AD スコアが 0 又は 1 であり，かつベースラインと比較して 2 グレード以上改善（低下）した被験者の割合
- EASI スコアのベースラインからの 50%/75%/90%以上の低下（以下「EASI 50/75/90」）を達成した被験者の割合
- EASI のベースラインからの変化量及び変化率
- 最悪のかゆみの NRS がベースラインから 4 以上改善（低下）した被験者の割合
- 最悪のかゆみの NRS のベースラインからの変化量及び変化率

統計手法：

安全性：

安全性は，安全性解析対象集団を用い，被験者が実際に受けた投与に基づいて，二重盲検投与期，盲検継続投与期，非盲検長期継続投与期及び通期の安全性解析を実施した。成人と青少年の安全性の結果はそれぞれ分けて提示した。安全性は，有害事象，身体検査，臨床検査及びバイタルサインにより評価した。欠測値の補完は行わなかった。

有害事象は ICH 国際医薬用語集（以下「MedDRA」）を使用してコード化した。有害事象は，治験薬初回投与から治験薬最終投与後 30 日までに発現した又は重症度が悪化した事象と定義した。有害事象が発現した被験者の数及び割合を，MedDRA の器官別大分類及び基本語を用いて，重症度別及び治験責任（担当）医師が評価した治験薬との因果関係別に示した。また，重篤な有害事象，死亡，中止に至った有害事象及び特に注目すべき有害事象の要約（発現割合及び 100 人年あたりの発現件数）も提示した。治験薬投与前の有害事象についても別途要約した。

臨床検査項目及びバイタルサインについて，ベースラインからの平均変化量及び事前に規定した臨床的に重要な値に合致する被験者の割合を要約した。

有効性：

有効性の解析には，臨床的なアトピー性皮膚炎の評価の要約を用いた。仮説検定は実施しなかった。

要約 / 結論：

有効性の結果：

16 週間の二重盲検投与期の結果は，24 週時総括報告書に示した。

本試験では，16 週間の二重盲検投与期の後，36 週間の盲検継続投与期（投与 16 週時～投与 52 週時）にウパダシチニブ 15 mg QD 又は 30 mg QD を投与した。二重盲検投与期にウパダシチニブ 15 mg 又は 30 mg の投与を受けた被験者では，プラセボの投与を受けた被験者と比較して，盲検継続投与期移行時の有効性の評価項目が数値的に改善しており，また，投与 52 週時に，有効性の評価項目を達成した被験者の割合は，盲検継続投与期移行時と類似していた。二重盲検投与期にプラセボの投与を受け，盲検継続投与期及び非盲検長期継続投与期でウパダシチニブ群にランダム化された被験者は，投与 52 週時に有効性の評価項目の改善を示した。この結果は二重盲検投与期にウパダシチニブの投与を受けた被験者の投与 52 週時の結果と類似していた。

安全性の結果：

本試験では，ウパダシチニブはアトピー性皮膚炎患者に対し，おおむね安全で忍容性も良好であり，安全性の結果は 24 週時総括報告書の結果と一貫していた。本試験では，ウパダシチニブの他の適応症（関節リウマチ及び乾癬性関節炎）の試験と比較して，新たな重大な安全性の懸念は認められなかったが，ウパダシチニブの投与を受けた被験者のざ瘡の発現率は，他の適応症の試験と比較して高かった。有害事象を発現した被験者の割合は，プラセボ対照期間を通してウパダシチニブ 15 mg 群及び 30 mg 群で類似しており，プラセボ群と比較してウパダシチニブ 15 mg 群及び 30 mg 群でわずかに高かった。データカットオフ日までにウパダシチニブの投与を受けたすべての被験者では，曝露期間で調整した有害事象の発現率は，ウパダシチニブ 15 mg 群と比較してウパダシチニブ 30 mg 群でわずかに高かった。ウパダシチニブの投与を受けた被験者で最も発現率が高かった有害事象（全ウパダシチニブ投与集団で発現率が 5 件 / 100 人年以上）は，上咽頭炎，ざ瘡，帯状疱疹，単純ヘルペス，インフルエンザ，毛包炎及び発熱であった。重篤な有害事象及び治験薬の投与中止に至った有害事象の発現率は全体的に低く，2 つの投与群で類似していた。重篤な有害事象として，帯状疱疹 3 件及び虫垂炎 2 件が認められた。他の重篤な有害事象で 2 件以上認められたものはなかった。本試験中に死亡は認められなかった。

ざ瘡の発現割合はウパダシチニブの用量反応関係が認められ，プラセボ群と比較してウパダシチニブ 15 mg 群及び 30 mg 群で高かった。ざ瘡の重症度は，いずれも軽度又は中等度であった。本試験のプラセボ及びウパダシチニブの投与群全体でざ瘡の既往歴を有する被験者の割合は高かった。これは，ざ瘡の有病率が若年層で高いことに起因している可能性があり，そのことが本試験に登録されたアトピー性皮膚炎患者集団に反映されたためである。盲検継続投与期でも，ざ瘡について同様の所見が認められた。

アトピー性皮膚炎は本試験の対象疾患であるため，有害事象のアトピー性皮膚炎は既存疾患の悪化を示す。これらの事象は予期された事象であり，曝露期間で調整したアトピー性皮膚炎の発現率がウパダシチニブ 15 mg 群と比較してウパダシチニブ 30 mg 群で低かったことは，アトピー性皮膚炎に対するウパダシチニブの用量依存的な治療効果を示している可能性がある。

データカットオフ日までにウパダシチニブの投与を受けたすべての被験者では，重篤な感染症はほとんど認められず，発現リスクの用量依存性も認められなかった。大部分の日和見感染はカポジ水痘様発疹（ヘルペス性状湿疹と同義）であった。ヘルペス性状湿疹は，アトピー性皮膚炎の，稀ではあるが既知のウイルス性合併症である。帯状疱疹はヤヌスキナーゼ（以下「JAK」）阻害薬では予期される有害事象であり，その発現率は，ウパダシチニブ 15 mg 群と比較して，ウパダシチニブ 30 mg 群で高かった。

判定された主要心血管事象（出血性卒中と判定された小脳出血）はウパダシチニブ 15 mg 群の 1 名（1 件）で報告されたが，本被験者には関連するリスク因子はなかった。

全体として，貧血，好中球減少症及びクレアチンホスホキナーゼ増加の発現率はウパダシチニブ 15 mg 群と比較してウパダシチニブ 30 mg 群で高かった。これらの事象により治験薬の投与を中止した被験者はいなかった。JAK 阻害薬では，これらの臨床検査異常に対するウパダシチニブの用量依存性は予期されている。

成人及び青少年のいずれの被験者でも中等度の体重増加が認められたが，ベースラインからの平均変化量は 3.5 kg 未満であった。体重増加は成長期の青少年では予期されているものであるが，成人では様々な病因が考えられた。

データカットオフ日までにウパダシチニブの投与を受けた青少年被験者での有害事象の発現率は，ウパダシチニ

ブ 15 mg 群と比較してウパダシチニブ 30 mg 群でわずかに高かった。全体として，青少年被験者で，重篤な有害事象は 1 件（虫垂炎）認められ，治験薬の投与中止に至った有害事象は 2 件（アトピー性皮膚炎，リンパ球形態異常）認められた。特に注目すべき有害事象は，青少年被験者で 7 件認められた。内訳は，非重篤な貧血及び非重篤なクレアチンホスホキナーゼ増加が各 2 件，並びに重篤な感染症（虫垂炎），非重篤な日和見感染症（カポジ水痘様発疹として報告された）及び非重篤なリンパ球形態異常（リンパ腫の検索分類に含まれていた）が各 1 件であった。このリンパ球形態異常は，血液検査で検出された異型リンパ球によるものであり，悪性腫瘍ではなかった。全体集団と比較して青少年被験者集団に対する新たなリスクは認められなかった。

本試験では，データカットオフ日までに，悪性腫瘍，非黒色腫皮膚癌，消化管穿孔，活動性結核及び判定された血栓症関連事象は報告されなかった。

結論：

M17-377 試験では，投与 52 週時までの安全性の結果から，ウパダシチニブ 15 mg 及び 30 mg QD の忍容性は良好であった。アトピー性皮膚炎患者を対象とした本試験では，ウパダシチニブの他の適応症（関節リウマチ）の試験と比較して，非重篤なざ瘡の発現率が高かった。しかし本試験では，アトピー性皮膚炎患者の治療におけるウパダシチニブのベネフィット・リスクプロファイルに影響を与える新たな重要な安全性の懸念は認められなかった。探索的な有効性の解析結果では，プラセボと比較してウパダシチニブで数値的に高い反応率が認められ，その効果はデータカットオフ日まで持続した。盲検継続投与期及び非盲検長期継続投与期でプラセボからウパダシチニブに切り替えた被験者では，有効性の評価項目で同様の改善が認められた。データカットオフ時点の安全性及び探索的な有効性の結果に基づき，本試験のウパダシチニブ（15 mg 及び 30 mg QD）のベネフィット・リスクプロファイルは，良好と考えられた。

表 1. ウパダシチニブ投与期間中に有害事象を発現した被験者数及び発現割合：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団）

	Active		
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=133) n (%)	UPA 30 mg QD (N=136) n (%)	UPA Total (N=269) n (%)
Any adverse event	100 (75.2)	110 (80.9)	210 (78.1)
血液およびリンパ系障害	4 (3.0)	8 (5.9)	12 (4.5)
貧血	2 (1.5)	3 (2.2)	5 (1.9)
リンパ節痛	0	1 (0.7)	1 (0.4)
リンパ節症	2 (1.5)	0	2 (0.7)
リンパ球減少症	0	1 (0.7)	1 (0.4)
好中球減少症	0	4 (2.9)	4 (1.5)
心臓障害	2 (1.5)	2 (1.5)	4 (1.5)
動悸	2 (1.5)	1 (0.7)	3 (1.1)
心室性期外収縮	0	1 (0.7)	1 (0.4)
耳および迷路障害	1 (0.8)	1 (0.7)	2 (0.7)
耳鳴	1 (0.8)	0	1 (0.4)
頭位性回転性めまい	0	1 (0.7)	1 (0.4)
眼障害	7 (5.3)	4 (2.9)	11 (4.1)
アトピー性白内障	1 (0.8)	0	1 (0.4)
白内障	1 (0.8)	0	1 (0.4)
糖尿病性白内障	1 (0.8)	0	1 (0.4)
結膜充血	1 (0.8)	0	1 (0.4)
アレルギー性結膜炎	3 (2.3)	2 (1.5)	5 (1.9)
ドライアイ	0	1 (0.7)	1 (0.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
夜盲	0	1 (0.7)	1 (0.4)
胃腸障害	9 (6.8)	19 (14.0)	28 (10.4)
腹部不快感	0	3 (2.2)	3 (1.1)
腹部膨満	0	1 (0.7)	1 (0.4)
腹痛	0	3 (2.2)	3 (1.1)
上腹部痛	2 (1.5)	1 (0.7)	3 (1.1)
慢性胃炎	0	1 (0.7)	1 (0.4)
便秘	0	2 (1.5)	2 (0.7)
齲歯	2 (1.5)	2 (1.5)	4 (1.5)
下痢	1 (0.8)	5 (3.7)	6 (2.2)
消化不良	0	1 (0.7)	1 (0.4)
腸炎	0	1 (0.7)	1 (0.4)
食中毒	1 (0.8)	0	1 (0.4)
胃食道逆流性疾患	1 (0.8)	0	1 (0.4)
血便排泄	1 (0.8)	0	1 (0.4)
胃酸過多	0	1 (0.7)	1 (0.4)
単径ヘルニア	1 (0.8)	0	1 (0.4)
粘液便	1 (0.8)	0	1 (0.4)
急性膵炎	0	1 (0.7)	1 (0.4)
口内炎	0	2 (1.5)	2 (0.7)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
嘔吐	1 (0.8)	0	1 (0.4)
一般・全身障害および投与部位の状態	9 (6.8)	13 (9.6)	22 (8.2)
胸痛	0	1 (0.7)	1 (0.4)
疲労	1 (0.8)	0	1 (0.4)
倦怠感	1 (0.8)	2 (1.5)	3 (1.1)
末梢性浮腫	1 (0.8)	3 (2.2)	4 (1.5)
発熱	7 (5.3)	7 (5.1)	14 (5.2)
肝胆道系障害	1 (0.8)	0	1 (0.4)
脂肪肝	1 (0.8)	0	1 (0.4)
感染症および寄生虫症	75 (56.4)	83 (61.0)	158 (58.7)
急性副鼻腔炎	1 (0.8)	0	1 (0.4)
虫垂炎	1 (0.8)	1 (0.7)	2 (0.7)
気管支炎	1 (0.8)	3 (2.2)	4 (1.5)
よう	0	1 (0.7)	1 (0.4)
蜂巣炎	2 (1.5)	0	2 (0.7)
結膜炎	2 (1.5)	4 (2.9)	6 (2.2)
膀胱炎	2 (1.5)	3 (2.2)	5 (1.9)
爪の皮膚糸状菌症	1 (0.8)	3 (2.2)	4 (1.5)
感染性腸炎	0	1 (0.7)	1 (0.4)
丹毒	1 (0.8)	1 (0.7)	2 (0.7)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
毛包炎	9 (6.8)	4 (2.9)	13 (4.8)
せつ	6 (4.5)	2 (1.5)	8 (3.0)
胃腸炎	3 (2.3)	3 (2.2)	6 (2.2)
ウイルス性胃腸炎	1 (0.8)	1 (0.7)	2 (0.7)
陰部ヘルペス	1 (0.8)	0	1 (0.4)
歯肉炎	1 (0.8)	1 (0.7)	2 (0.7)
手足口病	0	1 (0.7)	1 (0.4)
単純ヘルペス	9 (6.8)	4 (2.9)	13 (4.8)
ヘルペスウイルス感染	1 (0.8)	0	1 (0.4)
帯状疱疹	7 (5.3)	18 (13.2)	25 (9.3)
播種性帯状疱疹	1 (0.8)	0	1 (0.4)
耳帯状疱疹	0	1 (0.7)	1 (0.4)
麦粒腫	1 (0.8)	2 (1.5)	3 (1.1)
膿痂疹	1 (0.8)	1 (0.7)	2 (0.7)
感染	1 (0.8)	1 (0.7)	2 (0.7)
インフルエンザ	6 (4.5)	11 (8.1)	17 (6.3)
カポジ水痘様発疹	7 (5.3)	3 (2.2)	10 (3.7)
伝染性軟属腫	2 (1.5)	1 (0.7)	3 (1.1)
上咽頭炎	32 (24.1)	42 (30.9)	74 (27.5)
口腔ヘルペス	3 (2.3)	6 (4.4)	9 (3.3)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
外耳炎	2 (1.5)	2 (1.5)	4 (1.5)
中耳炎	0	1 (0.7)	1 (0.4)
爪囲炎	0	2 (1.5)	2 (0.7)
歯周炎	1 (0.8)	0	1 (0.4)
咽頭炎	4 (3.0)	3 (2.2)	7 (2.6)
細菌性咽頭炎	0	1 (0.7)	1 (0.4)
ニューモシスチス・イロベチイ肺炎	1 (0.8)	0	1 (0.4)
肺炎	1 (0.8)	1 (0.7)	2 (0.7)
術後創感染	0	1 (0.7)	1 (0.4)
副鼻腔炎	0	1 (0.7)	1 (0.4)
皮膚細菌感染	1 (0.8)	1 (0.7)	2 (0.7)
皮膚カンジダ	1 (0.8)	0	1 (0.4)
皮膚感染	1 (0.8)	0	1 (0.4)
ブドウ球菌感染	1 (0.8)	0	1 (0.4)
レンサ球菌感染	0	1 (0.7)	1 (0.4)
皮下組織膿瘍	1 (0.8)	0	1 (0.4)
股部白癬	1 (0.8)	2 (1.5)	3 (1.1)
足部白癬	2 (1.5)	5 (3.7)	7 (2.6)
癜風	1 (0.8)	0	1 (0.4)
扁桃炎	3 (2.3)	2 (1.5)	5 (1.9)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
上気道感染	4 (3.0)	2 (1.5)	6 (2.2)
尿路感染	1 (0.8)	0	1 (0.4)
ウイルス性上気道感染	0	1 (0.7)	1 (0.4)
傷害、中毒および処置合併症	8 (6.0)	10 (7.4)	18 (6.7)
動物咬傷	1 (0.8)	0	1 (0.4)
節足動物咬傷	0	3 (2.2)	3 (1.1)
節足動物刺傷	1 (0.8)	0	1 (0.4)
剥離骨折	1 (0.8)	0	1 (0.4)
骨挫傷	0	1 (0.7)	1 (0.4)
挫傷	1 (0.8)	1 (0.7)	2 (0.7)
大腿骨骨折	0	1 (0.7)	1 (0.4)
足骨折	1 (0.8)	0	1 (0.4)
手骨折	1 (0.8)	1 (0.7)	2 (0.7)
熱射病	0	1 (0.7)	1 (0.4)
靭帯捻挫	0	1 (0.7)	1 (0.4)
四肢損傷	1 (0.8)	0	1 (0.4)
肉離れ	1 (0.8)	0	1 (0.4)
肋骨骨折	0	1 (0.7)	1 (0.4)
皮膚擦過傷	0	1 (0.7)	1 (0.4)
皮膚創傷	1 (0.8)	0	1 (0.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
臨床検査	18 (13.5)	19 (14.0)	37 (13.8)
アラニンアミノトランスフェラーゼ増加	3 (2.3)	5 (3.7)	8 (3.0)
アスパラギン酸アミノトランスフェラーゼ増加	2 (1.5)	3 (2.2)	5 (1.9)
血中クレアチンホスホキナーゼ増加	3 (2.3)	6 (4.4)	9 (3.3)
血中トリグリセリド増加	2 (1.5)	0	2 (0.7)
γ－グルタミルトランスフェラーゼ増加	0	1 (0.7)	1 (0.4)
ヘモグロビン減少	1 (0.8)	3 (2.2)	4 (1.5)
肝酵素上昇	1 (0.8)	0	1 (0.4)
免疫グロブリン増加	0	1 (0.7)	1 (0.4)
リンパ球形態異常	0	1 (0.7)	1 (0.4)
骨髄球存在	0	1 (0.7)	1 (0.4)
好中球数減少	2 (1.5)	2 (1.5)	4 (1.5)
尿中蛋白陽性	2 (1.5)	0	2 (0.7)
赤血球数減少	1 (0.8)	0	1 (0.4)
尿中ウロビリノーゲン増加	1 (0.8)	0	1 (0.4)
体重減少	1 (0.8)	0	1 (0.4)
体重増加	1 (0.8)	1 (0.7)	2 (0.7)
白血球数減少	1 (0.8)	2 (1.5)	3 (1.1)
代謝および栄養障害	1 (0.8)	1 (0.7)	2 (0.7)
高脂血症	1 (0.8)	0	1 (0.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
高尿酸血症	0	1 (0.7)	1 (0.4)
筋骨格系および結合組織障害	9 (6.8)	11 (8.1)	20 (7.4)
関節痛	1 (0.8)	10 (7.4)	11 (4.1)
背部痛	3 (2.3)	1 (0.7)	4 (1.5)
足変形	0	1 (0.7)	1 (0.4)
椎間板突出	1 (0.8)	0	1 (0.4)
関節腫脹	0	1 (0.7)	1 (0.4)
筋骨格系胸痛	1 (0.8)	0	1 (0.4)
筋肉痛	1 (0.8)	2 (1.5)	3 (1.1)
変形性関節症	1 (0.8)	0	1 (0.4)
四肢痛	3 (2.3)	0	3 (1.1)
滑液嚢腫	1 (0.8)	0	1 (0.4)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	7 (5.3)	1 (0.7)	8 (3.0)
平滑筋腫	1 (0.8)	0	1 (0.4)
皮膚乳頭腫	6 (4.5)	1 (0.7)	7 (2.6)
神経系障害	7 (5.3)	8 (5.9)	15 (5.6)
小脳出血	1 (0.8)	0	1 (0.4)
頚髄神経根障害	1 (0.8)	0	1 (0.4)
浮動性めまい	0	1 (0.7)	1 (0.4)
頭痛	2 (1.5)	4 (2.9)	6 (2.2)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
感覚鈍麻	1 (0.8)	0	1 (0.4)
肋間神経痛	1 (0.8)	0	1 (0.4)
片頭痛	2 (1.5)	0	2 (0.7)
ヘルペス後神経痛	0	1 (0.7)	1 (0.4)
傾眠	0	3 (2.2)	3 (1.1)
舌の麻痺	1 (0.8)	0	1 (0.4)
精神障害	4 (3.0)	2 (1.5)	6 (2.2)
注意欠陥多動性障害	0	1 (0.7)	1 (0.4)
抑うつ気分	1 (0.8)	0	1 (0.4)
うつ病	1 (0.8)	0	1 (0.4)
不眠症	1 (0.8)	0	1 (0.4)
落ち着きのなさ	0	1 (0.7)	1 (0.4)
身体症状症	1 (0.8)	0	1 (0.4)
生殖系および乳房障害	2 (1.5)	1 (0.7)	3 (1.1)
無月経	0	1 (0.7)	1 (0.4)
性器出血	1 (0.8)	0	1 (0.4)
月経過多	1 (0.8)	0	1 (0.4)
不規則月経	1 (0.8)	0	1 (0.4)
卵巣嚢胞	1 (0.8)	0	1 (0.4)
呼吸器、胸郭および縦隔障害	10 (7.5)	14 (10.3)	24 (8.9)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
喘息	2 (1.5)	7 (5.1)	9 (3.3)
慢性気管支炎	0	1 (0.7)	1 (0.4)
咳嗽	4 (3.0)	2 (1.5)	6 (2.2)
鼻出血	0	1 (0.7)	1 (0.4)
口腔咽頭痛	4 (3.0)	3 (2.2)	7 (2.6)
胸膜炎	0	1 (0.7)	1 (0.4)
気胸	0	1 (0.7)	1 (0.4)
上気道の炎症	1 (0.8)	0	1 (0.4)
皮膚および皮下組織障害	39 (29.3)	53 (39.0)	92 (34.2)
ざ瘡	23 (17.3)	44 (32.4)	67 (24.9)
脱毛症	1 (0.8)	0	1 (0.4)
水疱	1 (0.8)	1 (0.7)	2 (0.7)
皮膚嚢腫	1 (0.8)	0	1 (0.4)
アトピー性皮膚炎	7 (5.3)	6 (4.4)	13 (4.8)
接触皮膚炎	2 (1.5)	1 (0.7)	3 (1.1)
湿疹	1 (0.8)	2 (1.5)	3 (1.1)
紅斑	1 (0.8)	0	1 (0.4)
過角化	1 (0.8)	0	1 (0.4)
汗疹	1 (0.8)	2 (1.5)	3 (1.1)
口囲皮膚炎	1 (0.8)	0	1 (0.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
発疹	1 (0.8)	0	1 (0.4)
小水疱性皮疹	0	1 (0.7)	1 (0.4)
脂漏性皮膚炎	2 (1.5)	0	2 (0.7)
皮膚亀裂	0	1 (0.7)	1 (0.4)
日光皮膚炎	2 (1.5)	0	2 (0.7)
中毒性皮疹	1 (0.8)	0	1 (0.4)
蕁麻疹	3 (2.3)	4 (2.9)	7 (2.6)
接触蕁麻疹	0	1 (0.7)	1 (0.4)
血管障害	3 (2.3)	1 (0.7)	4 (1.5)
高血圧	2 (1.5)	1 (0.7)	3 (1.1)
表在性静脈炎	1 (0.8)	0	1 (0.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W52 Table 14.3__1.5.2.1

表 2. ウパダシチニブ投与期間中に有害事象を発現した被験者数及び発現割合：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団，青少年）

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=14) n (%)	Active UPA 30 mg QD (N=14) n (%)	Active UPA Total (N=28) n (%)
Any adverse event	11 (78.6)	12 (85.7)	23 (82.1)
血液およびリンパ系障害	2 (14.3)	0	2 (7.1)
貧血	2 (14.3)	0	2 (7.1)
眼障害	1 (7.1)	1 (7.1)	2 (7.1)
アレルギー性結膜炎	1 (7.1)	1 (7.1)	2 (7.1)
胃腸障害	0	2 (14.3)	2 (7.1)
腹部不快感	0	1 (7.1)	1 (3.6)
腹痛	0	1 (7.1)	1 (3.6)
腸炎	0	1 (7.1)	1 (3.6)
一般・全身障害および投与部位の状態	2 (14.3)	1 (7.1)	3 (10.7)
倦怠感	1 (7.1)	0	1 (3.6)
発熱	2 (14.3)	1 (7.1)	3 (10.7)
感染症および寄生虫症	9 (64.3)	10 (71.4)	19 (67.9)
虫垂炎	1 (7.1)	0	1 (3.6)
気管支炎	0	1 (7.1)	1 (3.6)
結膜炎	0	1 (7.1)	1 (3.6)
膀胱炎	1 (7.1)	0	1 (3.6)
感染性腸炎	0	1 (7.1)	1 (3.6)
毛包炎	0	1 (7.1)	1 (3.6)
手足口病	0	1 (7.1)	1 (3.6)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=14) n (%)	Active UPA 30 mg QD (N=14) n (%)	Active UPA Total (N=28) n (%)
単純ヘルペス	0	1 (7.1)	1 (3.6)
膿痂疹	1 (7.1)	0	1 (3.6)
インフルエンザ	2 (14.3)	2 (14.3)	4 (14.3)
カポジ水痘様発疹	1 (7.1)	0	1 (3.6)
伝染性軟属腫	1 (7.1)	1 (7.1)	2 (7.1)
上咽頭炎	3 (21.4)	6 (42.9)	9 (32.1)
外耳炎	2 (14.3)	0	2 (7.1)
中耳炎	0	1 (7.1)	1 (3.6)
咽頭炎	1 (7.1)	2 (14.3)	3 (10.7)
副鼻腔炎	0	1 (7.1)	1 (3.6)
上気道感染	3 (21.4)	1 (7.1)	4 (14.3)
ウイルス性上気道感染	0	1 (7.1)	1 (3.6)
傷害、中毒および処置合併症	1 (7.1)	3 (21.4)	4 (14.3)
節足動物咬傷	0	1 (7.1)	1 (3.6)
剥離骨折	1 (7.1)	0	1 (3.6)
挫傷	0	1 (7.1)	1 (3.6)
手骨折	0	1 (7.1)	1 (3.6)
靭帯捻挫	0	1 (7.1)	1 (3.6)
臨床検査	2 (14.3)	1 (7.1)	3 (10.7)
血中クレアチンホスホキナーゼ増加	2 (14.3)	0	2 (7.1)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=14) n (%)	Active UPA 30 mg QD (N=14) n (%)	Active UPA Total (N=28) n (%)
リンパ球形態異常	0	1 (7.1)	1 (3.6)
骨髄球存在	0	1 (7.1)	1 (3.6)
尿中蛋白陽性	1 (7.1)	0	1 (3.6)
神経系障害	0	2 (14.3)	2 (7.1)
頭痛	0	2 (14.3)	2 (7.1)
呼吸器、胸郭および縦隔障害	3 (21.4)	3 (21.4)	6 (21.4)
喘息	1 (7.1)	2 (14.3)	3 (10.7)
咳嗽	1 (7.1)	0	1 (3.6)
口腔咽頭痛	1 (7.1)	1 (7.1)	2 (7.1)
皮膚および皮下組織障害	7 (50.0)	6 (42.9)	13 (46.4)
ざ瘡	5 (35.7)	6 (42.9)	11 (39.3)
アトピー性皮膚炎	1 (7.1)	1 (7.1)	2 (7.1)
接触皮膚炎	1 (7.1)	0	1 (3.6)
湿疹	0	1 (7.1)	1 (3.6)
紅斑	1 (7.1)	0	1 (3.6)
小水疱性皮疹	0	1 (7.1)	1 (3.6)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W52 Table 14.3__1.5.2.2

表 3. ウパダシチニブ投与期間中に有害事象を発現した被験者数及び発現割合：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団，成人）

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) n (%)	Active UPA 30 mg QD (N=122) n (%)	Active UPA Total (N=241) n (%)
Any adverse event	89 (74.8)	98 (80.3)	187 (77.6)
血液およびリンパ系障害	2 (1.7)	8 (6.6)	10 (4.1)
貧血	0	3 (2.5)	3 (1.2)
リンパ節痛	0	1 (0.8)	1 (0.4)
リンパ節症	2 (1.7)	0	2 (0.8)
リンパ球減少症	0	1 (0.8)	1 (0.4)
好中球減少症	0	4 (3.3)	4 (1.7)
心臓障害	2 (1.7)	2 (1.6)	4 (1.7)
動悸	2 (1.7)	1 (0.8)	3 (1.2)
心室性期外収縮	0	1 (0.8)	1 (0.4)
耳および迷路障害	1 (0.8)	1 (0.8)	2 (0.8)
耳鳴	1 (0.8)	0	1 (0.4)
頭位性回転性めまい	0	1 (0.8)	1 (0.4)
眼障害	6 (5.0)	3 (2.5)	9 (3.7)
アトピー性白内障	1 (0.8)	0	1 (0.4)
白内障	1 (0.8)	0	1 (0.4)
糖尿病性白内障	1 (0.8)	0	1 (0.4)
結膜充血	1 (0.8)	0	1 (0.4)
アレルギー性結膜炎	2 (1.7)	1 (0.8)	3 (1.2)
ドライアイ	0	1 (0.8)	1 (0.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) n (%)	Active UPA 30 mg QD (N=122) n (%)	Active UPA Total (N=241) n (%)
夜盲	0	1 (0.8)	1 (0.4)
胃腸障害	9 (7.6)	17 (13.9)	26 (10.8)
腹部不快感	0	2 (1.6)	2 (0.8)
腹部膨満	0	1 (0.8)	1 (0.4)
腹痛	0	2 (1.6)	2 (0.8)
上腹部痛	2 (1.7)	1 (0.8)	3 (1.2)
慢性胃炎	0	1 (0.8)	1 (0.4)
便秘	0	2 (1.6)	2 (0.8)
齲歯	2 (1.7)	2 (1.6)	4 (1.7)
下痢	1 (0.8)	5 (4.1)	6 (2.5)
消化不良	0	1 (0.8)	1 (0.4)
食中毒	1 (0.8)	0	1 (0.4)
胃食道逆流性疾患	1 (0.8)	0	1 (0.4)
血便排泄	1 (0.8)	0	1 (0.4)
胃酸過多	0	1 (0.8)	1 (0.4)
単径ヘルニア	1 (0.8)	0	1 (0.4)
粘液便	1 (0.8)	0	1 (0.4)
急性膵炎	0	1 (0.8)	1 (0.4)
口内炎	0	2 (1.6)	2 (0.8)
嘔吐	1 (0.8)	0	1 (0.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) n (%)	Active UPA 30 mg QD (N=122) n (%)	Active UPA Total (N=241) n (%)
一般・全身障害および投与部位の状態	7 (5.9)	12 (9.8)	19 (7.9)
胸痛	0	1 (0.8)	1 (0.4)
疲労	1 (0.8)	0	1 (0.4)
倦怠感	0	2 (1.6)	2 (0.8)
末梢性浮腫	1 (0.8)	3 (2.5)	4 (1.7)
発熱	5 (4.2)	6 (4.9)	11 (4.6)
肝胆道系障害	1 (0.8)	0	1 (0.4)
脂肪肝	1 (0.8)	0	1 (0.4)
感染症および寄生虫症	66 (55.5)	73 (59.8)	139 (57.7)
急性副鼻腔炎	1 (0.8)	0	1 (0.4)
虫垂炎	0	1 (0.8)	1 (0.4)
気管支炎	1 (0.8)	2 (1.6)	3 (1.2)
よう	0	1 (0.8)	1 (0.4)
蜂巣炎	2 (1.7)	0	2 (0.8)
結膜炎	2 (1.7)	3 (2.5)	5 (2.1)
膀胱炎	1 (0.8)	3 (2.5)	4 (1.7)
爪の皮膚糸状菌症	1 (0.8)	3 (2.5)	4 (1.7)
丹毒	1 (0.8)	1 (0.8)	2 (0.8)
毛包炎	9 (7.6)	3 (2.5)	12 (5.0)
せつ	6 (5.0)	2 (1.6)	8 (3.3)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) n (%)	Active UPA 30 mg QD (N=122) n (%)	Active UPA Total (N=241) n (%)
胃腸炎	3 (2.5)	3 (2.5)	6 (2.5)
ウイルス性胃腸炎	1 (0.8)	1 (0.8)	2 (0.8)
陰部ヘルペス	1 (0.8)	0	1 (0.4)
歯肉炎	1 (0.8)	1 (0.8)	2 (0.8)
単純ヘルペス	9 (7.6)	3 (2.5)	12 (5.0)
ヘルペスウイルス感染	1 (0.8)	0	1 (0.4)
帯状疱疹	7 (5.9)	18 (14.8)	25 (10.4)
播種性帯状疱疹	1 (0.8)	0	1 (0.4)
耳帯状疱疹	0	1 (0.8)	1 (0.4)
麦粒腫	1 (0.8)	2 (1.6)	3 (1.2)
膿痂疹	0	1 (0.8)	1 (0.4)
感染	1 (0.8)	1 (0.8)	2 (0.8)
インフルエンザ	4 (3.4)	9 (7.4)	13 (5.4)
カポジ水痘様発疹	6 (5.0)	3 (2.5)	9 (3.7)
伝染性軟属腫	1 (0.8)	0	1 (0.4)
上咽頭炎	29 (24.4)	36 (29.5)	65 (27.0)
口腔ヘルペス	3 (2.5)	6 (4.9)	9 (3.7)
外耳炎	0	2 (1.6)	2 (0.8)
爪囲炎	0	2 (1.6)	2 (0.8)
歯周炎	1 (0.8)	0	1 (0.4)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) n (%)	Active UPA 30 mg QD (N=122) n (%)	Active UPA Total (N=241) n (%)
咽頭炎	3 (2.5)	1 (0.8)	4 (1.7)
細菌性咽頭炎	0	1 (0.8)	1 (0.4)
ニューモシスチス・イロベチイ肺炎	1 (0.8)	0	1 (0.4)
肺炎	1 (0.8)	1 (0.8)	2 (0.8)
術後創感染	0	1 (0.8)	1 (0.4)
皮膚細菌感染	1 (0.8)	1 (0.8)	2 (0.8)
皮膚カンジダ	1 (0.8)	0	1 (0.4)
皮膚感染	1 (0.8)	0	1 (0.4)
ブドウ球菌感染	1 (0.8)	0	1 (0.4)
レンサ球菌感染	0	1 (0.8)	1 (0.4)
皮下組織膿瘍	1 (0.8)	0	1 (0.4)
股部白癬	1 (0.8)	2 (1.6)	3 (1.2)
足部白癬	2 (1.7)	5 (4.1)	7 (2.9)
癜風	1 (0.8)	0	1 (0.4)
扁桃炎	3 (2.5)	2 (1.6)	5 (2.1)
上気道感染	1 (0.8)	1 (0.8)	2 (0.8)
尿路感染	1 (0.8)	0	1 (0.4)
傷害、中毒および処置合併症	7 (5.9)	7 (5.7)	14 (5.8)
動物咬傷	1 (0.8)	0	1 (0.4)
節足動物咬傷	0	2 (1.6)	2 (0.8)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) n (%)	Active UPA 30 mg QD (N=122) n (%)	Active UPA Total (N=241) n (%)
節足動物刺傷	1 (0.8)	0	1 (0.4)
骨挫傷	0	1 (0.8)	1 (0.4)
挫傷	1 (0.8)	0	1 (0.4)
大腿骨骨折	0	1 (0.8)	1 (0.4)
足骨折	1 (0.8)	0	1 (0.4)
手骨折	1 (0.8)	0	1 (0.4)
熱射病	0	1 (0.8)	1 (0.4)
四肢損傷	1 (0.8)	0	1 (0.4)
肉離れ	1 (0.8)	0	1 (0.4)
肋骨骨折	0	1 (0.8)	1 (0.4)
皮膚擦過傷	0	1 (0.8)	1 (0.4)
皮膚創傷	1 (0.8)	0	1 (0.4)
臨床検査	16 (13.4)	18 (14.8)	34 (14.1)
アラニンアミノトランスフェラーゼ増加	3 (2.5)	5 (4.1)	8 (3.3)
アスパラギン酸アミノトランスフェラーゼ増加	2 (1.7)	3 (2.5)	5 (2.1)
血中クレアチンホスホキナーゼ増加	1 (0.8)	6 (4.9)	7 (2.9)
血中トリグリセリド増加	2 (1.7)	0	2 (0.8)
γ－グルタミルトランスフェラーゼ増加	0	1 (0.8)	1 (0.4)
ヘモグロビン減少	1 (0.8)	3 (2.5)	4 (1.7)
肝酵素上昇	1 (0.8)	0	1 (0.4)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) n (%)	Active UPA 30 mg QD (N=122) n (%)	Active UPA Total (N=241) n (%)
免疫グロブリン増加	0	1 (0.8)	1 (0.4)
好中球数減少	2 (1.7)	2 (1.6)	4 (1.7)
尿中蛋白陽性	1 (0.8)	0	1 (0.4)
赤血球数減少	1 (0.8)	0	1 (0.4)
尿中ウロビリノーゲン増加	1 (0.8)	0	1 (0.4)
体重減少	1 (0.8)	0	1 (0.4)
体重増加	1 (0.8)	1 (0.8)	2 (0.8)
白血球数減少	1 (0.8)	2 (1.6)	3 (1.2)
代謝および栄養障害	1 (0.8)	1 (0.8)	2 (0.8)
高脂血症	1 (0.8)	0	1 (0.4)
高尿酸血症	0	1 (0.8)	1 (0.4)
筋骨格系および結合組織障害	9 (7.6)	11 (9.0)	20 (8.3)
関節痛	1 (0.8)	10 (8.2)	11 (4.6)
背部痛	3 (2.5)	1 (0.8)	4 (1.7)
足変形	0	1 (0.8)	1 (0.4)
椎間板突出	1 (0.8)	0	1 (0.4)
関節腫脹	0	1 (0.8)	1 (0.4)
筋骨格系胸痛	1 (0.8)	0	1 (0.4)
筋肉痛	1 (0.8)	2 (1.6)	3 (1.2)
変形性関節症	1 (0.8)	0	1 (0.4)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) n (%)	Active UPA 30 mg QD (N=122) n (%)	Active UPA Total (N=241) n (%)
四肢痛	3 (2.5)	0	3 (1.2)
滑液嚢腫	1 (0.8)	0	1 (0.4)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	7 (5.9)	1 (0.8)	8 (3.3)
平滑筋腫	1 (0.8)	0	1 (0.4)
皮膚乳頭腫	6 (5.0)	1 (0.8)	7 (2.9)
神経系障害	7 (5.9)	6 (4.9)	13 (5.4)
小脳出血	1 (0.8)	0	1 (0.4)
頚髄神経根障害	1 (0.8)	0	1 (0.4)
浮動性めまい	0	1 (0.8)	1 (0.4)
頭痛	2 (1.7)	2 (1.6)	4 (1.7)
感覚鈍麻	1 (0.8)	0	1 (0.4)
肋間神経痛	1 (0.8)	0	1 (0.4)
片頭痛	2 (1.7)	0	2 (0.8)
ヘルペス後神経痛	0	1 (0.8)	1 (0.4)
傾眠	0	3 (2.5)	3 (1.2)
舌の麻痺	1 (0.8)	0	1 (0.4)
精神障害	4 (3.4)	2 (1.6)	6 (2.5)
注意欠陥多動性障害	0	1 (0.8)	1 (0.4)
抑うつ気分	1 (0.8)	0	1 (0.4)
うつ病	1 (0.8)	0	1 (0.4)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) n (%)	Active UPA 30 mg QD (N=122) n (%)	Active UPA Total (N=241) n (%)
不眠症	1 (0.8)	0	1 (0.4)
落ち着きのなさ	0	1 (0.8)	1 (0.4)
身体症状症	1 (0.8)	0	1 (0.4)
生殖系および乳房障害	2 (1.7)	1 (0.8)	3 (1.2)
無月経	0	1 (0.8)	1 (0.4)
性器出血	1 (0.8)	0	1 (0.4)
月経過多	1 (0.8)	0	1 (0.4)
不規則月経	1 (0.8)	0	1 (0.4)
卵巣嚢胞	1 (0.8)	0	1 (0.4)
呼吸器、胸郭および縦隔障害	7 (5.9)	11 (9.0)	18 (7.5)
喘息	1 (0.8)	5 (4.1)	6 (2.5)
慢性気管支炎	0	1 (0.8)	1 (0.4)
咳嗽	3 (2.5)	2 (1.6)	5 (2.1)
鼻出血	0	1 (0.8)	1 (0.4)
口腔咽頭痛	3 (2.5)	2 (1.6)	5 (2.1)
胸膜炎	0	1 (0.8)	1 (0.4)
気胸	0	1 (0.8)	1 (0.4)
上気道の炎症	1 (0.8)	0	1 (0.4)
皮膚および皮下組織障害	32 (26.9)	47 (38.5)	79 (32.8)
ざ瘡	18 (15.1)	38 (31.1)	56 (23.2)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) n (%)	Active UPA 30 mg QD (N=122) n (%)	Active UPA Total (N=241) n (%)
脱毛症	1 (0.8)	0	1 (0.4)
水疱	1 (0.8)	1 (0.8)	2 (0.8)
皮膚嚢腫	1 (0.8)	0	1 (0.4)
アトピー性皮膚炎	6 (5.0)	5 (4.1)	11 (4.6)
接触皮膚炎	1 (0.8)	1 (0.8)	2 (0.8)
湿疹	1 (0.8)	1 (0.8)	2 (0.8)
過角化	1 (0.8)	0	1 (0.4)
汗疹	1 (0.8)	2 (1.6)	3 (1.2)
口囲皮膚炎	1 (0.8)	0	1 (0.4)
発疹	1 (0.8)	0	1 (0.4)
脂漏性皮膚炎	2 (1.7)	0	2 (0.8)
皮膚亀裂	0	1 (0.8)	1 (0.4)
日光皮膚炎	2 (1.7)	0	2 (0.8)
中毒性皮疹	1 (0.8)	0	1 (0.4)
蕁麻疹	3 (2.5)	4 (3.3)	7 (2.9)
接触蕁麻疹	0	1 (0.8)	1 (0.4)
血管障害	3 (2.5)	1 (0.8)	4 (1.7)
高血圧	2 (1.7)	1 (0.8)	3 (1.2)
表在性静脈炎	1 (0.8)	0	1 (0.4)

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Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W52 Table 14.3__1.5.2.3

表 4. ウパダシチニブ投与期間中の有害事象の 100 人年あたりの発現率：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団）

	Active		
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=133) (PYS=151.2) Events (E/100PY)	UPA 30 mg QD (N=136) (PYS=149.7) Events (E/100PY)	UPA Total (N=269) (PYS=300.9) Events (E/100PY)
Any adverse event	339 (224.2)	386 (257.8)	725 (240.9)
血液およびリンパ系障害	4 (2.6)	12 (8.0)	16 (5.3)
貧血	2 (1.3)	4 (2.7)	6 (2.0)
リンパ節痛	0	1 (0.7)	1 (0.3)
リンパ節症	2 (1.3)	0	2 (0.7)
リンパ球減少症	0	1 (0.7)	1 (0.3)
好中球減少症	0	6 (4.0)	6 (2.0)
心臓障害	2 (1.3)	2 (1.3)	4 (1.3)
動悸	2 (1.3)	1 (0.7)	3 (1.0)
心室性期外収縮	0	1 (0.7)	1 (0.3)
耳および迷路障害	1 (0.7)	1 (0.7)	2 (0.7)
耳鳴	1 (0.7)	0	1 (0.3)
頭位性回転性めまい	0	1 (0.7)	1 (0.3)
眼障害	8 (5.3)	4 (2.7)	12 (4.0)
アトピー性白内障	1 (0.7)	0	1 (0.3)
白内障	1 (0.7)	0	1 (0.3)
糖尿病性白内障	1 (0.7)	0	1 (0.3)
結膜充血	1 (0.7)	0	1 (0.3)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=151.2) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=149.7) Events (E/100PY)	Active UPA Total (N=269) (PYS=300.9) Events (E/100PY)
アレルギー性結膜炎	4 (2.6)	2 (1.3)	6 (2.0)
ドライアイ	0	1 (0.7)	1 (0.3)
夜盲	0	1 (0.7)	1 (0.3)
胃腸障害	11 (7.3)	25 (16.7)	36 (12.0)
腹部不快感	0	3 (2.0)	3 (1.0)
腹部膨満	0	1 (0.7)	1 (0.3)
腹痛	0	3 (2.0)	3 (1.0)
上腹部痛	2 (1.3)	1 (0.7)	3 (1.0)
慢性胃炎	0	1 (0.7)	1 (0.3)
便秘	0	2 (1.3)	2 (0.7)
齲歯	2 (1.3)	2 (1.3)	4 (1.3)
下痢	1 (0.7)	5 (3.3)	6 (2.0)
消化不良	0	1 (0.7)	1 (0.3)
腸炎	0	1 (0.7)	1 (0.3)
食中毒	1 (0.7)	0	1 (0.3)
胃食道逆流性疾患	1 (0.7)	0	1 (0.3)
血便排泄	1 (0.7)	0	1 (0.3)
胃酸過多	0	1 (0.7)	1 (0.3)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=151.2) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=149.7) Events (E/100PY)	Active UPA Total (N=269) (PYS=300.9) Events (E/100PY)
鼠径ヘルニア	1 (0.7)	0	1 (0.3)
粘液便	1 (0.7)	0	1 (0.3)
急性膵炎	0	1 (0.7)	1 (0.3)
口内炎	0	3 (2.0)	3 (1.0)
嘔吐	1 (0.7)	0	1 (0.3)
一般・全身障害および投与部位の状態	11 (7.3)	13 (8.7)	24 (8.0)
胸痛	0	1 (0.7)	1 (0.3)
疲労	1 (0.7)	0	1 (0.3)
倦怠感	1 (0.7)	2 (1.3)	3 (1.0)
末梢性浮腫	1 (0.7)	3 (2.0)	4 (1.3)
発熱	8 (5.3)	7 (4.7)	15 (5.0)
肝胆道系障害	1 (0.7)	0	1 (0.3)
脂肪肝	1 (0.7)	0	1 (0.3)
感染症および寄生虫症	156 (103.2)	174 (116.2)	330 (109.7)
急性副鼻腔炎	1 (0.7)	0	1 (0.3)
虫垂炎	1 (0.7)	1 (0.7)	2 (0.7)
気管支炎	1 (0.7)	3 (2.0)	4 (1.3)
よう	0	1 (0.7)	1 (0.3)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=151.2) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=149.7) Events (E/100PY)	Active UPA Total (N=269) (PYS=300.9) Events (E/100PY)
蜂巣炎	2 (1.3)	0	2 (0.7)
結膜炎	2 (1.3)	4 (2.7)	6 (2.0)
膀胱炎	2 (1.3)	3 (2.0)	5 (1.7)
爪の皮膚糸状菌症	1 (0.7)	3 (2.0)	4 (1.3)
感染性腸炎	0	1 (0.7)	1 (0.3)
丹毒	1 (0.7)	2 (1.3)	3 (1.0)
毛包炎	11 (7.3)	4 (2.7)	15 (5.0)
せつ	6 (4.0)	3 (2.0)	9 (3.0)
胃腸炎	3 (2.0)	3 (2.0)	6 (2.0)
ウイルス性胃腸炎	2 (1.3)	1 (0.7)	3 (1.0)
陰部ヘルペス	1 (0.7)	0	1 (0.3)
歯肉炎	1 (0.7)	2 (1.3)	3 (1.0)
手足口病	0	1 (0.7)	1 (0.3)
単純ヘルペス	14 (9.3)	7 (4.7)	21 (7.0)
ヘルペスウイルス感染	1 (0.7)	0	1 (0.3)
帯状疱疹	7 (4.6)	19 (12.7)	26 (8.6)
播種性帯状疱疹	1 (0.7)	0	1 (0.3)
耳帯状疱疹	0	1 (0.7)	1 (0.3)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=151.2) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=149.7) Events (E/100PY)	Active UPA Total (N=269) (PYS=300.9) Events (E/100PY)
麦粒腫	1 (0.7)	2 (1.3)	3 (1.0)
膿痂疹	1 (0.7)	1 (0.7)	2 (0.7)
感染	1 (0.7)	1 (0.7)	2 (0.7)
インフルエンザ	6 (4.0)	11 (7.3)	17 (5.6)
カポジ水痘様発疹	9 (6.0)	3 (2.0)	12 (4.0)
伝染性軟属腫	2 (1.3)	1 (0.7)	3 (1.0)
上咽頭炎	44 (29.1)	59 (39.4)	103 (34.2)
口腔ヘルペス	5 (3.3)	9 (6.0)	14 (4.7)
外耳炎	2 (1.3)	2 (1.3)	4 (1.3)
中耳炎	0	1 (0.7)	1 (0.3)
爪囲炎	0	2 (1.3)	2 (0.7)
歯周炎	1 (0.7)	0	1 (0.3)
咽頭炎	4 (2.6)	4 (2.7)	8 (2.7)
細菌性咽頭炎	0	1 (0.7)	1 (0.3)
ニューモシスチス・イロベチイ肺炎	1 (0.7)	0	1 (0.3)
肺炎	1 (0.7)	1 (0.7)	2 (0.7)
術後創感染	0	1 (0.7)	1 (0.3)
副鼻腔炎	0	1 (0.7)	1 (0.3)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=151.2) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=149.7) Events (E/100PY)	Active UPA Total (N=269) (PYS=300.9) Events (E/100PY)
皮膚細菌感染	1 (0.7)	1 (0.7)	2 (0.7)
皮膚カンジダ	1 (0.7)	0	1 (0.3)
皮膚感染	1 (0.7)	0	1 (0.3)
ブドウ球菌感染	1 (0.7)	0	1 (0.3)
レンサ球菌感染	0	1 (0.7)	1 (0.3)
皮下組織膿瘍	1 (0.7)	0	1 (0.3)
股部白癬	1 (0.7)	2 (1.3)	3 (1.0)
足部白癬	2 (1.3)	5 (3.3)	7 (2.3)
癜風	1 (0.7)	0	1 (0.3)
扁桃炎	6 (4.0)	3 (2.0)	9 (3.0)
上気道感染	4 (2.6)	2 (1.3)	6 (2.0)
尿路感染	1 (0.7)	0	1 (0.3)
ウイルス性上気道感染	0	1 (0.7)	1 (0.3)
傷害、中毒および処置合併症	9 (6.0)	11 (7.3)	20 (6.6)
動物咬傷	1 (0.7)	0	1 (0.3)
節足動物咬傷	0	3 (2.0)	3 (1.0)
節足動物刺傷	1 (0.7)	0	1 (0.3)
剥離骨折	1 (0.7)	0	1 (0.3)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=151.2) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=149.7) Events (E/100PY)	Active UPA Total (N=269) (PYS=300.9) Events (E/100PY)
骨挫傷	0	1 (0.7)	1 (0.3)
挫傷	1 (0.7)	1 (0.7)	2 (0.7)
大腿骨骨折	0	1 (0.7)	1 (0.3)
足骨折	1 (0.7)	0	1 (0.3)
手骨折	1 (0.7)	1 (0.7)	2 (0.7)
熱射病	0	1 (0.7)	1 (0.3)
靱帯捻挫	0	1 (0.7)	1 (0.3)
四肢損傷	1 (0.7)	0	1 (0.3)
肉離れ	1 (0.7)	0	1 (0.3)
肋骨骨折	0	1 (0.7)	1 (0.3)
皮膚擦過傷	0	1 (0.7)	1 (0.3)
皮膚創傷	1 (0.7)	0	1 (0.3)
臨床検査	23 (15.2)	28 (18.7)	51 (16.9)
アラニンアミノトランスフェラーゼ増加	4 (2.6)	6 (4.0)	10 (3.3)
アスパラギン酸アミノトランスフェラーゼ増加	2 (1.3)	3 (2.0)	5 (1.7)
血中クレアチンホスホキナーゼ増加	3 (2.0)	6 (4.0)	9 (3.0)
血中トリグリセリド増加	2 (1.3)	0	2 (0.7)
γ-グルタミルトランスフェラーゼ増加	0	2 (1.3)	2 (0.7)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=151.2) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=149.7) Events (E/100PY)	Active UPA Total (N=269) (PYS=300.9) Events (E/100PY)
ヘモグロビン減少	2 (1.3)	3 (2.0)	5 (1.7)
肝酵素上昇	1 (0.7)	0	1 (0.3)
免疫グロブリン増加	0	1 (0.7)	1 (0.3)
リンパ球形態異常	0	1 (0.7)	1 (0.3)
骨髄球存在	0	1 (0.7)	1 (0.3)
好中球数減少	2 (1.3)	2 (1.3)	4 (1.3)
尿中蛋白陽性	2 (1.3)	0	2 (0.7)
赤血球数減少	1 (0.7)	0	1 (0.3)
尿中ウロビリノーゲン増加	1 (0.7)	0	1 (0.3)
体重減少	1 (0.7)	0	1 (0.3)
体重増加	1 (0.7)	1 (0.7)	2 (0.7)
白血球数減少	1 (0.7)	2 (1.3)	3 (1.0)
代謝および栄養障害	1 (0.7)	1 (0.7)	2 (0.7)
高脂血症	1 (0.7)	0	1 (0.3)
高尿酸血症	0	1 (0.7)	1 (0.3)
筋骨格系および結合組織障害	12 (7.9)	17 (11.4)	29 (9.6)
関節痛	1 (0.7)	12 (8.0)	13 (4.3)
背部痛	3 (2.0)	1 (0.7)	4 (1.3)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=151.2) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=149.7) Events (E/100PY)	Active UPA Total (N=269) (PYS=300.9) Events (E/100PY)
足変形	0	1 (0.7)	1 (0.3)
椎間板突出	1 (0.7)	0	1 (0.3)
関節腫脹	0	1 (0.7)	1 (0.3)
筋骨格系胸痛	1 (0.7)	0	1 (0.3)
筋肉痛	1 (0.7)	2 (1.3)	3 (1.0)
変形性関節症	1 (0.7)	0	1 (0.3)
四肢痛	3 (2.0)	0	3 (1.0)
滑液嚢腫	1 (0.7)	0	1 (0.3)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	7 (4.6)	1 (0.7)	8 (2.7)
平滑筋腫	1 (0.7)	0	1 (0.3)
皮膚乳頭腫	6 (4.0)	1 (0.7)	7 (2.3)
神経系障害	12 (7.9)	9 (6.0)	21 (7.0)
小脳出血	1 (0.7)	0	1 (0.3)
頚髄神経根障害	1 (0.7)	0	1 (0.3)
浮動性めまい	0	1 (0.7)	1 (0.3)
頭痛	5 (3.3)	4 (2.7)	9 (3.0)
感覚鈍麻	1 (0.7)	0	1 (0.3)
肋間神経痛	1 (0.7)	0	1 (0.3)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=151.2) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=149.7) Events (E/100PY)	Active UPA Total (N=269) (PYS=300.9) Events (E/100PY)
片頭痛	2 (1.3)	0	2 (0.7)
ヘルペス後神経痛	0	1 (0.7)	1 (0.3)
傾眠	0	3 (2.0)	3 (1.0)
舌の麻痺	1 (0.7)	0	1 (0.3)
精神障害	4 (2.6)	2 (1.3)	6 (2.0)
注意欠陥多動性障害	0	1 (0.7)	1 (0.3)
抑うつ気分	1 (0.7)	0	1 (0.3)
うつ病	1 (0.7)	0	1 (0.3)
不眠症	1 (0.7)	0	1 (0.3)
落ち着きのなさ	0	1 (0.7)	1 (0.3)
身体症状症	1 (0.7)	0	1 (0.3)
生殖系および乳房障害	4 (2.6)	1 (0.7)	5 (1.7)
無月経	0	1 (0.7)	1 (0.3)
性器出血	1 (0.7)	0	1 (0.3)
月経過多	1 (0.7)	0	1 (0.3)
不規則月経	1 (0.7)	0	1 (0.3)
卵巣嚢胞	1 (0.7)	0	1 (0.3)
呼吸器、胸郭および縦隔障害	12 (7.9)	17 (11.4)	29 (9.6)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=151.2) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=149.7) Events (E/100PY)	Active UPA Total (N=269) (PYS=300.9) Events (E/100PY)
喘息	2 (1.3)	8 (5.3)	10 (3.3)
慢性気管支炎	0	1 (0.7)	1 (0.3)
咳嗽	5 (3.3)	2 (1.3)	7 (2.3)
鼻出血	0	1 (0.7)	1 (0.3)
口腔咽頭痛	4 (2.6)	3 (2.0)	7 (2.3)
胸膜炎	0	1 (0.7)	1 (0.3)
気胸	0	1 (0.7)	1 (0.3)
上気道の炎症	1 (0.7)	0	1 (0.3)
皮膚および皮下組織障害	58 (38.4)	67 (44.7)	125 (41.5)
ざ瘡	29 (19.2)	46 (30.7)	75 (24.9)
脱毛症	1 (0.7)	0	1 (0.3)
水疱	1 (0.7)	1 (0.7)	2 (0.7)
皮膚嚢腫	1 (0.7)	0	1 (0.3)
アトピー性皮膚炎	7 (4.6)	6 (4.0)	13 (4.3)
接触皮膚炎	2 (1.3)	1 (0.7)	3 (1.0)
湿疹	1 (0.7)	2 (1.3)	3 (1.0)
紅斑	1 (0.7)	0	1 (0.3)
過角化	2 (1.3)	0	2 (0.7)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=151.2) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=149.7) Events (E/100PY)	Active UPA Total (N=269) (PYS=300.9) Events (E/100PY)
汗疹	1 (0.7)	2 (1.3)	3 (1.0)
口囲皮膚炎	1 (0.7)	0	1 (0.3)
発疹	2 (1.3)	0	2 (0.7)
小水疱性皮疹	0	1 (0.7)	1 (0.3)
脂漏性皮膚炎	2 (1.3)	0	2 (0.7)
皮膚亀裂	0	1 (0.7)	1 (0.3)
日光皮膚炎	2 (1.3)	0	2 (0.7)
中毒性皮疹	1 (0.7)	0	1 (0.3)
蕁麻疹	4 (2.6)	6 (4.0)	10 (3.3)
接触蕁麻疹	0	1 (0.7)	1 (0.3)
血管障害	3 (2.0)	1 (0.7)	4 (1.3)
高血圧	2 (1.3)	1 (0.7)	3 (1.0)
表在性静脈炎	1 (0.7)	0	1 (0.3)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W52 Table 14.3__1.6.2.1

表 5. ウパダシチニブ投与期間中の有害事象の 100 人年あたりの発現率：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団，青少年）

	Active		
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=14) (PYS=17.0) Events (E/100PY)	UPA 30 mg QD (N=14) (PYS=14.6) Events (E/100PY)	UPA Total (N=28) (PYS=31.6) Events (E/100PY)
Any adverse event	41 (240.6)	48 (329.1)	89 (281.4)
血液およびリンパ系障害	2 (11.7)	0	2 (6.3)
貧血	2 (11.7)	0	2 (6.3)
眼障害	2 (11.7)	1 (6.9)	3 (9.5)
アレルギー性結膜炎	2 (11.7)	1 (6.9)	3 (9.5)
胃腸障害	0	3 (20.6)	3 (9.5)
腹部不快感	0	1 (6.9)	1 (3.2)
腹痛	0	1 (6.9)	1 (3.2)
腸炎	0	1 (6.9)	1 (3.2)
一般・全身障害および投与部位の状態	3 (17.6)	1 (6.9)	4 (12.6)
倦怠感	1 (5.9)	0	1 (3.2)
発熱	2 (11.7)	1 (6.9)	3 (9.5)
感染症および寄生虫症	18 (105.6)	23 (157.7)	41 (129.6)
虫垂炎	1 (5.9)	0	1 (3.2)
気管支炎	0	1 (6.9)	1 (3.2)
結膜炎	0	1 (6.9)	1 (3.2)
膀胱炎	1 (5.9)	0	1 (3.2)
感染性腸炎	0	1 (6.9)	1 (3.2)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=14) (PYS=17.0) Events (E/100PY)	Active UPA 30 mg QD (N=14) (PYS=14.6) Events (E/100PY)	Active UPA Total (N=28) (PYS=31.6) Events (E/100PY)
毛包炎	0	1 (6.9)	1 (3.2)
手足口病	0	1 (6.9)	1 (3.2)
単純ヘルペス	0	1 (6.9)	1 (3.2)
膿痂疹	1 (5.9)	0	1 (3.2)
インフルエンザ	2 (11.7)	2 (13.7)	4 (12.6)
カポジ水痘様発疹	1 (5.9)	0	1 (3.2)
伝染性軟属腫	1 (5.9)	1 (6.9)	2 (6.3)
上咽頭炎	5 (29.3)	7 (48.0)	12 (37.9)
外耳炎	2 (11.7)	0	2 (6.3)
中耳炎	0	1 (6.9)	1 (3.2)
咽頭炎	1 (5.9)	3 (20.6)	4 (12.6)
副鼻腔炎	0	1 (6.9)	1 (3.2)
上気道感染	3 (17.6)	1 (6.9)	4 (12.6)
ウイルス性上気道感染	0	1 (6.9)	1 (3.2)
傷害、中毒および処置合併症	1 (5.9)	4 (27.4)	5 (15.8)
節足動物咬傷	0	1 (6.9)	1 (3.2)
剥離骨折	1 (5.9)	0	1 (3.2)
挫傷	0	1 (6.9)	1 (3.2)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=14) (PYS=17.0) Events (E/100PY)	Active UPA 30 mg QD (N=14) (PYS=14.6) Events (E/100PY)	Active UPA Total (N=28) (PYS=31.6) Events (E/100PY)
手骨折	0	1 (6.9)	1 (3.2)
靭帯捻挫	0	1 (6.9)	1 (3.2)
臨床検査	3 (17.6)	2 (13.7)	5 (15.8)
血中クレアチンホスホキナーゼ増加	2 (11.7)	0	2 (6.3)
リンパ球形態異常	0	1 (6.9)	1 (3.2)
骨髄球存在	0	1 (6.9)	1 (3.2)
尿中蛋白陽性	1 (5.9)	0	1 (3.2)
神経系障害	0	2 (13.7)	2 (6.3)
頭痛	0	2 (13.7)	2 (6.3)
呼吸器、胸郭および縦隔障害	4 (23.5)	3 (20.6)	7 (22.1)
喘息	1 (5.9)	2 (13.7)	3 (9.5)
咳嗽	2 (11.7)	0	2 (6.3)
口腔咽頭痛	1 (5.9)	1 (6.9)	2 (6.3)
皮膚および皮下組織障害	8 (46.9)	9 (61.7)	17 (53.8)
ざ瘡	5 (29.3)	6 (41.1)	11 (34.8)
アトピー性皮膚炎	1 (5.9)	1 (6.9)	2 (6.3)
接触皮膚炎	1 (5.9)	0	1 (3.2)
湿疹	0	1 (6.9)	1 (3.2)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=14) (PYS=17.0) Events (E/100PY)	Active UPA 30 mg QD (N=14) (PYS=14.6) Events (E/100PY)	Active UPA Total (N=28) (PYS=31.6) Events (E/100PY)
紅斑	1 (5.9)	0	1 (3.2)
小水疱性皮疹	0	1 (6.9)	1 (3.2)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W52 Table 14.3__1.6.2.2

表 6. ウパダシチニブ投与期間中の有害事象の 100 人年あたりの発現率：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団, 成人）

	Active		
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=119) (PYS=134.2) Events (E/100PY)	UPA 30 mg QD (N=122) (PYS=135.1) Events (E/100PY)	UPA Total (N=241) (PYS=269.3) Events (E/100PY)
Any adverse event	298 (222.1)	338 (250.1)	636 (236.2)
血液およびリンパ系障害	2 (1.5)	12 (8.9)	14 (5.2)
貧血	0	4 (3.0)	4 (1.5)
リンパ節痛	0	1 (0.7)	1 (0.4)
リンパ節症	2 (1.5)	0	2 (0.7)
リンパ球減少症	0	1 (0.7)	1 (0.4)
好中球減少症	0	6 (4.4)	6 (2.2)
心臓障害	2 (1.5)	2 (1.5)	4 (1.5)
動悸	2 (1.5)	1 (0.7)	3 (1.1)
心室性期外収縮	0	1 (0.7)	1 (0.4)
耳および迷路障害	1 (0.7)	1 (0.7)	2 (0.7)
耳鳴	1 (0.7)	0	1 (0.4)
頭位性回転性めまい	0	1 (0.7)	1 (0.4)
眼障害	6 (4.5)	3 (2.2)	9 (3.3)
アトピー性白内障	1 (0.7)	0	1 (0.4)
白内障	1 (0.7)	0	1 (0.4)
糖尿病性白内障	1 (0.7)	0	1 (0.4)
結膜充血	1 (0.7)	0	1 (0.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) (PYS=134.2) Events (E/100PY)	Active UPA 30 mg QD (N=122) (PYS=135.1) Events (E/100PY)	Active UPA Total (N=241) (PYS=269.3) Events (E/100PY)
アレルギー性結膜炎	2 (1.5)	1 (0.7)	3 (1.1)
ドライアイ	0	1 (0.7)	1 (0.4)
夜盲	0	1 (0.7)	1 (0.4)
胃腸障害	11 (8.2)	22 (16.3)	33 (12.3)
腹部不快感	0	2 (1.5)	2 (0.7)
腹部膨満	0	1 (0.7)	1 (0.4)
腹痛	0	2 (1.5)	2 (0.7)
上腹部痛	2 (1.5)	1 (0.7)	3 (1.1)
慢性胃炎	0	1 (0.7)	1 (0.4)
便秘	0	2 (1.5)	2 (0.7)
齲歯	2 (1.5)	2 (1.5)	4 (1.5)
下痢	1 (0.7)	5 (3.7)	6 (2.2)
消化不良	0	1 (0.7)	1 (0.4)
食中毒	1 (0.7)	0	1 (0.4)
胃食道逆流性疾患	1 (0.7)	0	1 (0.4)
血便排泄	1 (0.7)	0	1 (0.4)
胃酸過多	0	1 (0.7)	1 (0.4)
鼡径ヘルニア	1 (0.7)	0	1 (0.4)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) (PYS=134.2) Events (E/100PY)	Active UPA 30 mg QD (N=122) (PYS=135.1) Events (E/100PY)	Active UPA Total (N=241) (PYS=269.3) Events (E/100PY)
粘液便	1 (0.7)	0	1 (0.4)
急性膵炎	0	1 (0.7)	1 (0.4)
口内炎	0	3 (2.2)	3 (1.1)
嘔吐	1 (0.7)	0	1 (0.4)
一般・全身障害および投与部位の状態	8 (6.0)	12 (8.9)	20 (7.4)
胸痛	0	1 (0.7)	1 (0.4)
疲労	1 (0.7)	0	1 (0.4)
倦怠感	0	2 (1.5)	2 (0.7)
末梢性浮腫	1 (0.7)	3 (2.2)	4 (1.5)
発熱	6 (4.5)	6 (4.4)	12 (4.5)
肝胆道系障害	1 (0.7)	0	1 (0.4)
脂肪肝	1 (0.7)	0	1 (0.4)
感染症および寄生虫症	138 (102.9)	151 (111.7)	289 (107.3)
急性副鼻腔炎	1 (0.7)	0	1 (0.4)
虫垂炎	0	1 (0.7)	1 (0.4)
気管支炎	1 (0.7)	2 (1.5)	3 (1.1)
よう	0	1 (0.7)	1 (0.4)
蜂巣炎	2 (1.5)	0	2 (0.7)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) (PYS=134.2) Events (E/100PY)	Active UPA 30 mg QD (N=122) (PYS=135.1) Events (E/100PY)	Active UPA Total (N=241) (PYS=269.3) Events (E/100PY)
結膜炎	2 (1.5)	3 (2.2)	5 (1.9)
膀胱炎	1 (0.7)	3 (2.2)	4 (1.5)
爪の皮膚糸状菌症	1 (0.7)	3 (2.2)	4 (1.5)
丹毒	1 (0.7)	2 (1.5)	3 (1.1)
毛包炎	11 (8.2)	3 (2.2)	14 (5.2)
せつ	6 (4.5)	3 (2.2)	9 (3.3)
胃腸炎	3 (2.2)	3 (2.2)	6 (2.2)
ウイルス性胃腸炎	2 (1.5)	1 (0.7)	3 (1.1)
陰部ヘルペス	1 (0.7)	0	1 (0.4)
歯肉炎	1 (0.7)	2 (1.5)	3 (1.1)
単純ヘルペス	14 (10.4)	6 (4.4)	20 (7.4)
ヘルペスウイルス感染	1 (0.7)	0	1 (0.4)
帯状疱疹	7 (5.2)	19 (14.1)	26 (9.7)
播種性帯状疱疹	1 (0.7)	0	1 (0.4)
耳帯状疱疹	0	1 (0.7)	1 (0.4)
麦粒腫	1 (0.7)	2 (1.5)	3 (1.1)
膿痂疹	0	1 (0.7)	1 (0.4)
感染	1 (0.7)	1 (0.7)	2 (0.7)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) (PYS=134.2) Events (E/100PY)	Active UPA 30 mg QD (N=122) (PYS=135.1) Events (E/100PY)	Active UPA Total (N=241) (PYS=269.3) Events (E/100PY)
インフルエンザ	4 (3.0)	9 (6.7)	13 (4.8)
カポジ水痘様発疹	8 (6.0)	3 (2.2)	11 (4.1)
伝染性軟属腫	1 (0.7)	0	1 (0.4)
上咽頭炎	39 (29.1)	52 (38.5)	91 (33.8)
口腔ヘルペス	5 (3.7)	9 (6.7)	14 (5.2)
外耳炎	0	2 (1.5)	2 (0.7)
爪囲炎	0	2 (1.5)	2 (0.7)
歯周炎	1 (0.7)	0	1 (0.4)
咽頭炎	3 (2.2)	1 (0.7)	4 (1.5)
細菌性咽頭炎	0	1 (0.7)	1 (0.4)
ニューモシスチス・イロベチイ肺炎	1 (0.7)	0	1 (0.4)
肺炎	1 (0.7)	1 (0.7)	2 (0.7)
術後創感染	0	1 (0.7)	1 (0.4)
皮膚細菌感染	1 (0.7)	1 (0.7)	2 (0.7)
皮膚カンジダ	1 (0.7)	0	1 (0.4)
皮膚感染	1 (0.7)	0	1 (0.4)
ブドウ球菌感染	1 (0.7)	0	1 (0.4)
レンサ球菌感染	0	1 (0.7)	1 (0.4)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) (PYS=134.2) Events (E/100PY)	Active UPA 30 mg QD (N=122) (PYS=135.1) Events (E/100PY)	Active UPA Total (N=241) (PYS=269.3) Events (E/100PY)
皮下組織膿瘍	1 (0.7)	0	1 (0.4)
股部白癬	1 (0.7)	2 (1.5)	3 (1.1)
足部白癬	2 (1.5)	5 (3.7)	7 (2.6)
癜風	1 (0.7)	0	1 (0.4)
扁桃炎	6 (4.5)	3 (2.2)	9 (3.3)
上気道感染	1 (0.7)	1 (0.7)	2 (0.7)
尿路感染	1 (0.7)	0	1 (0.4)
傷害、中毒および処置合併症	8 (6.0)	7 (5.2)	15 (5.6)
動物咬傷	1 (0.7)	0	1 (0.4)
節足動物咬傷	0	2 (1.5)	2 (0.7)
節足動物刺傷	1 (0.7)	0	1 (0.4)
骨挫傷	0	1 (0.7)	1 (0.4)
挫傷	1 (0.7)	0	1 (0.4)
大腿骨骨折	0	1 (0.7)	1 (0.4)
足骨折	1 (0.7)	0	1 (0.4)
手骨折	1 (0.7)	0	1 (0.4)
熱射病	0	1 (0.7)	1 (0.4)
四肢損傷	1 (0.7)	0	1 (0.4)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) (PYS=134.2) Events (E/100PY)	Active UPA 30 mg QD (N=122) (PYS=135.1) Events (E/100PY)	Active UPA Total (N=241) (PYS=269.3) Events (E/100PY)
肉離れ	1 (0.7)	0	1 (0.4)
肋骨骨折	0	1 (0.7)	1 (0.4)
皮膚擦過傷	0	1 (0.7)	1 (0.4)
皮膚創傷	1 (0.7)	0	1 (0.4)
臨床検査	20 (14.9)	26 (19.2)	46 (17.1)
アラニンアミノトランスフェラーゼ増加	4 (3.0)	6 (4.4)	10 (3.7)
アスパラギン酸アミノトランスフェラーゼ増加	2 (1.5)	3 (2.2)	5 (1.9)
血中クレアチンホスホキナーゼ増加	1 (0.7)	6 (4.4)	7 (2.6)
血中トリグリセリド増加	2 (1.5)	0	2 (0.7)
γ－グルタミルトランスフェラーゼ増加	0	2 (1.5)	2 (0.7)
ヘモグロビン減少	2 (1.5)	3 (2.2)	5 (1.9)
肝酵素上昇	1 (0.7)	0	1 (0.4)
免疫グロブリン増加	0	1 (0.7)	1 (0.4)
好中球数減少	2 (1.5)	2 (1.5)	4 (1.5)
尿中蛋白陽性	1 (0.7)	0	1 (0.4)
赤血球数減少	1 (0.7)	0	1 (0.4)
尿中ウロビリノーゲン増加	1 (0.7)	0	1 (0.4)
体重減少	1 (0.7)	0	1 (0.4)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) (PYS=134.2) Events (E/100PY)	Active UPA 30 mg QD (N=122) (PYS=135.1) Events (E/100PY)	Active UPA Total (N=241) (PYS=269.3) Events (E/100PY)
体重増加	1 (0.7)	1 (0.7)	2 (0.7)
白血球数減少	1 (0.7)	2 (1.5)	3 (1.1)
代謝および栄養障害	1 (0.7)	1 (0.7)	2 (0.7)
高脂血症	1 (0.7)	0	1 (0.4)
高尿酸血症	0	1 (0.7)	1 (0.4)
筋骨格系および結合組織障害	12 (8.9)	17 (12.6)	29 (10.8)
関節痛	1 (0.7)	12 (8.9)	13 (4.8)
背部痛	3 (2.2)	1 (0.7)	4 (1.5)
足変形	0	1 (0.7)	1 (0.4)
椎間板突出	1 (0.7)	0	1 (0.4)
関節腫脹	0	1 (0.7)	1 (0.4)
筋骨格系胸痛	1 (0.7)	0	1 (0.4)
筋肉痛	1 (0.7)	2 (1.5)	3 (1.1)
変形性関節症	1 (0.7)	0	1 (0.4)
四肢痛	3 (2.2)	0	3 (1.1)
滑液嚢腫	1 (0.7)	0	1 (0.4)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	7 (5.2)	1 (0.7)	8 (3.0)
平滑筋腫	1 (0.7)	0	1 (0.4)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) (PYS=134.2) Events (E/100PY)	Active UPA 30 mg QD (N=122) (PYS=135.1) Events (E/100PY)	Active UPA Total (N=241) (PYS=269.3) Events (E/100PY)
皮膚乳頭腫	6 (4.5)	1 (0.7)	7 (2.6)
神経系障害	12 (8.9)	7 (5.2)	19 (7.1)
小脳出血	1 (0.7)	0	1 (0.4)
頚髄神経根障害	1 (0.7)	0	1 (0.4)
浮動性めまい	0	1 (0.7)	1 (0.4)
頭痛	5 (3.7)	2 (1.5)	7 (2.6)
感覚鈍麻	1 (0.7)	0	1 (0.4)
肋間神経痛	1 (0.7)	0	1 (0.4)
片頭痛	2 (1.5)	0	2 (0.7)
ヘルペス後神経痛	0	1 (0.7)	1 (0.4)
傾眠	0	3 (2.2)	3 (1.1)
舌の麻痺	1 (0.7)	0	1 (0.4)
精神障害	4 (3.0)	2 (1.5)	6 (2.2)
注意欠陥多動性障害	0	1 (0.7)	1 (0.4)
抑うつ気分	1 (0.7)	0	1 (0.4)
うつ病	1 (0.7)	0	1 (0.4)
不眠症	1 (0.7)	0	1 (0.4)
落ち着きのなさ	0	1 (0.7)	1 (0.4)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) (PYS=134.2) Events (E/100PY)	Active UPA 30 mg QD (N=122) (PYS=135.1) Events (E/100PY)	Active UPA Total (N=241) (PYS=269.3) Events (E/100PY)
身体症状症	1 (0.7)	0	1 (0.4)
生殖系および乳房障害	4 (3.0)	1 (0.7)	5 (1.9)
無月経	0	1 (0.7)	1 (0.4)
性器出血	1 (0.7)	0	1 (0.4)
月経過多	1 (0.7)	0	1 (0.4)
不規則月経	1 (0.7)	0	1 (0.4)
卵巣嚢胞	1 (0.7)	0	1 (0.4)
呼吸器、胸郭および縦隔障害	8 (6.0)	14 (10.4)	22 (8.2)
喘息	1 (0.7)	6 (4.4)	7 (2.6)
慢性気管支炎	0	1 (0.7)	1 (0.4)
咳嗽	3 (2.2)	2 (1.5)	5 (1.9)
鼻出血	0	1 (0.7)	1 (0.4)
口腔咽頭痛	3 (2.2)	2 (1.5)	5 (1.9)
胸膜炎	0	1 (0.7)	1 (0.4)
気胸	0	1 (0.7)	1 (0.4)
上気道の炎症	1 (0.7)	0	1 (0.4)
皮膚および皮下組織障害	50 (37.3)	58 (42.9)	108 (40.1)
ざ瘡	24 (17.9)	40 (29.6)	64 (23.8)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) (PYS=134.2) Events (E/100PY)	Active UPA 30 mg QD (N=122) (PYS=135.1) Events (E/100PY)	Active UPA Total (N=241) (PYS=269.3) Events (E/100PY)
脱毛症	1 (0.7)	0	1 (0.4)
水疱	1 (0.7)	1 (0.7)	2 (0.7)
皮膚嚢腫	1 (0.7)	0	1 (0.4)
アトピー性皮膚炎	6 (4.5)	5 (3.7)	11 (4.1)
接触皮膚炎	1 (0.7)	1 (0.7)	2 (0.7)
湿疹	1 (0.7)	1 (0.7)	2 (0.7)
過角化	2 (1.5)	0	2 (0.7)
汗疹	1 (0.7)	2 (1.5)	3 (1.1)
口囲皮膚炎	1 (0.7)	0	1 (0.4)
発疹	2 (1.5)	0	2 (0.7)
脂漏性皮膚炎	2 (1.5)	0	2 (0.7)
皮膚亀裂	0	1 (0.7)	1 (0.4)
日光皮膚炎	2 (1.5)	0	2 (0.7)
中毒性皮疹	1 (0.7)	0	1 (0.4)
蕁麻疹	4 (3.0)	6 (4.4)	10 (3.7)
接触蕁麻疹	0	1 (0.7)	1 (0.4)
血管障害	3 (2.2)	1 (0.7)	4 (1.5)
高血圧	2 (1.5)	1 (0.7)	3 (1.1)

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E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=119) (PYS=134.2) Events (E/100PY)	Active UPA 30 mg QD (N=122) (PYS=135.1) Events (E/100PY)	Active UPA Total (N=241) (PYS=269.3) Events (E/100PY)
表在性静脈炎	1 (0.7)	0	1 (0.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W52 Table 14.3__1.6.2.3

表 7. ウパダシチニブ投与期間中に治験薬と関連ありの有害事象を発現した被験者数及び発現割合：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団）

	Active		
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=133) n (%)	UPA 30 mg QD (N=136) n (%)	UPA Total (N=269) n (%)
Any adverse event	45 (33.8)	53 (39.0)	98 (36.4)
血液およびリンパ系障害	2 (1.5)	6 (4.4)	8 (3.0)
貧血	1 (0.8)	2 (1.5)	3 (1.1)
リンパ節症	1 (0.8)	0	1 (0.4)
リンパ球減少症	0	1 (0.7)	1 (0.4)
好中球減少症	0	4 (2.9)	4 (1.5)
眼障害	1 (0.8)	1 (0.7)	2 (0.7)
アレルギー性結膜炎	1 (0.8)	1 (0.7)	2 (0.7)
胃腸障害	3 (2.3)	6 (4.4)	9 (3.3)
腹部不快感	0	1 (0.7)	1 (0.4)
腹部膨満	0	1 (0.7)	1 (0.4)
便秘	0	1 (0.7)	1 (0.4)
下痢	1 (0.8)	2 (1.5)	3 (1.1)
鼡径ヘルニア	1 (0.8)	0	1 (0.4)
粘液便	1 (0.8)	0	1 (0.4)
急性膵炎	0	1 (0.7)	1 (0.4)
口内炎	0	1 (0.7)	1 (0.4)
一般・全身障害および投与部位の状態	2 (1.5)	4 (2.9)	6 (2.2)
倦怠感	1 (0.8)	2 (1.5)	3 (1.1)
末梢性浮腫	0	1 (0.7)	1 (0.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
発熱	1 (0.8)	1 (0.7)	2 (0.7)
感染症および寄生虫症	29 (21.8)	32 (23.5)	61 (22.7)
虫垂炎	1 (0.8)	1 (0.7)	2 (0.7)
よう	0	1 (0.7)	1 (0.4)
結膜炎	0	2 (1.5)	2 (0.7)
膀胱炎	1 (0.8)	1 (0.7)	2 (0.7)
丹毒	1 (0.8)	0	1 (0.4)
毛包炎	4 (3.0)	0	4 (1.5)
せつ	3 (2.3)	2 (1.5)	5 (1.9)
ウイルス性胃腸炎	0	1 (0.7)	1 (0.4)
歯肉炎	1 (0.8)	0	1 (0.4)
単純ヘルペス	4 (3.0)	2 (1.5)	6 (2.2)
ヘルペスウイルス感染	1 (0.8)	0	1 (0.4)
帯状疱疹	6 (4.5)	16 (11.8)	22 (8.2)
播種性帯状疱疹	1 (0.8)	0	1 (0.4)
耳帯状疱疹	0	1 (0.7)	1 (0.4)
麦粒腫	1 (0.8)	1 (0.7)	2 (0.7)
膿痂疹	1 (0.8)	1 (0.7)	2 (0.7)
感染	0	1 (0.7)	1 (0.4)
カポジ水痘様発疹	6 (4.5)	2 (1.5)	8 (3.0)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
伝染性軟属腫	2 (1.5)	1 (0.7)	3 (1.1)
上咽頭炎	2 (1.5)	2 (1.5)	4 (1.5)
口腔ヘルペス	2 (1.5)	5 (3.7)	7 (2.6)
中耳炎	0	1 (0.7)	1 (0.4)
ニューモシスチス・イロベチイ肺炎	1 (0.8)	0	1 (0.4)
肺炎	0	1 (0.7)	1 (0.4)
皮膚細菌感染	1 (0.8)	1 (0.7)	2 (0.7)
ブドウ球菌感染	1 (0.8)	0	1 (0.4)
足部白癬	0	1 (0.7)	1 (0.4)
扁桃炎	2 (1.5)	0	2 (0.7)
尿路感染	1 (0.8)	0	1 (0.4)
傷害、中毒および処置合併症	0	1 (0.7)	1 (0.4)
熱射病	0	1 (0.7)	1 (0.4)
臨床検査	10 (7.5)	6 (4.4)	16 (5.9)
アラニンアミノトランスフェラーゼ増加	1 (0.8)	1 (0.7)	2 (0.7)
アスパラギン酸アミノトランスフェラーゼ増加	1 (0.8)	1 (0.7)	2 (0.7)
γ－グルタミルトランスフェラーゼ増加	0	1 (0.7)	1 (0.4)
ヘモグロビン減少	1 (0.8)	2 (1.5)	3 (1.1)
肝酵素上昇	1 (0.8)	0	1 (0.4)
リンパ球形態異常	0	1 (0.7)	1 (0.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
骨髄球存在	0	1 (0.7)	1 (0.4)
好中球数減少	2 (1.5)	1 (0.7)	3 (1.1)
尿中蛋白陽性	2 (1.5)	0	2 (0.7)
赤血球数減少	1 (0.8)	0	1 (0.4)
尿中ウロビリノーゲン増加	1 (0.8)	0	1 (0.4)
白血球数減少	1 (0.8)	1 (0.7)	2 (0.7)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2 (1.5)	0	2 (0.7)
皮膚乳頭腫	2 (1.5)	0	2 (0.7)
神経系障害	1 (0.8)	3 (2.2)	4 (1.5)
小脳出血	1 (0.8)	0	1 (0.4)
ヘルペス後神経痛	0	1 (0.7)	1 (0.4)
傾眠	0	2 (1.5)	2 (0.7)
精神障害	0	1 (0.7)	1 (0.4)
落ち着きのなさ	0	1 (0.7)	1 (0.4)
生殖系および乳房障害	0	1 (0.7)	1 (0.4)
無月経	0	1 (0.7)	1 (0.4)
呼吸器、胸郭および縦隔障害	1 (0.8)	3 (2.2)	4 (1.5)
喘息	1 (0.8)	2 (1.5)	3 (1.1)
気胸	0	1 (0.7)	1 (0.4)
皮膚および皮下組織障害	13 (9.8)	18 (13.2)	31 (11.5)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
ざ瘡	7 (5.3)	18 (13.2)	25 (9.3)
脱毛症	1 (0.8)	0	1 (0.4)
アトピー性皮膚炎	4 (3.0)	0	4 (1.5)
脂漏性皮膚炎	1 (0.8)	0	1 (0.4)
蕁麻疹	1 (0.8)	0	1 (0.4)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

相互参照：M17-377 試験 CSR W52 Table 14.3__1.9.2

表 8. ウパダシチニブ投与期間中の治験薬と関連ありの有害事象の 100 人年あたりの発現率：MedDRA 器官別大分類及び基本語別（全ウパダシチニブ投与集団）

	Active		
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=133) (PYS=151.2) Events (E/100PY)	UPA 30 mg QD (N=136) (PYS=149.7) Events (E/100PY)	UPA Total (N=269) (PYS=300.9) Events (E/100PY)
Any adverse event	90 (59.5)	108 (72.1)	198 (65.8)
血液およびリンパ系障害	2 (1.3)	10 (6.7)	12 (4.0)
貧血	1 (0.7)	3 (2.0)	4 (1.3)
リンパ節症	1 (0.7)	0	1 (0.3)
リンパ球減少症	0	1 (0.7)	1 (0.3)
好中球減少症	0	6 (4.0)	6 (2.0)
眼障害	1 (0.7)	1 (0.7)	2 (0.7)
アレルギー性結膜炎	1 (0.7)	1 (0.7)	2 (0.7)
胃腸障害	3 (2.0)	8 (5.3)	11 (3.7)
腹部不快感	0	1 (0.7)	1 (0.3)
腹部膨満	0	1 (0.7)	1 (0.3)
便秘	0	1 (0.7)	1 (0.3)
下痢	1 (0.7)	2 (1.3)	3 (1.0)
鼠径ヘルニア	1 (0.7)	0	1 (0.3)
粘液便	1 (0.7)	0	1 (0.3)
急性膵炎	0	1 (0.7)	1 (0.3)
口内炎	0	2 (1.3)	2 (0.7)
一般・全身障害および投与部位の状態	3 (2.0)	4 (2.7)	7 (2.3)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=151.2) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=149.7) Events (E/100PY)	Active UPA Total (N=269) (PYS=300.9) Events (E/100PY)
倦怠感	1 (0.7)	2 (1.3)	3 (1.0)
末梢性浮腫	0	1 (0.7)	1 (0.3)
発熱	2 (1.3)	1 (0.7)	3 (1.0)
感染症および寄生虫症	50 (33.1)	48 (32.1)	98 (32.6)
虫垂炎	1 (0.7)	1 (0.7)	2 (0.7)
よう	0	1 (0.7)	1 (0.3)
結膜炎	0	2 (1.3)	2 (0.7)
膀胱炎	1 (0.7)	1 (0.7)	2 (0.7)
丹毒	1 (0.7)	0	1 (0.3)
毛包炎	4 (2.6)	0	4 (1.3)
せつ	3 (2.0)	3 (2.0)	6 (2.0)
ウイルス性胃腸炎	0	1 (0.7)	1 (0.3)
歯肉炎	1 (0.7)	0	1 (0.3)
単純ヘルペス	7 (4.6)	3 (2.0)	10 (3.3)
ヘルペスウイルス感染	1 (0.7)	0	1 (0.3)
帯状疱疹	6 (4.0)	17 (11.4)	23 (7.6)
播種性帯状疱疹	1 (0.7)	0	1 (0.3)
耳帯状疱疹	0	1 (0.7)	1 (0.3)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=151.2) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=149.7) Events (E/100PY)	Active UPA Total (N=269) (PYS=300.9) Events (E/100PY)
麦粒腫	1 (0.7)	1 (0.7)	2 (0.7)
膿痂疹	1 (0.7)	1 (0.7)	2 (0.7)
感染	0	1 (0.7)	1 (0.3)
カポジ水痘様発疹	8 (5.3)	2 (1.3)	10 (3.3)
伝染性軟属腫	2 (1.3)	1 (0.7)	3 (1.0)
上咽頭炎	2 (1.3)	2 (1.3)	4 (1.3)
口腔ヘルペス	2 (1.3)	6 (4.0)	8 (2.7)
中耳炎	0	1 (0.7)	1 (0.3)
ニューモシスチス・イロベチイ肺炎	1 (0.7)	0	1 (0.3)
肺炎	0	1 (0.7)	1 (0.3)
皮膚細菌感染	1 (0.7)	1 (0.7)	2 (0.7)
ブドウ球菌感染	1 (0.7)	0	1 (0.3)
足部白癬	0	1 (0.7)	1 (0.3)
扁桃炎	4 (2.6)	0	4 (1.3)
尿路感染	1 (0.7)	0	1 (0.3)
傷害、中毒および処置合併症	0	1 (0.7)	1 (0.3)
熱射病	0	1 (0.7)	1 (0.3)
臨床検査	12 (7.9)	10 (6.7)	22 (7.3)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=151.2) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=149.7) Events (E/100PY)	Active UPA Total (N=269) (PYS=300.9) Events (E/100PY)
アラニンアミノトランスフェラーゼ増加	1 (0.7)	1 (0.7)	2 (0.7)
アスパラギン酸アミノトランスフェラーゼ増加	1 (0.7)	1 (0.7)	2 (0.7)
γ－グルタミルトランスフェラーゼ増加	0	2 (1.3)	2 (0.7)
ヘモグロビン減少	2 (1.3)	2 (1.3)	4 (1.3)
肝酵素上昇	1 (0.7)	0	1 (0.3)
リンパ球形態異常	0	1 (0.7)	1 (0.3)
骨髄球存在	0	1 (0.7)	1 (0.3)
好中球数減少	2 (1.3)	1 (0.7)	3 (1.0)
尿中蛋白陽性	2 (1.3)	0	2 (0.7)
赤血球数減少	1 (0.7)	0	1 (0.3)
尿中ウロビリノーゲン増加	1 (0.7)	0	1 (0.3)
白血球数減少	1 (0.7)	1 (0.7)	2 (0.7)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2 (1.3)	0	2 (0.7)
皮膚乳頭腫	2 (1.3)	0	2 (0.7)
神経系障害	1 (0.7)	3 (2.0)	4 (1.3)
小脳出血	1 (0.7)	0	1 (0.3)
ヘルペス後神経痛	0	1 (0.7)	1 (0.3)
傾眠	0	2 (1.3)	2 (0.7)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]

MedDRA 22.1 System Organ Class Preferred Term	Active UPA 15 mg QD (N=133) (PYS=151.2) Events (E/100PY)	Active UPA 30 mg QD (N=136) (PYS=149.7) Events (E/100PY)	Active UPA Total (N=269) (PYS=300.9) Events (E/100PY)
精神障害	0	1 (0.7)	1 (0.3)
落ち着きのなさ	0	1 (0.7)	1 (0.3)
生殖系および乳房障害	0	1 (0.7)	1 (0.3)
無月経	0	1 (0.7)	1 (0.3)
呼吸器、胸郭および縦隔障害	1 (0.7)	3 (2.0)	4 (1.3)
喘息	1 (0.7)	2 (1.3)	3 (1.0)
気胸	0	1 (0.7)	1 (0.3)
皮膚および皮下組織障害	15 (9.9)	18 (12.0)	33 (11.0)
ざ瘡	8 (5.3)	18 (12.0)	26 (8.6)
脱毛症	1 (0.7)	0	1 (0.3)
アトピー性皮膚炎	4 (2.6)	0	4 (1.3)
脂漏性皮膚炎	1 (0.7)	0	1 (0.3)
蕁麻疹	1 (0.7)	0	1 (0.3)

Note: TEAEs are defined as any event with an onset or worsening date on or after the first dose of upadacitinib and no more than 30 days after the last dose of upadacitinib in the study.
E/100PY = Events per 100 patient-years.

Program Source Code: [redacted]
相互参照：M17-377 試験 CSR W52 Table 14.3__1.9.3